SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2019

or

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

For the transition period from _____ to

Commission File Number:

Precision Therapeutics Inc.
(Exact name of registrant as specified in its charter)

Delaware	83-4360734
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
2915 Commers Drive, Suite 900	Eagan, Minnesota 55121
(Address of principal executive offices)	(Zip Code)

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

(Former name, former address and former fiscal year, if changed since last report)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

☒ Yes ☐ No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

☒ Yes ☐ No

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

Large accelerated filer ☐
Non-accelerated filer ☐
Accelerated filer ☐
Smaller reporting company ☒
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. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

☐ Yes ☒ No

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, $0.01 par value	AIPT	Nasdaq Capital Market

APPLICABLE ONLY TO CORPORATE ISSUERS:

Indicate the number of shares outstanding of each of the issuer’s classes of common stock, as of the latest practicable date. As of May 14, 2019, the registrant had 30,680,570 shares of common stock, par value $.01 per share outstanding.

PRECISION THERAPEUTICS INC.

TABLE OF CONTENTS

PART 1. FINANCIAL INFORMATION
Item 1. Condensed Consolidated Financial Statements

PRECISION THERAPEUTICS INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)

	March 31, 2019	December 31, 2018
ASSETS		
Current Assets:		
Cash and Cash Equivalents	$ 1,124,730	$ 162,152
Accounts Receivable	173,443	232,602
Notes Receivable (inclusive of $738,138 and $452,775 in advances to Helomics)	1,801,479	497,276
Inventories	289,023	241,066
Prepaid Expense and other assets	265,584	318,431
Total Current Assets	3,654,259	1,451,527
Notes Receivable	-	1,112,524
Fixed Assets, net	148,709	180,453
Intangibles, net	950,049	964,495
Lease Right-of-Use Assets	333,944	-
Total Assets	$ 5,086,961	$ 3,708,999
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts Payable	$ 432,198	$ 445,689
Note Payable – Bridge Loan Net of Discount of $646,524 and $969,786	1,812,037	1,327,942
Notes Payable – Net of Discount of $352,961 and $63,028	1,267,039	306,972
Accrued Expenses	797,599	1,279,114
Derivative Liability	353,210	272,745
Deferred Revenue	20,929	23,065
Current Lease Liability	78,819	-
Total Current Liabilities	4,761,831	3,655,527
Lease Liability	255,125	-
Total Liabilities	5,016,956	3,655,527
Stockholders’ Equity:		
Series B Convertible Preferred Stock, $.01 par value, 20,000,000 authorized, 79,246 and 79,246 outstanding	792	792
Common Stock, $.01 par value, 100,000,000 authorized, 17,360,144 and 14,091,748 outstanding	173,601	140,917
Additional paid-in capital	66,296,741	63,019,708
Accumulated Deficit	(66,401,129)	(63,107,945)
Total Stockholders' Equity	70,005	53,472
Total Liabilities and Stockholders' Equity	$ 5,086,961	$ 3,708,999

See Notes to Condensed Consolidated Financial Statements

PRECISION THERAPEUTICS INC.
CONDENSED CONSOLIDATED STATEMENTS OF NET LOSS
(Unaudited)

	Three Months Ended March 31,	
	2019	**2018**
Revenue	$ 255,241	$ 411,593
Cost of goods sold	73,717	117,343
Gross margin	181,524	294,250
General and administrative expense	1,497,945	1,241,961
Operations expense	466,566	287,590
Sales and marketing expense	554,216	550,538
Total operating loss	2,337,203	1,785,839
Other income	53,432	27,655
Other expense	569,776	1,838
Loss on equity method investment	439,637	-
Net loss attributable to common shareholders	$ (3,293,184)	$ (1,760,022)
Loss per common share - basic and diluted	$ (0.21)	$ (0.15)
Weighted average shares used in computation - basic and diluted	15,731,517	11,383,217

See Notes to Condensed Consolidated Financial Statements

PRECISION THERAPEUTICS INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(Unaudited)

				Common Stock					
	Preferred Stock	# Shares Preferred C	# Shares Preferred B	Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Other Comprehensive Income	Total
Balance at 1/1/2018	$ 7,271	647,819	79,246	6,943,283	$ 69,432	$ 57,380,256	$ (54,765,045)	$ -	$ 2,691,913
Preferred conversion to common shares pursuant to private placement agreement	(6,479)	(647,819)		589,747	5,897	582			(0)
Shares issued pursuant to S-3 public offering				2,900,000	29,000	2,726,087			2,755,087
Investment pursuant to Helomics 20% acquisition				1,100,000	11,000	1,031,250			1,042,250
E Warrant exercises pursuant to S-3 public offering at $1.00 exercise price per share				55,796	558	55,238			55,796
Shares issued pursuant to S-3 public offering over-allotment option at $0.9497 exercise price per share				215,247	2,153	202,268	1		204,422
Vesting Expense						226,387			226,837
Net loss							(1,760,022)		(1,760,022)
Balance at 3/31/2018	$ 792	-	79,246	11,804,073	$ 118,040	$ 61,622,067	$ (56,525,066)	$ -	$ 5,215,833
Balance at 1/1/2019	$ 792	-	79,246	14,091,748	$ 140,917	$ 63,019,708	$ (63,107,945)	$ -	$ 53,472
Investment by CEO				78,125	781	49,219			50,000
Shares issued in forbearance agreement				166,667	1,666	156,684			158,350
Shares issued pursuant to S-3 public offering				2,863,750	28,638	2,401,071			2,429,709
Shares issued pursuant to note conversions – bridge loan				159,854	1,599	88,401			90,000
Warrants issued pursuant to CEO note payable						318,058			318,058
Vesting expense						263,600			263,600
Net loss							(3,293,184)		(3,293,184)
Balance at 3/31/2019	$ 792	-	79,246	17,360,144	$ 173,601	$ 66,296,741	$ (66,401,129)	$ -	$ 70,005

See Notes to Condensed Consolidated Financial Statements

PRECISION THERAPEUTICS INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)

	Three Months Ended March 31,	
	2019	**2018**
Cash flow from operating activities:		
Net loss	$ (3,293,184)	$ (1,760,022)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss on equity method investment	439,637	-
Depreciation and amortization	39,526	18,167
Vesting expense for stock options	263,600	226,387
Amortization of debt discount	468,564	-
Loss on valuation of equity-linked instruments	19,408	-
Changes in assets and liabilities:		
Accounts receivable	59,159	(104,265)
Inventories	(47,957)	(7,511)
Prepaid expense and other assets	(3,273)	81,661
Accounts payable	(13,491)	45,847
Accrued expenses	21,494	(226,775)
Deferred revenue	(2,136)	32,193
Net cash used in operating activities:	(2,048,653)	(1,694,318)
Cash flow from investing activities:		
Redemption of certificates of deposit	-	244,971
Advance on notes receivable	(631,316)	(42,524)
Purchase of fixed assets	-	(32,789)
Transfer of fixed assets to inventory	9,863	-
Acquisition of intangibles	(3,198)	(24,029)
Net cash (used in) provided by investing activities:	(624,651)	145,629
Cash flow from financing activities:		
Extinguishment of convertible debt	(93,827)	-
Proceeds from debt issuance	1,250,000	-
Proceeds from exercise of warrants into common stock	-	55,794
Issuance of common stock	2,479,709	2,959,509
Net cash provided by financing activities	3,635,882	3,015,303
Net increase in cash and cash equivalents	962,578	1,466,614
Cash at beginning of period	162,152	766,189
Cash at end of period	$ 1,124,730	$ 2,232,803
Non-cash transactions:		
Bridge loan conversion into common stock	$ 90,000	$ -
Forbearance settlement bridge loan	$ 503,009	$ -
Additional warrants issued pursuant to CEO note payable	$ 8,665	$ -
Conversion of preferred stock to common stock	$ -	$ 6,479
Equity method investment - Helomics	$ -	$ 1,542,250

See Notes to Condensed Consolidated Financial Statements

PRECISION THERAPEUTICS INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

NOTE 1 — SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Nature of Operations and Continuance of Operations

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. Pursuant to an Agreement and Plan of Merger effective December 16, 2013, the Company merged with and into a Delaware corporation with the same name that was its wholly-owned subsidiary, with such Delaware corporation as the surviving corporation of the merger. On August 31, 2015, the Company completed a successful offering and concurrent uplisting to the NASDAQ Capital Market. On February 1, 2018, the Company filed with the Secretary of State of Delaware a Certificate of Amendment to its Certificate of Incorporation to change the corporate name from Skyline Medical Inc. to Precision Therapeutics Inc., effective February 1, 2018. Because of this change, the Company's common stock trades under the new ticker symbol "AIPT," effective February 2, 2018. Skyline Medical ("Skyline") remains as an incorporated division of Precision Therapeutics Inc.

As of March 31, 2019, the Company had 17,360,144 shares of common stock outstanding, par value $.01 per share. The Company is a healthcare company that provides personalized medicine solution and medical devices in two main areas: (1) precision medicine, which aims to apply artificial intelligence to personalized medicine and drug discovery; and (2) the Company has developed an environmentally safe system for the collection and disposal of infectious fluids that result from surgical procedures and post-operative care. The Company also makes ongoing sales of proprietary cleaning fluid and filters to users of its systems. In April 2009, the Company received 510(k) clearance from the Food and Drug Administration (the "FDA") to authorize the Company to market and sell its STREAMWAY System products.

The Company acquired 25% of the capital stock of Helomics Holding Corporation ("Helomics"), in transactions in the first quarter of 2018, and in April 2018 the Company entered into a letter of intent for a proposed merger transaction to acquire the remaining ownership of Helomics. In June 2018, the Company and Helomics entered into a definitive merger agreement. On April 4, 2019, the Company completed the acquisition and is now the sole owner of Helomics – see Note 10. The Company's precision medicine services – designed to use artificial intelligence and a comprehensive disease database to improve the effectiveness of cancer therapy – were launched with the Company's investment in Helomics. 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 artificial intelligence 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. In addition, the Company has formed a wholly-owned subsidiary, TumorGenesis Inc., to develop the next generation, patient derived tumor models for precision cancer therapy and drug development. TumorGenesis Inc., formed during the first quarter of 2018, is presented as part of the unaudited condensed consolidated financial statements ("financial statements").

The accompanying financial statements have been prepared assuming the Company will continue as a going concern. The Company has incurred recurring losses from operations and has an accumulated deficit of $66,401,129. The Company does not expect to generate sufficient operating revenue to sustain its operations in the near-term. In the first quarter the Company incurred negative cash flows from operations. Although the Company has attempted to curtail expenses, there is no guarantee that the Company will be able to reduce these expenses significantly, and expenses may need to be higher to prepare product lines for broader sales in order to generate sustainable revenues.

The Company had cash and cash equivalents of $1,124,730 as of March 31, 2019 and needs to raise significant additional capital to meet its operating needs, pay debt obligations coming due, and fund the continued operating needs of Helomics; therefore, there is substantial doubt about the Company's ability to continue as a going concern for one year after the date that the financial statements are issued. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. The Company has available financing options including a shelf registration statement on Form S-3, with which the Company has raised approximately $2.1 million in net proceeds in early 2019. The Company may raise up to approximately $5.0 million in additional gross proceeds, now that the Helomics acquisition is completed.

Since inception to March 31, 2019, the Company has raised approximately $38,970,000 in equity and $9,120,000 in debt financing. Equity raises include: a January 2018 public offering with net proceeds of $2,475,000; and March 2019 public offerings with net proceeds of $1,112,000 and $1,053,000. Included in debt financing were raises in September 2018 on senior secured promissory notes with net proceeds of $1,815,000. In November 2018, the Company received a loan from the CEO for $370,000. In February 2019, the Company received a loan from the CEO for $950,000, and in March 2019 the Company received a loan from the CEO for $300,000.

Interim Financial Statements

The Company has prepared the unaudited interim financial statements and related unaudited financial information in the footnotes in accordance with accounting principles generally accepted in the United States of America ("GAAP") and the rules and regulations of the Securities and Exchange Commission ("SEC") for interim financial statements. These interim financial statements reflect all adjustments consisting of normal recurring accruals, which in the opinion of management, are necessary to present fairly the Company's position, the results of its operations and its cash flows for the interim periods. These interim financial statements reflect all intercompany eliminations. These interim financial statements should be read in conjunction with the annual financial statements and the notes thereto contained in the Annual Report on Form 10-K filed with the SEC on April 1, 2019. The nature of the Company's business is such that the results of any interim period may not be indicative of the results to be expected for the entire year.

Recent Accounting Developments

Accounting Policies and Estimates

The presentation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

In February 2016, the FASB issued ASU No. 2016-02, "*Leases (Topic 842)*" ("ASU 2016-02"), which requires lessees to put most leases on their balance sheets but recognize the expenses on their income statements in a manner similar to current practice. The standard states that a lessee would recognize a lease liability for the obligation to make lease payments and a right-to-use asset for the right to use the underlying asset for the lease term. The standard is effective for fiscal years and interim periods within those fiscal years beginning after December 15, 2018. Early adoption is permitted. The Company adopted the standard on January 1, 2019, using the transition relief to the modified retrospective approach, presenting prior year information based on the previous standard. Upon adoption, the Company recognized $353,007 of lease right-of-use (ROU) assets and liabilities for operating leases on its condensed consolidated balance sheet, of which, $79,252 were classified as current liabilities. The adoption of ASU 2016-02 did not have a material impact on the Company's consolidated results of operations or cash flows.

The Company leases facilities under long-term operating leases that are non-cancelable and expire on various dates. At the lease commencement date, lease ROU assets and lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term, which includes all fixed obligations arising from the lease contract. If an interest rate is not explicit in a lease, the Company utilizes its incremental borrowing rate for a period that closely matches the lease term.

See Note 8 – Leases

Cash Equivalents

The Company considers all highly liquid debt instruments with a maturity of three months or less when purchased to be cash equivalents. Cash equivalents are stated at cost, which approximates fair value.

Fair Value Measurements

Under generally accepted accounting principles as outlined in the FASB's Accounting Standards Codification (ASC) 820, fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The accounting standards ASC 820 establishes a three-level fair value hierarchy that prioritizes information used in developing assumptions when pricing an asset or liability as follows:

Level 1 – Observable inputs such as quoted prices in active markets;

Level 2 – Inputs other than quoted prices in active markets, that are observable either directly or indirectly; and

Level 3 – Unobservable inputs where there is little or no market data, which requires the reporting entity to develop its own assumptions.

The Company uses observable market data, when available, in making fair value measurements. Fair value measurements are classified according to the lowest level input that is significant to the valuation.

The fair value of the Company's investment securities was determined based on Level 1 inputs.

Inventories

Inventories are stated at the net realizable value, with cost determined on a first-in, first-out basis. Inventory balances are as follows:

	March 31, 2019	December 31, 2018
Finished goods	$ 88,849	$ 58,701
Raw materials	139,183	127,003
Work-In-Process	60,991	55,362
Total	$ 289,023	$ 241,066

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation of property and equipment is computed using the straight-line method over the estimated useful lives of the respective assets. Estimated useful asset life by classification is as follows:

	Years
Computers and office equipment	3 - 7
Leasehold improvements	3
Manufacturing tooling	3 - 7
Demo equipment	3

The Company's fixed assets consist of the following:

	March 31, 2019	December 31, 2018
Computers and office equipment	$ 205,758	$ 204,903
Leasehold improvements	140,114	140,114
Manufacturing tooling	108,955	108,955
Demo equipment	74,529	85,246
Total	529,356	539,218
Less: Accumulated depreciation	380,647	358,765
Total Fixed Assets, Net	$ 148,709	$ 180,453

Upon retirement or sale, the cost and related accumulated depreciation are removed from the balance sheet and the resulting gain or loss is reflected in operations. Maintenance and repairs are charged to operations as incurred.

Depreciation expense was $21,882 in the three months ended March 31, 2019 and was $14,496 for the three months ended March 31, 2018.

Intangible Assets

Intangible assets consist of trademarks, patent costs and license fees. Amortization expense was $17,644 in the three months ended March 31, 2019 and was $3,671 in the three months ended March 31, 2018. The Company reviews identifiable intangible assets for impairment in accordance with ASC 360 — *Intangibles —Goodwill and Other*, whenever events or changes in circumstances indicate the carrying amount may not be recoverable. The Company's intangible assets are definite lived and currently solely the costs of obtaining licensing fees, trademarks, and patents. Events or changes in circumstances that indicate the carrying amount may not be recoverable include, but are not limited to, a significant change in the medical device marketplace and a significant adverse change in the business climate in which the Company operates.

Income Taxes

The Company accounts for income taxes in accordance with ASC 740 - *Income Taxes* ("ASC 740"). Under ASC 740, deferred tax assets and liabilities are determined based on the differences between the financial reporting and tax bases of assets and liabilities and net operating loss and credit carryforwards using enacted tax rates in effect for the year in which the differences are expected to impact taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

There is no income tax provision in the accompanying statements of net loss due to the cumulative operating losses that indicate a 100% valuation allowance for the deferred tax assets and state income taxes is appropriate.

The Company reviews income tax positions expected to be taken in income tax returns to determine if there are any income tax uncertainties. The Company recognizes tax benefits from uncertain tax positions only if it is more likely than not that the tax positions will be sustained on examination by taxing authorities, based on technical merits of the positions. The Company has identified no income tax uncertainties.

Tax years subsequent to 2015 remain open to examination by federal and state tax authorities.

Offering Costs

Costs incurred which are direct and incremental to an offering of the Company's securities are deferred and charged against the proceeds of the offering, unless such costs are deemed to be insignificant in which case they are expensed as incurred.

Credit Risk

Financial instruments which potentially subject the Company to concentrations of credit risk consist principally of cash. The Company places its cash with high credit quality financial institutions and, by policy, generally limits the amount of credit exposure to any one financial institution. The Company has credit risk concentration for cash amounts held in a single institution that are in excess of amounts issued by the Federal Deposit Insurance Corporation.

Segments

The Company has two operating segments; domestic and international sales. The segment revenues and net losses for the three-month period ended March 31, 2019 are described in the table below. Substantially all of the Company's revenues and expenses in the prior year were related to the domestic segment.

	Domestic	International	Totals
Revenue	$ 219,660	$ 35,581	$ 255,241
Segment Loss	$ (887,831)	$ (84,569)	$ (972,400)

Reconciliation of Segment Loss

Description	Amounts
Domestic loss	$ 887,831
International loss	84,569
Corporate losses	2,320,784
Total	$ 3,293,184

Risks and Uncertainties

The Company is subject to risks common to companies in the medical device industry, including, but not limited to, development by the Company or its competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, and compliance with regulations of the FDA and other governmental agencies.

NOTE 2 – EQUITY METHOD INVESTMENT

The Company has an equity method investment in Helomics. Summarized financial information for Helomics is presented below:

Helomics Holdings Corporation

	For the three Months Ended March 31, 2019
Revenue	$ 45,835
Gross margin	$ 7,348
Net loss from continuing operations	$ (1,555,542)
Net loss to investee	$ (1,166,656)[1]

[1]The loss to investee was calculated at 75% for the three-month period representing the ownership percentage in Helomics owned by other parties.

NOTE 3 – REVENUE RECOGNITION

Revenue from Product Sales

The Company's revenue consists primarily of sales of the STREAMWAY System, as well as sales of the proprietary cleaning fluid and filters for use with the STREAMWAY System. The Company sells its products directly to hospitals and other medical facilities using employed sales representatives and independent contractors. Purchase orders, which are governed by sales agreements in all cases, state the final terms for unit price, quantity, shipping and payment terms. The unit price is considered the observable stand-alone selling price for the arrangements. The Company sales agreement, Terms and Conditions, is a dually executed contract providing explicit criteria supporting the sale of the STREAMWAY System. The Company considers the combination of a purchase order and the Terms and Conditions to be a customer's contract in all cases.

The Company recognizes revenue when it satisfies a performance obligation by transferring control of the promised goods or services to its customers, in an amount that reflects the consideration the Company expects to be entitled to in exchange for those goods or services. Sales taxes are imposed on the Company's sales to nonexempt customers. The Company collects the taxes from the customers and remits the entire amounts to the governmental authorities. The Company has elected the accounting policy to exclude sales taxes from revenue and expenses.

Product sales consist of a single performance obligation that the Company satisfies at a point in time. The Company recognizes product revenue when the following events have occurred: (a) the Company has transferred physical possession of the products, (b) the Company has a present right to payment, (c) the customer has legal title to the products, and (d) the customer bears significant risks and rewards of ownership of the products. Based on the shipping terms specified in the sales agreements and purchase orders, these criteria are generally met when the products are shipped from the Company's facilities ("FOB origin", which is the Company's standard shipping terms). As a result, the Company determined that the customer is able to direct the use of, and obtain substantially all of the benefits from, the products at the time the products are shipped. The Company may, at its discretion, negotiate different shipping terms with customers which may affect the timing of revenue recognition. The Company's standard payment terms for its customers are generally 30 to 60 days after the Company transfers control of the product to its customer. The Company allows returns of defective disposable merchandise if the customer requests a return merchandise authorization from the Company.

Customers may also purchase a maintenance plan from the Company, which requires the Company to service the STREAMWAY System for a period of one year subsequent to the one-year anniversary date of the original STREAMWAY System invoice. The maintenance plan is considered a separate performance obligation from the product sale, is charged separately from the product sale, and is recognized over time (ratably over the one-year period) as maintenance services are provided. A time-elapsed output method is used to measure progress because the Company transfers control evenly by providing a stand-ready service. The Company has determined that this method provides a faithful depiction of the transfer of services to its customers.

All amounts billed to a customer in a sales transaction related to shipping and handling, if any, represent revenues earned for the goods provided, and these amounts have been included in revenue. Costs related to such shipping and handling billing are classified as cost of goods sold.

Variable Consideration

The Company records revenue from distributors and direct end customers in an amount that reflects the transaction price it expects to be entitled to after transferring control of those goods or services. The Company's current contracts do not contain any features that create variability in the amount or timing of revenue to be earned.

Warranty

The Company generally provides one-year warranties against defects in materials and workmanship and will either repair the products or provide replacements at no charge to customers. As they are considered assurance-type warranties, the Company does not account for them as separate performance obligations. Warranty reserve requirements are based on a specific assessment of the products sold with warranties where a customer asserts a claim for warranty or a product defect.

Contract Balances

The Company records a receivable when it has an unconditional right to receive consideration after the performance obligations are satisfied. As of March 31, 2019, and December 31, 2018, accounts receivable totaled $173,443 and $232,602, respectively. For the three months ended March 31, 2019, the Company did not incur material impairment losses with respect to its receivables.

The Company deferred revenues related primarily to maintenance plans of $20,929 and $23,065 as of March 31, 2019 and December 31, 2018, respectively.

Practical Expedients

The Company has elected the practical expedient not to determine whether contracts with customers contain significant financing components.

NOTE 4 – STOCKHOLDERS' EQUITY, STOCK OPTIONS AND WARRANTS

2019 Registered Direct Offerings

On March 1, 2019, the Company completed a registered direct offering selling 1,385,000 shares of the Company's common stock and warrants to purchase up to 692,500 shares of common stock. The common stock and warrants were sold in units with each unit consisting of one share of common stock and a warrant to purchase 0.5 of a share of common stock at an exercise price of $1.00 per whole share. The units were sold at a price of $0.90 per unit, resulting in gross proceeds to the Company of $1,246,608, before deducting expenses. The Company granted the underwriter unit purchase options, pursuant to which the Company granted the underwriter or its assignees the right to purchase from the Company up to an aggregate of 69,250 units and an exercise price equal to 125% of the public offering price of the units in the offering, or $1.125 per unit. The unit purchase options shall expire on February 27, 2024.

On March 29, 2019, the Company completed a registered direct offering selling 1,478,750 shares of the Company's common stock and warrants to purchase up to 739,377 shares of common stock. The common stock and warrants were sold in units with each unit consisting of one share of common stock and a warrant to purchase 0.5 of a share of common stock at an exercise price of $1.00 per whole share. The units were sold at a price of $0.80 per unit, resulting in gross proceeds to the Company of $1,183,101, before deducting expenses. The Company granted the underwriter unit purchase options, pursuant to which the Company granted the underwriter or its assignees the right to purchase from the Company up to an aggregate of 73,937 units and an exercise price equal to 125% of the public offering price of the units in the offering, or $1.00 per unit. The unit purchase options shall expire on March 27, 2024.

Increases in Authorized Shares

At the annual meeting on December 28, 2017, the stockholders approved a proposal to increase the number of authorized shares of common stock from 24,000,000 to 50,000,000 shares of common stock, $0.01 par value. The amendment to the certificate of incorporation to affect this increase was filed on January 2, 2018.

At a special meeting of the stockholders on March 22, 2019, the stockholders approved a proposal to increase the number of authorized shares of common stock from 50,000,000 to 100,000,000 shares of common stock, $0.01 par value. The amendment to the certificate of incorporation to affect this measure was filed on March 22, 2019.

At a special meeting of the stockholders on March 22, 2019, the stockholders approved an amendment to the Amended and Restated 2012 Stock Incentive Plan to (a) increase the reserve of shares of common stock authorized for issuance thereunder to 10,000,000, (b) increase certain thresholds for limitations on grants, and (c) reapprove the performance goals thereunder.

Equity Incentive Plan

The Company has an equity incentive plan, which allows issuance of incentive and non-qualified stock options to employees, directors and consultants of the Company, where permitted under the plan. The exercise price for each stock option is determined by the Board of Directors. Vesting requirements are determined by the Board of Directors when granted and currently range from immediate to three years. Options under this plan have terms ranging from three to ten years.

Accounting for share-based payment

The Company uses the Black-Scholes option valuation model which requires the input of significant assumptions including an estimate of the average period of time employees will retain vested stock options before exercising them, the estimated volatility of the Company's common stock price over the expected term, the expected dividend rate, the risk-free interest rate, and forfeiture taken at occurrence. Changes in the assumptions can materially affect the estimate of fair value of stock-based compensation and, consequently, the related expense recognized. The assumptions the Company uses in calculating the fair value of stock-based payment awards represent the Company's best estimates, which involve inherent uncertainties and the application of management's judgment. As a result, if factors change and the Company uses different assumptions, the Company's equity-based compensation expense could be materially different in the future.

The Company has experienced no significant option exercises in its history. Beginning in 2019, the Company began calculating the estimated volatility used in the Black-Scholes option valuation model based on the trading history of the Company’s own stock. Given the limited trading history of the Company’s common stock, the Company had previously used the volatility of comparable companies in order to value options and warrants granted in prior years.

When an option or warrant is granted in place of cash compensation for services, the Company deems the value of the service rendered to be the value of the option or warrant. In most cases, however, an option or warrant is granted in addition to other forms of compensation and its separate value is difficult to determine without utilizing an option pricing model. For that reason the Company also uses the Black-Scholes option-pricing model to value options and warrants granted to non-employees, which requires the input of significant assumptions including an estimate of the average period the investors or consultants will retain vested stock options and warrants before exercising them, the estimated volatility of the Company's common stock price over the expected term, the number of options and warrants that will ultimately be forfeited before completing vesting requirements, the expected dividend rate and the risk-free interest rate. Changes in the assumptions can materially affect the estimate of fair value of stock-based consulting and/or compensation and, consequently, the related expense recognized.

Valuation and accounting for options and warrants

The Company determines the grant date fair value of options and warrants using a Black-Scholes option valuation model based upon assumptions regarding risk-free interest rate, expected dividend rate, volatility and estimated term.

For grants of stock option and warrants issued during the quarter ended March 31, 2019, the Company used 2.41% to 2.76% risk free interest rate, 0% dividend rate, 79.8% volatility and estimated terms of 5 to 10 years. Value computed using these assumptions ranged from $0.4112 to $.7644 per share.

The following summarizes transactions for stock options and warrants for the periods indicated:

	Stock Options		Warrants	
	Number of Shares	Average Exercise Price	Number of Shares	Average Exercise Price
Outstanding at December 31, 2017	2,764,983	$ 2.00	1,951,257	$ 23.74
Issued	1,098,858	1.01	2,336,154	1.07
Expired	(194,564)	2.00	(10,706)	199.55
Exercised	-	-	(650,062)	1.00
Outstanding at December 31, 2018	3,669,277	$ 1.70	3,626,643	$ 4.17
Issued	459,169	0.73	2,325,406	0.92
Expired	(56,867)	2.00	(919)	603.89
Outstanding at March 31, 2019	4,071,579	$ 1.59	5,951,130	$ 3.29

At March 31, 2019, 3,346,375 stock options are fully vested and currently exercisable with a weighted average exercise price of $1.70 and a weighted average remaining term of 8.72 years. There are 4,750,221 warrants that are fully vested and exercisable. Stock-based compensation recognized for the three months ended March 31, 2019 and March 31, 2018 was $263,600 and $226,387, respectively. The Company has $130,839 of unrecognized compensation expense related to non-vested stock options that are expected to be recognized over the next 20 months.

The following summarizes the status of options and warrants outstanding at March 31, 2019:

	Range of Prices	***Shares***	***Weighted Remaining Life***
Options			
$	0.619	524,958	9.77
$	0.75	33,335	10.00
$	0.82	60,000	9.67
$	0.849	3,534	9.80
$	0.90	30,000	9.92
$	0.91	10,000	9.05
$	0.965	3,000	9.13
$	0.97	191,753	8.77
$	1.01	149,110	8.88
$	1.06	23,585	9.51
$	1.10	86,958	9.22
$	1.125	69,250	4.92
$	1.13	195,931	9.31
$	1.15	21,740	9.34
$	1.16	66,451	9.35
$	1.18	30,000	9.36
$	1.20	41,668	9.34
$	1.21	30,000	9.86
$	1.35	111,112	8.96
$	1.454	17,200	8.51
$	1.47	2,271,476	8.24
$	2.10	14,286	8.01
$	2.25	293	7.41
$	2.42	20,640	7.39
$	2.80	57,145	7.76
$	3.75	4,000	7.25
$	4.125	3,636	7.51
$	4.1975	7,147	7.47
$	4.25	3,529	7.01
$	5.125	3,902	7.44
$	65.75	190	6.56
$	73.50	1,157	6.76
$	77.50	2,323	6.25
$	80.25	187	6.51
$	86.25	232	6.01
$	131.25	81	3.44
$	148.125	928	3.97
$	150.00	1,760	3.38
$	162.50	123	5.76
$	206.25	121	5.51
$	248.4375	121	4.29
$	262.50	77	4.26
$	281.25	529	3.80
$	318.75	3	4.11
$	346.875	72	5.01
$	431.25	306	4.94
$	506.25	188	4.76
$	596.25	42	4.50
		4,071,579	
Warrants			
$	0.70	754,642	4.78
$	0.836	221,292	4.67
$	1.00	2,495,811	4.34
$	1.07	697,946	3.60
$	1.155	1,071,776	4.50
$	1.188	138,889	4.78
$	1.3125	86,086	4.51
$	2.25	385,000	2.82
$	123.75	94,084	1.42
$	243.75	2,529	0.35
$	309.375	2,850	0.86
$	309.50	223	0.60
		5,951,130	

Stock Options and Warrants Granted by the Company

The following table is the listing of stock options and warrants as of March 31, 2019 by year of grant:

Stock Options:

Year	Shares	Price		
2011	173	$281.25		
2012	1,841	131.25	–	150.00
2013	1,500	148.13	–	596.25
2014	836	162.50	–	431.25
2015	4,088	65.75	–	86.25
2016	100,294	2.25	–	5.13
2017	2,427,320	1.01	–	2.10
2018	1,076,358	0.62	–	1.35
2019	459,169	0.62	–	1.13
Total	4,071,579	$0.62	–	$596.25

Warrants:

Year	Shares	Price		
2014	5,536	$243.75	–	$309.50
2015	94,151	0.00	–	243.75
2016	252,333	1.00		
2017	1,082,946	1.07	–	2.25
2018	2,190,758	0.84	–	1.155
2019	2,325,406	0.704	–	1.19
Total	5,951,130	$0.00	–	$309.50

NOTE 5 – NOTES RECEIVABLE

The Company has a secured promissory note receivable from CytoBioscience notes for $1,112,524, plus interest paid monthly at the per annum rate of (8%) on the principal amount. Unpaid principal and unpaid accrued interest on the note are due and payable on February 28, 2020. In 2019, CytoBioscience and its parent company, InventaBioTech, were current on all interest amounts due through April 2019. At this time the Company does not believe a reserve is needed.

As of December 31, 2018, the Company had a principal balance of $1,165,013, plus interest of $39,092, due from Helomics. In January and February 2019, the Company advanced Helomics $305,000. In March 2019, the Company advanced $420,000 to Helomics and advanced an additional $250,000 in April 2019. The balance to date owed by Helomics is $2,140,013 plus interest. On the balance sheet there is a reduction to the loan of $1,190,967 due to the cumulative equity method investments losses incurred from Helomics ownership; see Note 2. There were no further advances to Helomics prior to the completion of the merger. Upon completion of the merger with Helomics all intercompany notes were eliminated; see Note 10.

NOTE 6 – CONVERTIBLE DEBT AND DERIVATIVE LIABILITY

Effective September 28, 2018, the Company issued convertible secured promissory notes to two private investors in the original principal amount of an aggregate $2,297,727 (the “bridge loan”). The Company has loaned one-half of the net proceeds to Helomics. The Company and Helomics have granted to each of the investors a security interest in their assets to secure repayment of the bridge loan. The securities purchase agreements with the investors also provided for a second investment of an aggregate of $500,000 by the investors at the consummation of the Merger transaction with Helomics; however, the investors and the Company have agreed that the investors will not make the second investment. As additional consideration for the investment, the Company issued an aggregate 650,000 shares of its common stock (the “Inducement Shares”) to the investors or their affiliates plus warrants to acquire up to an aggregate 1,071,776 shares of the Company’s common stock at an exercise price of $1.155 per share. Each warrant is exercisable by the investor beginning on the six-month anniversary of the effective date through the fifth-year anniversary thereof.

The bridge loan accrues interest at a rate of 8% per annum (with twelve months of interest guaranteed). The bridge loan is due on September 28, 2019. Upon the earlier to occur of an event of default or the filing of certain registration statements, each investor will have the right at any time thereafter to convert all or any part of its bridge loan into shares of the Company’s common stock at a conversion price which is equal to the lesser of: (i) $1.00 and (ii) 70% of the lowest volume-weighted average price (the “VWAP”) of the Company’s common stock during the 20-trading day period ending on either the last complete trading day prior to the conversion date, or the conversion date (“Conversion Shares”). The number of Conversion Shares that may be issued is subject to an exchange cap such that the sum of (a) the total number of Conversion Shares plus (b) the number of Inducement Shares is limited to an aggregate 2,678,328 shares.

Management has concluded the conversion feature is an embedded derivative that is required to be bifurcated and separately presented as a liability on the balance sheet. The embedded derivative’s value was determined using 70% of the VWAP for the 20 trading days preceding the balance sheet date, and assuming conversion on that date as management believed it is probable that the bridge loan will be convertible based on management’s expectation that additional financing will be required. The derivative liability initially recorded in September 2018 was $645,008. The Company has recognized changes in the fair value of the derivative as unrealized gains and losses. The Company recognized an unrealized loss for the corresponding change in fair value of $19,408 for the three-month period ended March 31, 2019. The fair value of the derivative liability as of March 31, 2019 was $292,153.

The Company accounted for the warrants by deriving the Black-Scholes value ascertained with a discount rate of 2.94% over five years with a 59% volatility rate and a calculated value per warrant of ..5361 resulting in a fair value of $574,631. Management concluded that the warrants and Inducement Shares qualify for equity classification. The proceeds from the bridge loan were allocated between the convertible note, warrants, and inducement shares based on the relative fair value of the individual elements.

Effective February 7, 2019, the Company entered into a Forbearance Agreement with each of the bridge loan investors pursuant to which, among other things, the investors agreed to forbear on their rights to accelerate the bridge loan based on an event of default and a claimed event of default. In connection with such forbearance, the Company issued Amended and Restated Senior Secured Promissory Notes that replaced the original agreement and, among other things, increased the aggregate principal amount of its indebtedness to the investors by $344,659 to a balance of $2,642,387. Additionally, the investors received 166,667 inducement shares of the Company’s common stock, par value $0.01 per share, valued at $158,350, increasing common stock and additional paid-in capital.

In March 2019, one of the bridge loan investors twice converted a portion of the principal balance of the note. The investor converted $90,000 from the principal balance and received 159,854 shares of the Company’s common stock. Additionally, pursuant to the bridge loan agreement, as a result of the two public offerings a portion of the principal balance was reduced by $93,826.

The value of the embedded derivative from the bridge loan as well as the derivative included in the note payable agreements with the Company's CEO (See – Note 9) were based upon level 3 inputs – see the Fair Value Caption in Note 1. The flow table below discloses all changes in value of those derivative liabilities during the three-month period ended March 31, 2019.

Derivative Liability Balance at December 31, 2018	Derivative Instrument Issued	Loss Recognized to Revalue Derivative Instrument at Fair Value	Adjustments to Derivative Liability for Warrants Issued	Derivative Liability Balance at March 31, 2019
$ 272,745	69,722	19,408	8,665	$ 353,210

NOTE 7 - LOSS PER SHARE

The following table presents the shares used in the basic and diluted loss per common share computations:

	Three Months Ended March 31,	
	2019	2018
Numerator		
Net loss available in basic and diluted calculation	$ (3,293,184)	$ (1,760,022)
Comprehensive loss	(3,293,184)	(1,760,022)
Denominator:		
Weighted average common shares outstanding-basic	15,731,517	11,383,217
Effect of diluted stock options warrants and preferred stock (1)	-	-
Weighted average common shares outstanding-basic and diluted	15,731,517	11,383,217
Loss per common share-basic and diluted	$ (0.21)	$ (0.15)

(1) The number of shares underlying options and warrants outstanding as of March 31, 2019 and March 31, 2018 are 10,022,709 and 5,950,630, respectively. The number of shares underlying the convertible debt as of March 31, 2019 is 5,047,700. The number of shares underlying the preferred stock as of March 31, 2019 and March 31, 2018 is 79,246. The effect of the shares that would be issued upon exercise of such options, warrants, convertible debt and preferred stock has been excluded from the calculation of diluted loss per share because those shares are anti-dilutive.

Note 8 – LEASES

The Company's corporate offices are located at 2915 Commers Drive, Suite 900, Eagan, Minnesota 55121. On November 22, 2017, the Company signed a second amendment to its lease last amended on January 28, 2013. The lease as amended has a three-year term effective February 1, 2018 ending January 31, 2021. The Company leases 5,773 square feet at this location, of which 2,945 square feet is used for office space and 2,828 is used for manufacturing.

Skyline Medical Europe's offices are located at 9 Chemin de la Fraite – 1380 Ohain, Belgium. The lease agreement was signed April 24, 2018 and started on June 15, 2018. The Company leases around 2,000 square feet at this location, 750 of which is used for storage and 1,250 for office space. The lease is effective through June 14, 2027. Lease expense is 3,000 Euros per month.

Lease expense was $29,212 and $17,244 for the three months ended on March 31, 2019 and March 31, 2018, respectively.

The following table summarizes other information related to our operating leases:

	March 31, 2019
Weighted average remaining lease term – operating leases in years	7.02
Weighted average discount rate – operating leases	8%

The Company's rent obligation for the next five years are as follows:

2019	$ 60,060
2020	82,320
2021	43,320
2022	40,320
2023	40,320
2024 and thereafter	161,280
Total lease payments	427,620
Less interest	93,676
Present value of lease liabilities	$ 333,944

NOTE 9 – RELATED PARTY TRANSACTIONS

The Audit Committee has the responsibility to review and approve all transactions to which a related party and the Company may be a party prior to their implementation, to assess whether such transactions meet applicable legal requirements.

One of the Company's directors, Richard L. Gabriel, is the Chief Operating Officer and serves as a director of GLG Pharma ("GLG"). Another Company director, Tim Krochuk, is on the supervisory board for GLG. The Company and GLG have a partnership agreement with Helomics for the purpose of bringing together their proprietary technologies to build out personalized medicine platform for the diagnosis and treatment of women's cancer. There has been no revenue or expenses generated by this partnership to date.

In April 2018, one of the Company's directors, Richard L. Gabriel, executed a six-month consulting contract to help guide operations for the Company's wholly-owned subsidiary TumorGenesis. Under the terms of the agreement Mr. Gabriel will receive $12,000 in monthly cash payments. In addition, Mr. Gabriel will receive a grant of 240,000 performance-based restricted stock units ("RSU's") under the Company's Amended and Restated 2012 Stock Incentive Plan, with the vesting and payment of the RSU's based on performance milestones as set forth in the agreement. As of this filing date Mr. Gabriel has not reached any of the prescribed milestones for earning performance based restricted stock units. Mr. Gabriel executed another six-month consulting contract for these services in October 2018. The contract has the same terms as the April 2018 contract except for the stock grants and performance milestones, which are covered under the original contract. On May 1, 2019, Mr. Gabriel executed a one-year contract with renewable three-month periods. Mr. Gabriel will receive $13,500 in monthly cash payments otherwise the contract remains the same as the previously signed agreement.

On November 30, 2018, the Company's CEO, Dr. Carl Schwartz, made an investment of $370,000 in the Company and received a note and a common stock purchase warrant for 221,292 warrant shares at $0.836 per share. As of January 8, 2019, Dr. Schwartz made an additional investment of $950,000 and received an amended and restated note in the original principal amount of $1,320,000 and an amended and restated warrant, which added a second tranche of 742,188 warrant shares at an exercise price of $0.704. Each tranche is exercisable beginning on the sixth month anniversary of the date of the related investment through the fifth-year anniversary of the date of the related investment. On January 8, 2019, Dr. Schwartz also purchased 78,125 shares of the Company's common stock in a private investment for $50,000, representing a price of $0.64 per share, pursuant to a subscription agreement. On February 6, 2019, Dr. Schwartz made an additional investment of $300,000 in the Company and received an amended and restated note in the original principal amount of $1,620,000 and an amended and restated warrant, which added a third tranche of 138,889 warrant shares at an exercise price of $1.188 per share. Management concluded that the warrants qualified as equity classification. The proceeds from the loan from Dr. Schwartz were allocated between the note payable and warrants based on the relative fair value of the individual elements. On February 1, 2019 and the first day of each calendar month thereafter while the note and the warrant remain outstanding, a number of additional shares will be added to the second tranche and the third tranche equal to (1) one-half percent (1/2%) of the outstanding principal balance of the Note on such date, divided by (2) the closing price of the Company's common stock on that date. The Company has accounted for this liability to issue more warrants as a derivative liability as the exact number of warrants that will be issued was uncertain at the time of the agreement. The Company determined the fair value of this derivative liability by estimating the value and number of warrants that would be issued under various note payment scenarios. Based on this valuation, the Company recorded an initial derivative liability of $69,722. The Company issued 12,454 additional warrants to Dr. Schwartz under the agreement in February and March 2019, which reduced the value of the derivative liability by $8,665. As of March 31, 2019, the recorded derivative liability related to the agreement is $61,057.

NOTE 10 – SUBSEQUENT EVENTS

On April 4, 2019, the closing date, the Company acquired all of the outstanding common stock of Helomics. Helomics' precision medicine services are designed to use artificial intelligence and a comprehensive disease database to improve the effectiveness of cancer therapy. This transaction will be accounted for as a business combination.

The consideration for the remaining 75% of Helomics was approximately $7,822,632, consisting of 4.0 million shares of common stock with a merger date valuation of $2,993,200 and 3.5 million shares of preferred stock with a merger date valuation of $2,619,050. There was additional value of $2,210,382 for the extinguishment of the note due to the Company from Helomics. On the date of the transaction the Company's previous 25% interest in Helomics was recorded as an equity method investment (see – Note 2). This investment had a recorded value of zero dollars due to the previous recognition of the portion of Helomics net loss attributable to the Company. On the day of the transaction the Company revalued the previous 25% investment at fair value using the consideration paid for the remaining 75% to determine the approximate fair value of the previous investment. As the result of this revaluation the Company recognized $2,607,544. Given the timing of the closing of this transaction, the Company is currently in the process of valuing the assets acquired and liabilities assumed in the business combination. As a result, the Company is not yet able to provide amounts to be recognized as of the closing date for the major classes of assets acquired and liabilities assumed and other related disclosures. Also, on the day of the transaction the Company issued 8,637,323 shares of common stock to extinguish notes payable from Helomics. The Company issued the noteholders 14,245,063 warrants as part of the debt extinguishment. The Company agreed to issue options for 900,000 shares of common stock to Helomics employees. The Company is not yet able to provide amounts to be recognized as of the closing date.

On May 9, 2019, Dr. Schwartz advanced $75,000 to the Company. The loan earns 8% interest and is due in 60 days.

ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

Overview

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. Pursuant to an Agreement and Plan of Merger effective December 16, 2013, the Company merged with and into a Delaware corporation with the same name that was its wholly-owned subsidiary, with such Delaware Corporation as the surviving corporation of the merger. On August 31, 2015, the Company completed a successful offering and concurrent uplisting to The NASDAQ Capital Market. On February 1, 2018, we filed with the Secretary of State of Delaware a Certificate of Amendment to our Certificate of Incorporation to change our corporate name from Skyline Medical Inc. to Precision Therapeutics Inc., effective February 1, 2018. Because of this change, our common stock trades under the new ticker symbol "AIPT," effective February 2, 2018.

We are a healthcare products and services company that is expanding its business to take advantage of emerging areas of the dynamic healthcare market through sales of its products, through our ownership of Helomics Holding Corporation ("Helomics") a pioneering Contract Research Organization ("CRO") Services company and through pursuit of other strategic relationships to build value. In our STREAMWAY business, we manufacture an environmentally-conscious system for the collection and disposal of infectious fluids that result from surgical procedures and post-operative care. Since our inception in 2002, we have invested significant resources into product development. We believe that our success depends upon converting the traditional process of collecting and disposing of infectious fluids from the operating rooms of medical facilities to our wall-mounted Fluid Management System ("System") and use of our proprietary cleaning solution and bifurcated filter. Precision's CRO services business is committed to improving the effectiveness of cancer therapy using the power of artificial intelligence applied to rich data diseases databases. Precision has identified the CRO market as a burgeoning sector with significant growth potential. Effective April 4, 2019, we completed the merger with Helomics and as of then own 100% of Helomics. The merger was completed on April 4, 2019, and we believe that the merger will enable both companies to enhance potential value for stockholders, and that both companies will benefit from the merger. The merger resulted in a significant issuance of equity securities and will significantly increase the Company's capital needs.

In addition, we have formed a wholly-owned subsidiary, TumorGenesis Inc., to develop the next generation, patient derived tumor models for precision cancer therapy and drug development.

We sell our STREAMWAY products through an experienced direct sales force. The Company has one VP of Sales & Marketing, one VP of International Sales, and eight regional sales managers on staff as of March 2019. We have twelve independent distributors in the United States, Canada and overseas. We incorporated Skyline Medical Europe with an office in Belgium in February 2018 and hired a direct salesperson to cover Germany and France. We have contracted with two General Purchasing Organizations in the United States, Vizient and Intalere, providing customer exposure to more than 10,000 hospitals. The Company has contracted with Alliant Enterprises, LLC, a Service Disabled Veterans Owned Small Business supplier to the federal government. We have executed contracts with eleven international distributors: Quadromed, a Canadian distributor; MediBridge Sarl, a Swiss distributor; Device Technologies Australia PTY LTD, is an Australian distributor representing us throughout Australia, New Zealand, Fiji and the Pacific Islands; Century Scientific and Equipment Company in Kuwait; Mediurge in Pakistan; Prenit World in India; Sesneber in Saudi Arabia; Winner Scientific in Taiwan; Anifco in Bangladesh; Aras in the United Arab Emirates and Alfaisal Scientific Bureau in Iraq.

Precision's subsidiary, TumorGenesis, is pursuing 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. TumorGenesis intends to develop next generation, patient derived, ("PDx") tumor models for precision cancer therapy and drug development. This approach should provide a much more relevant model of the patient tumor that may be used for testing of drugs for personalized therapy or for the development of new drugs. Precision has entered into licensing arrangements with three medical technology companies.

Helomics Merger and Related Exchange Offer; Previous Minority Investment in Helomics

On April 4, 2019, the Company completed the merger in accordance with the terms of the merger agreement. On the same date, the Company completed a related exchange offer. These transactions resulted in the issuance of a significant number of shares of common stock, Series D Preferred Stock and warrants. See the description of the transactions in Note 10 to the condensed consolidated financial statements, "Subsequent Events". For all periods commencing April 4, 2019, our consolidated financial statements will reflect ownership of Helomics, which has been merged into a wholly owned subsidiary of the Company.

Prior to the effective date of the merger, the Company was a minority stockholder of Helomics. On January 11, 2018, the Company engaged in a share exchange transaction with Helomics in which the Company acquired beneficial ownership of 20% of Helomics' outstanding stock. On February 27, 2018, the Company exchanged $500,000 in promissory notes of Helomics for an addition 5% of Helomics' stock. As a result, prior to the effective date of the merger, the Company was required to record net income or loss to investee, based on a percentage of the net income or loss equal to the Company's percentage ownership. The merger with Helomics was completed after March 31, 2019, thus investee reporting is required for the first quarter in 2019.

Helomics experienced a net loss from continuing operations of $1,555,542, for the three-month period ended March 31, 2019. As a result, the Company recorded net loss to the Company of $439,637 for the three-month period ended March 31, 2019. Helomics' loss is due to a reduction of revenue by reserving a substantial amount of third-party revenue from insurance companies on diagnostic income. In the first quarter there was approximately $46,000 of initial CRO and D-CHIP revenue. Effective April 4, 2019, the Company owns 100% of the Helomics business. Therefore, Helomics' losses are likely to have a material adverse effect on the Company's financial position and results of operations for future periods.

Capital Requirements

Since inception, we have been unprofitable. We incurred net losses of approximately $3.3 million for the three months ended March 31, 2019, and $1.8 million for the three months ended March 31, 2018, respectively. As of March 31, 2019, and December 31, 2018, we had an accumulated deficit of approximately $66.4 million and $63.1 million, respectively. We received approval from the FDA in April 2009 to commence sales and marketing activities of the STREAMWAY System and shipped the first system in 2009. However, there was no significant revenue prior to 2011, primarily due to lack of funds to build and ship the product.

We have never generated sufficient revenues to fund our capital requirements. We have funded our operations through a variety of debt and equity instruments. See “Liquidity and Capital Resources – Liquidity, Plan of Financing and Going Concern Qualification” and “Liquidity and Capital Resources – Financing Transactions” below.

Our future cash requirements and the adequacy of available funds depend on our ability to sell our products and the availability of future financing to fulfill our business plans. We have committed significant capital and management resources to developing our contract research organization business and other new business areas. In addition, we have increased our expenditures to develop the business of our TumorGenesis subsidiary, to pursue a new rapid approach to growing tumors in the laboratory. It is likely that we will make further investments and advances in other businesses as we develop our CRO business and other business models. With completion of the Helomics merger, we expect that our operating cash needs will increase significantly. See “Plan of Financing; Going Concern Qualification” below.

As a company, our limited history of operations makes prediction of future operating results difficult. We believe that period to period comparisons of our operating results should not be relied on as predictive of our future results.

Results of Operations

Revenue.

	Three Months Ended March 31,			
	2019	**2018**	**$ Difference**	**% Difference**
Revenue	$ 255,000	$ 412,000	$ (157,000)	-38%

There were 7 sales of STREAMWAY units, three domestically and four internationally, in the three months ended March 31, 2019, compared to 16 sales of STREAMWAY units in the comparable 2018 period.

Cost of sales. Cost of sales was $74,000 in the three months ended March 31, 2019 and $117,000 in the three months ended March 31, 2018. The gross profit margin was approximately 71% in the three months ended March 31, 2019, compared to 71% in the prior year. Eventually, we expect increased sales to allow us to achieve volume purchasing discounts on both equipment components and our cleaning solution, which we expect to improve our margins.

General and Administrative expense. General and administrative expense primarily consists of management salaries, professional fees, consulting fees, travel expense, administrative fees and general office expenses.

General & Administrative (G&A) expenses increased by $256,000 for the three months ended March 31, 2019 compared to the 2018 period. The increase in the three-month period is due to $141,000 in legal fees resulting from two public offerings and the completion of the merger with Helomics; $106,000 in accounting and audit fees also resulting from the two public offerings and the completion of the merger with Helomics; $100,000 due to investors stock compensation for expenses related to the public offerings; $85,000 in stock based compensation for employee stock options; $56,000 in salaries and employee benefits due to an increase in staff and employee salaries; $23,000 in penalty fees due to a forbearance agreement with current noteholders; $21,000 in additional depreciation and amortization predominantly due to the amortization of license fees for TumorGenesis; other increases were $6,000 for consulting fees, $12,000 in rent due to the addition of the Belgium office, $5,000 in office supplies and $11,000 in state taxes. Offsets were $296,000 in investor relations expenses due to a conversion of preferred stock into cash in 2018 for a 2017 private placement and for increased fees for a S-3 takedown in January 2018; $13,000 in reduced corporate insurance fees and $6,000 in reduced recruiting fees.

Operations expense. Operations expense primarily consists of expenses related to product development and prototyping and testing in the company's current stage.

Operations expense increased by $179,000 in the three months ended March 31, 2019 compared to the three months ended March 31, 2018. Increases consisted of $101,000 in research and development due to producing our next generation STREAMWAY System; $56,000 in consulting expenses predominantly due to TumorGenesis and for hiring outside engineering resources; $38,000 in increased salaries and employee benefits due to the addition of staff and $10,000 in increased shipping and postage. There was a $31,000 offset in stock compensation expense due to reduced stock options for employees.

Sales and Marketing expense. Sales and marketing expense consists of expenses required to sell products through independent reps, attendance at trades shows, product literature and other sales and marketing activities**.**

Sales and marketing expenses increased by $4,000 in the three months ended March 31, 2019 compared to the three months ended March 31, 2018. The increase in 2019 resulted from $146,000 in payroll, taxes and employee benefits due to increasing our sales staff; $30,000 in higher travel and entertainment expenses for the increased sales staff; $10,000 in consulting for international sales; and, $9,000 in increased trade show attendance and advertising and promotion expense. Offsets were $110,000 in reduced website expense because the 2018 period included expenses to revamp the website, and $20,000 in marketing research because in 2018 we hired an independent researcher to write a combined analysis of the Company post-merger.

Impact of minority investment on net loss. The Company's net loss for the three-month period ended March 31, 2019 included loss on equity method investment of $439,637. This represents a portion of Helomics' net loss from continuing operations of $1,555,542 and results from the Company's ownership of 25% of Helomics' capital stock during this period. Commencing with the Merger effective April 4, 2019, the Company owns 100% of the Helomics business, which will be included in the Company's consolidated financial statements.

Liquidity and Capital Resources

Cash Flows

Net cash used in operating activities was $2,049,000 for the three months ended March 31, 2019 compared with net cash used of $1,694,000 for the 2018 period. Cash used increased by $794,000 in the 2019 period primarily because of increases in net losses, prepaid expenses and payments to accounts payable; offset by accrued expenses and an increase in amortization and debt discount.

Cash flows used in investing activities was $625,000 for the three months ended March 31, 2019 as compared to $146,000 of cash flows provided for the three months ended March 31, 2018. The Company had an increase in notes receivable relating to advances made to Helomics. As of April 4, 2019, these notes receivable were eliminated in connection with the Merger.

Net cash provided by financing activities was $3,636,000 for the three months ended March 31, 2019 compared to net cash provided of $3,015,000 for the three months ended March 31, 2018. The cash provided were proceeds from debt issuance due to the loan we received from the CEO and proceeds of the two public offerings of units we completed in the period.

Capital Resources

Our cash balance was approximately $1,125,000 as of March 31, 2019. We had a cash balance of $162,000 as of December 31, 2018. In the last week of March 2019, we received $1,183,100 gross proceeds from a registered direct offering; in April 2019 $250,000 of that amount was advanced to Helomics. As of March 31, 2019, we had an accumulated deficit of approximately $66,401,000.

Since inception to March 31, 2019, the Company has raised approximately $38,970,000 in equity and $9,120,000 in debt financing. Equity raises include: a January 2018 public offering with gross proceeds of $2,755,000; and March 2019 public offerings with gross proceeds of $1,246,608 and $1,183,101. Included in debt financing were raises in September 2018 on senior secured promissory notes with net proceeds of $1,815,000. In November 2018, the Company received a loan from the CEO for $370,000. In February 2019, the Company received a loan from the CEO for $950,000, and in March 2019 the Company received a loan from the CEO for $300,000.

In the first three months of 2019, we recognized $255,000 in revenues.

Plan of Financing; Going Concern Qualification

Since our inception, we have incurred significant losses, and our accumulated deficit was approximately $66,401,000 as of March 31, 2019. Our operations from inception have been funded with private placements of convertible debt securities and equity securities, public offerings and loan agreements.

In February 2019, the Company received an additional loan and investment equaling $1,300,000 from the Company's CEO. On March 1, 2019 the Company closed on a public offering receiving a net $1,111,880. The Company advanced $420,000 from this funding to Helomics for operating expenses. On March 29, 2019 the Company closed on a public offering receiving a net $1,053,360. The Company will continue to fund Helomics and will require additional funding as we have not achieved profitability and anticipate that we will continue to incur net losses at least through the remainder of 2019. The Company has classified such advances to Helomics as notes receivable on the Company's balance sheet, however all such receivables were eliminated upon the Company's acquisition of Helomics.

We had revenues of $255,000 in the quarter ended March 31, 2019, but we had negative operating cash flows of $2.0 million. Our cash balance was $1.1 million as of March 31, 2019, and our accounts payable and accrued expenses were an aggregate $1.2 million. Additionally, the debt agreements the Company entered into in 2018 and 2019 are all due within one year. A total of $4,078,561 principal balances are due under such agreements between September 2019 and February 2020. We are currently incurring negative operating cash flows. Although we are attempting to curtail our expenses, there is no guarantee that we will be able to reduce these expenses significantly, and expenses for some periods may be higher as we prepare our product for broader sales, increase our sales efforts and maintain adequate inventories.

We will require additional funding to finance operating expenses of our STREAMWAY business to invest in our sales organization and new product development and to pursue sales in the international marketplace. We have committed significant capital and management resources to develop our CRO business and other new business areas, and we intend to continue to devote significant management resources to new businesses. Our businesses will need to generate significant more revenue for the Company to sufficiently fund its operations without external financing. There is no assurance that we will be successful in raising sufficient capital, and the terms of any such financing will be dilutive to our stockholders. We may also acquire technologies or companies by issuing stock or other equity securities rather than or in addition to payment of cash, which may have the result of diluting the investment of our stockholders. Further, the energy and resources of our officers and personnel are being substantially diverted to these new lines of business, which are unproven. If these businesses are unsuccessful or require too great of a financial investment to be profitable, our business may fail regardless of the level of success of our STREAMWAY business.

If necessary, we will attempt to raise these funds through equity or debt financing, alternative offerings or other means. If we are successful in securing adequate funding we plan to make significant capital or equipment investments, and we will also continue to make human resource additions over the next 12 months. Such additional financing may 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, we will be forced to limit our business activities, which will have a material adverse effect on our results of operations and financial condition.

As a result of the above factors, we have concluded that there is substantial doubt about our ability to continue as a going concern. The financial statements have been prepared assuming the Company will continue as a going concern. Furthermore, our independent registered public accounting firm has indicated in their audit opinion, contained in our financial statements included in this Annual Report on Form 10-K within Item 8, that there is substantial doubt about our ability to continue as a going concern.

Forbearance Agreements with Prior Investors and Amended and Restated Notes

Effective as of February 7, 2019 (the "Effective Date"), Precision Therapeutics Inc. (the "Company," "we," or "our") entered into a: (1) a Forbearance Agreement with each of L2 Capital, LLC ("L2") and Peak One Opportunity Fund, LP ("Peak One" and, together with L2, the "Investors") (together, the "Forbearance Agreements"), and (2) an Amended and Restated Senior Secured Promissory Note with each of the Investors (together, the "Amended and Restated Notes").

The Amended and Restated Notes amend and restate in their entirety the Senior Secured Promissory Notes dated September 28, 2018 issued by the Company to the Investors on September 28, 2018 (together, the "Notes"). The Notes were in the original principal amount of an aggregate $2,297,728 and were issued in exchange for a $2,000,000 (less commissions) investment by the Investors in the Company, with net proceeds to the Company of $1,815,000 (the "Note Offering"). In connection with the Note Offering, the Company entered into, among other things, a Registration Rights Agreement with each of the Investors (together, the "Registration Rights Agreements").

Pursuant to the Forbearance Agreements, the Investors will forbear on their rights to accelerate the Notes and the Company will pay default penalties in connection with (1) a claimed event of default under the Registration Rights Agreements from the timing of filing a registration statement to register the Investors' shares of the Company's common stock issuable in connection with the Offering and (2) an event of default under the Notes from failing to obtain shareholder approval of the Company's proposed merger with Helomics Holding Corporation (the "Merger") by January 1, 2019.

On the Effective Date, the principal amount of the Notes (and as amended and restated, the Amended and Restated Notes) was increased by 15% of the current principal amount (i.e., by $242,386 for L2 and $102,273 for Peak One). On February 11, 2019, the Company issued 116,667 additional shares of common stock to L2 and 50,000 additional shares of common stock to Peak One (collectively, the "Forbearance Shares"). Pursuant to the Forbearance Agreements, the Company also agreed to use its best efforts to file with the SEC a registration statement covering the Forbearance Shares and to cause such registration statement to become effective as quickly as practicable.

The Company and the Investors also agreed that if (a) the Company obtains shareholder approval of the Merger by March 31, 2019, (b) the Registration Statement on Form S-3 filed by the Company on December 19, 2013 covering the transaction shares stays effective and (c) there are no other defaults under the Notes (and as amended and restated, the Amended and Restated Notes), the Registration Rights Agreements or any document issued in connection with the Offering, then the above defaults will be considered cured (the "Default Cure"), and the Amended and Restated Notes will not be accelerated and no additional default penalties will be paid. The Company believes that, as a result of the effectiveness of such registration statement on February 13, 2019 and the stockholder approval of the Merger on March 22, 2019, the Default Cure has been achieved. However, there can be no assurance that there will not be additional defaults under terms of the Amended and Restated Notes. If there is any other default under the transaction documents, the Amended and Restated Notes will accelerate, and the Investors may assert all of their rights.

Interest on the Notes (and as amended and restated, the Amended and Restated Notes) accrued at a default rate of 18% beginning November 15, 2018 through the date of the Default Cure. Upon certain financings, the Company is required to apply a portion of the proceeds to repayment of the Amended and Restated Notes.

November 2018 Investment by Dr. Carl Schwartz

Effective as of November 30, 2018, Dr. Carl Schwartz, our CEO, made an investment of $370,000 in Precision Therapeutics Inc. (the "Company") and received a Promissory Note (the "Note") and a Common Stock Purchase Warrant (the "Warrant"). The Note is currently in the principal amount of $370,000. Dr. Schwartz will make another investment of $130,000 on a mutually agreed date, at which time the total principal amount will be $500,000. The Note bears interest at the rate of eight percent (8%) per annum on the principal amount. The maturity date for the Note shall be the earlier of (a) the date five (5) business days after the closing of the Company's sale of equity or debt securities of the Company resulting in gross proceeds of at least $1,000,000, or (b) twelve (12) months from the date that the Note is issued, and is the date upon which the principal sum, as well as any accrued and unpaid interest and other fees, shall be due and payable.

As additional consideration for the investment, the Company issued the Warrant for a prorated number of shares of common stock based upon each tranche funded, which number is currently 221,292 warrant shares, and would be 299,043 warrant shares (representing an additional 77,751 warrant shares) if that the second tranche of $130,000 under the Note is funded. The exercise price is $0.836 per share, which was 110% of the closing sale price of the common stock on the date of issuance. The Warrant is exercisable beginning on the sixth month anniversary of the date of issuance through the fifth-year anniversary thereof.

Additional Investments in 2019 by Dr. Carl Schwartz

On January 8, 2019, Dr. Carl Schwartz, our Chief Executive officer, made an additional investment of $950,000 in a loan and $50,000 in a common stock purchase in the Company. On February 6, 2019, Dr. Schwartz, made an additional investment of $300,000 in the Company, following his November 30, 2018 and January 8, 2019 investments in the Company now aggregating $1,670,000. In connection with the new investment, Dr. Schwartz received a Second Amended and Restated Promissory Note in the original principal amount of $1,620,000. (the "Dr. Schwartz Note") and a Second Amended and Restated Common Stock Purchase Warrant (the "Dr. Schwartz Warrant"). The Dr. Schwartz Note and the Dr. Schwartz Warrant amend and restate the amended and restated promissory note and amended and restated common stock purchase warrant issued to Dr. Schwartz in connection with the previous investments.

The Dr. Schwartz Note bears interest at the rate of eight percent (8%) per annum on the principal amount. The maturity date for the Dr. Schwartz Note is February 6, 2020, and is the date upon which the principal sum, as well as any accrued and unpaid interest and other fees, shall be due and payable. The Dr. Schwartz Note may be prepaid in whole or in part at any time, and upon certain financings, the Company is required to apply a portion of the proceeds to repayment of the Dr. Schwartz Note.

As additional consideration for the investment, the Company issued the Dr. Schwartz Warrant with an exercise price of $0.836 per share for the initial 221,292 shares that related to the November 2018 investment (the "First Tranche"), an exercise price of $0.704 per share for the additional 748,415 shares (subject to increase as described below) relating to the second investment (the "Second Tranche"), and an exercise price of $1.188 per share for the additional 138,889 shares (subject to increase as described below) relating to the current investment (the "Third Tranche"). The exercise price in each case is equal to 110% of the closing sale price of the common stock on the date of the applicable investment. Each tranche of the Dr. Schwartz Warrant is exercisable beginning on the sixth month anniversary of the date of the related investment through the fifth-year anniversary of the date of the related investment.

On February 1, 2019, and the first day of each calendar month thereafter, while the Dr. Schwartz Note and the Dr. Schwartz Warrant remain outstanding, a number of additional shares will be added to the Second Tranche and the Third Tranche equal to (1) one-half percent (1/2%) of the outstanding principal balance of the Dr. Schwartz Note on such date, divided by (2) the closing price of the Company's common stock on that date. The number of warrant shares will be subject to a share limit such that the total of (a) the 78,128 shares of common stock purchased by Dr. Dr. Schwartz on January 8, 2019, and (b) the total number of warrant shares (1,108,596 warrant shares as of February 6, 2019) may not exceed 2,818,350 shares (equal to 19.9% of the outstanding shares of Common Stock on January 8, 2019). If the Second Tranche and/or Third Tranche cannot be increased as required herein due to the share limit, then in lieu of any such increase, the Company shall pay to Dr. Schwartz a cash amount equal to one-half percent (1/2%) of the principal balance of the Dr. Schwartz Note in lieu of such increase.

March 1, 2019 Registered Sale of Common Stock and Warrants

On February 27, 2019, we entered into a placement agency agreement pursuant to which Dawson James Securities, Inc. ("Dawson James") served as placement agent on a "best efforts" basis for a registered direct offering in which the Company sold 1,385,000 shares of common stock and warrants to purchase up to 692,500 shares of Common Stock. The common stock and warrants were sold in units, with each unit consisting of one share of Common Stock and a Warrant to purchase 0.5 of a share of our Common Stock at an exercise price of $1.00 per whole share. The Warrants are exercisable at any time on or after the date of issuance and expire on the fifth anniversary of issuance. The units were sold at a price of $0.90 per unit, resulting in gross proceeds to the Company of approximately $1.25 million, before deducting placement agent fees and estimated offering expenses. The net offering proceeds to the Company, after deducting the placement agent's fees and other estimated offering expenses payable by the Company, were $1.1 million. The closing of this offering occurred on March 1, 2019. Pursuant to the placement agency agreement, Dawson James received cash compensation of $134,720 for commissions and expenses. Also pursuant to the placement agency agreement, the Company entered into unit purchase option agreements, dated as of March 1, 2019, pursuant to which the Company granted Dawson James or its assigns the right to purchase from the Company up to an aggregate of 69,250 units (which represents 5% of the units sold to investors in the offering) at an exercise price equal to 125% of the public offering price of the units in the offering, or $1.125 per unit. The unit purchase options shall expire on February 27, 2024.

March 29, 2019 Registered Sale of Common Stock and Warrants

On March 26, 2019, we entered into a placement agency agreement pursuant to which Dawson James Securities, Inc. ("Dawson James") served as placement agent on a "best efforts" basis for a registered direct offering in which the Company sold 1,478,750 shares of common stock and warrants to purchase up to 739,375 shares of Common Stock. The common stock and warrants were sold in units, with each unit consisting of one share of Common Stock and a Warrant to purchase 0.5 of a share of our Common Stock at an exercise price of $1.00 per whole share. The Warrants are exercisable at any time on or after the date of issuance and expire on the fifth anniversary of issuance. The units were sold at a price of $0.80 per unit, resulting in gross proceeds to the Company of approximately $1.2 million, before deducting placement agent fees and estimated offering expenses. The net offering proceeds to the Company, after deducting the placement agent's fees and other estimated offering expenses payable by the Company, were $1.05 million. The closing of this offering occurred on March 29, 2019. Pursuant to the placement agency agreement, Dawson James received cash compensation of $129,640 for commissions and expenses. Also pursuant to the placement agency agreement, the Company entered into unit purchase option agreements, dated as of March 29, 2019, pursuant to which the Company granted Dawson James or its assigns the right to purchase from the Company up to an aggregate of 73,938 units (which represents 5% of the units sold to investors in the offering) at an exercise price equal to 125% of the public offering price of the units in the offering, or $1.00 per unit. The unit purchase options shall expire on March 29, 2024.

Off-Balance Sheet Arrangements

We have not engaged in any off-balance sheet activities as defined in Item 303(a)(4) of Regulation S-K.

Accounting Standards

Revenue Recognition. Effective January 1, 2018, we adopted Accounting Standards Update ("ASU") *No. 2014-09, Revenue from Contracts with Customers (Topic 606),* which outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers. The standard's core principle is that an entity will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services.

Our product sales consist of a single performance obligation that the Company satisfies at a point in time. We recognize product revenue when the following events have occurred: (a) the Company has transferred physical possession of the products, (b) the Company has a present right to payment, (c) the customer has legal title to the products, and (d) the customer bears significant risks and rewards of ownership of the products. Based on the shipping terms specified in the sales agreements and purchase orders, these criteria are generally met when the products are shipped from the Company's facilities ("FOB origin", which is the Company's standard shipping terms). As a result, we determined that the customer is able to direct the use of, and obtain substantially all of the benefits from, the products at the time the products are shipped. We may, at our discretion, negotiate different shipping terms with customers which may affect the timing of revenue recognition. Standard payment terms for our customers are generally 30 to 60 days after the Company transfers control of the product to its customer.

Customers may also purchase a maintenance plan from the Company, which requires that we service the STREAMWAY System for a period of one year subsequent to the one-year anniversary date of the original STREAMWAY System invoice. The maintenance plan is considered a separate performance obligation from the product sale, is charged separately from the product sale, and is recognized over time (ratably over the one-year period) as maintenance services are provided. A time-elapsed output method is used to measure progress because we transfer control evenly by providing a stand-ready service. We have determined that this method provides a faithful depiction of the transfer of services to our customers.

We record receivables when we have an unconditional right to receive consideration after the performance obligations are satisfied. As of March 31, 2019, and December 31, 2018, accounts receivable totaled $173,443 and $232,602, respectively. For the three months ended March 31, 2019, we did not incur material impairment losses with respect to our receivables.

See “Note 3 – Revenue Recognition,” in Notes to Condensed Consolidated Financial Statements of this Quarterly Report on Form 10-Q for further discussion.

Stock-Based Compensation. Effective January 1, 2006, we adopted ASC 718- Compensation-Stock Compensation (“ASC 718”). Under ASC 718 stock-based employee compensation cost is recognized using the fair value-based method for all new awards granted after January 1, 2006 and unvested awards outstanding at January 1, 2006. Compensation costs for unvested stock options and non-vested awards that were outstanding at January 1, 2006, are being recognized over the requisite service period based on the grant-date fair value of those options and awards, using a straight-line method. We elected the modified-prospective method in adopting ASC 718 under which prior periods are not retroactively restated.

ASC 718 requires companies to estimate the fair value of stock-based payment awards on the date of grant using an option-pricing model. We use the Black-Scholes option-pricing model which requires the input of significant assumptions including an estimate of the average period of time employees and directors will retain vested stock options before exercising them, the estimated volatility of our common stock price over the expected term, the number of options that will ultimately be forfeited before completing vesting requirements and the risk-free interest rate.

The Company has experienced no significant option exercises in its history. Beginning in 2019, the Company began calculating the estimated volatility used in the Black-Scholes option valuation model based on the trading history of the Company’s own stock. Given the limited trading history of the Company’s common stock, the Company had previously used the volatility of comparable companies in order to value options and warrants granted in prior years.

When an option or warrant is granted in place of cash compensation for services, we deem the value of the service rendered to be the value of the option or warrant. In most cases, however, an option or warrant is granted in addition to other forms of compensation and its separate value is difficult to determine without utilizing an option pricing model. For that reason we also use the Black-Scholes option-pricing model to value options and warrants granted to non-employees, which requires the input of significant assumptions including an estimate of the average period that investors or consultants will retain vested stock options and warrants before exercising them, the estimated volatility of our common stock price over the expected term, the number of options and warrants that will ultimately be forfeited before completing vesting requirements and the risk-free interest rate. Changes in the assumptions can materially affect the estimate of fair value of stock-based compensation and, consequently, the related expense recognizes that. Since we have no trading history in our common stock and no first-hand experience with how our investors and consultants have acted in similar circumstances, the assumptions we use in calculating the fair value of stock-based payment awards represent our best estimates, which involve inherent uncertainties and the application of management's judgment. As a result, if factors change and we use different assumptions, our equity-based consulting and interest expense could be materially different in the future.

Notes Receivable. We review open notes receivable balances for collectability each reporting period. If it is determined that it is probable that we will not collect the full amount due under a note agreement, we record reserves against the note receivable balance in accordance with ASC 310 – *Receivables*. In order to reasonably conclude on the collectability of such balances, we consider the borrower’s current status on payments received, the financial health and other sources of funding available to each borrower, our ability to secure assets collateralized by contractual agreements, as well as other factors.

Recent Accounting Developments

See Note 1 - “Summary of Significant Accounting Policies” to the Condensed Consolidated Financial Statements of this Quarterly Report on Form 10-Q for a discussion of recent accounting developments.

Information Regarding Forward-Looking Statements

This Form 10-Q contains “forward-looking statements” that indicate certain risks and uncertainties related to the Company, many of which are beyond the Company’s control. The Company’s actual results could differ materially and adversely from those anticipated in such forward-looking statements as a result of certain factors, including those set forth below and elsewhere in this report. Important factors that may cause actual results to differ from projections include:

- Current negative operating cash flows;
- The terms of any further financing, which may be highly dilutive and may include onerous terms;
- Risks related to the recent Merger with Helomics; 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 the disruption of the Company’s and Helomics’ existing businesses; and distraction of management and diversion of resources; delay in completion of the merger may significantly reduce the expected benefits;
- 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.
- Risk that we will be unable to protect our intellectual property or claims that we are infringing on others’ intellectual property;
- The impact of competition, the obtaining and maintenance of any necessary regulatory clearances applicable to applications of the Company’s technology;
- Inability to attract or retain qualified senior management personnel, including sales and marketing personnel;
- Risk that we never become profitable if our product is not accepted by potential customers;
- Possible impact of government regulation and scrutiny;
- Unexpected costs and operating deficits, and lower than expected sales and revenues, if any;
- Adverse results of any legal proceedings;
- The volatility of our operating results and financial condition, and,
- Other specific risks that may be alluded to in this report.

All statements other than statements of historical facts, included in this report regarding the Company’s growth strategy, future operations, financial position, estimated revenue or losses, projected costs, prospects and plans and objectives of management are forward-looking statements. When used in this report, the words “will”, “may”, “believe”, “anticipate”, “intend”, “estimate”, “expect”, “project”, “plan” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain such identifying words. All forward-looking statements speak only as of the date of this report. The Company does not undertake any obligation to update any forward-looking statements or other information contained herein. Potential investors should not place undue reliance on these forward-looking statements. Although the Company believes that its plans, intentions and expectations reflected in or suggested by the forward-looking statements in this report are reasonable the Company cannot assure potential investors that these plans, intentions or expectations will be achieved. The Company discloses important factors that could cause the Company’s actual results to differ materially from its expectations in the “Risk Factors” section and elsewhere our Annual Report on Form 10-K for the year ended December 31, 2018 and in item 1A of Part II below. These cautionary statements qualify all forward-looking statements attributable to the Company or persons acting on its behalf.

Information regarding market and industry statistics contained in this report is included based on information available to the Company that it believes is accurate. It is generally based on academic and other publications that are not produced for purposes of securities offerings or economic analysis. The Company has not reviewed or included data from all sources, and the Company cannot assure potential investors of the accuracy or completeness of the data included in this report. Forecasts and other forward-looking information obtained from these sources are subject to the same qualifications and the additional uncertainties accompanying any estimates of future market size, revenue and market acceptance of products and services. The Company has no obligation to update forward-looking information to reflect actual results or changes in assumptions or other factors that could affect those statements.

ITEM 3. Quantitative and Qualitative Disclosures About Market Risk

Not required.

ITEM 4. Controls and Procedures

With the participation of the Chief Executive Officer and the Chief Financial Officer, management has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934). Based on that evaluation, the Chief Executive Officer and the Chief Financial Officer concluded that our disclosure controls and procedures were effective as of March 31, 2019.

There were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Securities Exchange Act of 1934) during the three months ended March 31, 2019 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. Legal Proceedings

None

ITEM 1A. Risk Factors

In addition to the other information set forth in the Quarterly Report on Form 10-Q, the reader should carefully the risks described below before making an investment decision. Our business could be harmed by any of these risks. The trading price of our common stock could decline due to any of these risks, and you may lose all or part of your investment. The following risk factors amend, restate and supplement the risk factors discussed in the Company's Annual Report on Form 10-K for the year ended December 31, 2018.

We will require additional financing to finance operating expenses and fulfill our business plan. Such financing will be dilutive. Our independent public accounting firm has indicated in their audit opinion, contained in our financial statements, that they have serious doubts about our ability to remain a going concern.

We have not achieved profitability and anticipate that we will continue to incur net losses at least through the remainder of fiscal 2019. We had revenues of $1,412,000 in 2018, but we had negative operating cash flows of $5.3 million. We had revenues of $255,000 in the first three months of 2019, but we had negative operating cash flows of $2.0 million. The Company had cash and cash equivalents of $1,124,730 as of March 31, 2019 and needs to raise significant additional capital to meet its operating needs, pay debt obligations coming due, and the continued operating needs of Helomics, therefore there is substantial doubt about the Company's ability to continue as a going concern for one year after the date that the financial statements are issued. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. The Company has available financing options including a shelf registration statement on Form S-3, with which the Company has raised approximately $2.1 million in net proceeds in early 2019. The Company may raise up to approximately $5.0 million in additional gross proceeds, now that the Helomics acquisition is completed.

As of March 31, 2019, the Company had debt totaling $3.1 million. Our accounts payable and accrued expenses as of March 31, 2019 were an aggregate $1,230,000. Although we are attempting to curtail our expenses, there is no guarantee that we will be able to reduce these expenses significantly, and expenses for some periods may be higher as we prepare our product for broader sales, increase our sales efforts and maintain adequate inventories. Further, Helomics continues to incur negative operating cash flows, and the Helomics business continues to require significant cash resources following the completion of the Merger.

We will require additional funding to finance operating expenses and to invest in our sales organization and new product development and to compete in the international marketplace, as well as to develop the Helomics business and other aspects of our CRO business. We will attempt to raise these funds through equity or debt financing, alternative offerings or other means. If we are successful in securing adequate funding we plan to make significant capital or equipment investments, and we will also 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, we will be forced to limit our business activities, which will have a material adverse effect on our results of operations and financial condition.

As a result of the above factors, the Company has concluded that there is substantial doubt about its' ability to continue as a going concern. The financial statements have been prepared assuming the Company will continue as a going concern. Furthermore, our independent registered public accounting firm has indicated in their audit opinion, contained in our financial statements included in this Annual Report on Form 10-K within Item 8, that there is substantial doubt about our ability to continue as a going concern. See "Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources."

In connection with developing our CRO business, we have committed and will continue to commit significant capital to investments in early stage companies, all of which may be lost, and which may require us to raise significant additional capital, and our entering into new lines of business will result in significant diversion of management resources, all of which may result in failure of our business.

We have committed significant capital and management resources to developing our CRO business and other new business areas, and we intend to continue to devote significant and management resources to new businesses. Through the effective date of the Merger, we provided approximately $2.1 million in financing to Helomics, of which $500,000 in principal amount was converted into an equity interest in Helomics and the remaining $1.7 million in principal and accrued interest was canceled in connection with the Merger. In addition, in August 2017, we entered into a merger agreement with CytoBioscience, which was subsequently terminated in November 2017. From July 2017 through November 2017, we advanced $1,070,000 to CytoBioscience in the form of secured notes, which are still outstanding. CytoBioscience has defaulted on the notes, but in January 2019 reached repayment agreement with the Company and remitted approximately $61,000 covering a portion of principal, interest and legal bills toward collection processes. CytoBioscience made a second payment of $65,458 in March 2019 bringing the note current pursuant to the repayment agreement. The Company has a Confession of Judgment and UCC protection on collateral, however this does not guarantee timely or full payment on the notes. Unpaid principal and unpaid accrued interest on the note are due and payable on February 28, 2020. In 2019, CytoBioscience and its parent company, InventaBioTech, were current on all interest amounts due through April 2019. InventaBioTech informed the Company that May interest will be paid prior to month end. At this time the Company does not believe a reserve is needed. It is likely that we will make further investments and advances in other businesses as we develop our CRO business and other business models. There can be no assurance that any of the outstanding balances of our existing promissory notes or future advances will be repaid. Therefore, we could invest significant capital in other business enterprises with no certainty when or whether we will realize a return on these investments. Investments in cash will deplete our capital resources, meaning that we will be required to raise significant amounts of new capital. There is no assurance that we will be successful in raising sufficient capital, and the terms of any such financing will be dilutive to our stockholders. We may also acquire technologies or companies by issuing stock or other equity securities rather than or in addition to payment of cash, which may have the result of diluting the investment of our stockholders. Further, the energy and resources of our officers and personnel are being substantially diverted to new lines of business, which are unproven. If these businesses are unsuccessful or require too great of a financial investment to be profitable, our business may fail regardless of the level of success of our STREAMWAY business.

Our limited operating history makes evaluation of our business difficult.

We were formed on April 23, 2002 and to date have generated only moderate revenue year by year. Our ability to implement a successful business plan remains unproven and no assurance can be given that we will ever generate sufficient revenues to sustain our business. We have a limited operating history which makes it difficult to evaluate our performance. You must consider our 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 we will be able to:

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

STREAMWAY Business Risk Factors

Our business is dependent upon proprietary intellectual property rights, which if we were unable to protect, could have a material adverse effect on our business.

We rely on a combination of patent, trade secret and other intellectual property rights and measures to protect our intellectual property. We currently own 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 our products. We rely on patent laws and other intellectual property laws, nondisclosure and other contractual provisions and technical measures to protect our products and intangible assets. These intellectual property rights are important to our ongoing operations and no assurance can be given that any measure we implement will be sufficient to protect our intellectual property rights. Also, with respect to our trade secrets and proprietary know-how, we cannot be certain that the confidentiality agreements we have entered into with employees will not be breached, or that we will have adequate remedies for any breach. We may lose the protection afforded by these rights through patent expirations, legal challenges or governmental action. If we cannot protect our rights, we may lose our competitive advantage if these patents were found to be invalid in the jurisdictions in which we sell or plan to sell our products. The loss of our intellectual property rights could have a material adverse effect on our business.

If we become subject to intellectual property actions, this could hinder our ability to deliver our products and services and our business could be negatively impacted.

We could be subject to legal or regulatory actions alleging intellectual property infringement or similar claims against us. Companies may apply for or be awarded patents or have other intellectual property rights covering aspects of our technologies or businesses. Moreover, if it is determined that our products infringe on the intellectual property rights of third parties, we could be prevented from marketing our products. While we are currently not subject to any material intellectual property litigation, any future litigation alleging intellectual property infringement could be costly, particularly in light of our limited resources. Similarly, if we determine that third parties are infringing on our patents or other intellectual property rights, our limited resources may prevent us from litigating or otherwise taking actions to enforce our rights. Any such litigation or inability to enforce our rights could require us to change our business practices, hinder or prevent our ability to deliver our products and services, and result in a negative impact to our business. Expansion of our 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 our competitors and/or suppliers. Our inability to successfully mitigate those factors may significantly reduce our market opportunity and subsequent growth.

We face significant competition, including competition from companies with considerably greater resources than ours, and if we are unable to compete effectively with these companies, our market share may decline and our business could be harmed.

Our industry is highly competitive with numerous competitors ranging from well-established manufacturers to innovative start-ups. A number of our competitors have significantly greater financial, technological, engineering, manufacturing, marketing and distribution resources than we do. 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.

Our 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 our market. Both of these competitors are substantially larger than our company and are better capitalized than we are.

Companies with significantly greater resources than ours may be able to reverse engineer our products and/or circumvent our intellectual property position. Such action, if successful, would greatly reduce our competitive advantage in the marketplace.

We believe our ability to compete successfully depends on a number of factors, including our technical innovations of unlimited suction and unlimited capacity capabilities, our innovative and advanced research and development capabilities, strength of our intellectual property rights, sales and distribution channels and advanced manufacturing capabilities. We plan to employ these and other elements as we develop our products and technologies, but there are many other factors beyond our control. We 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 our development and marketing of new products, which could adversely impact the trading price of the shares of our common stock.

Our business is subject to intense governmental regulation and scrutiny, both in the U.S. and abroad.

The production, marketing, and research and development of our products is subject to extensive regulation and review by the FDA and other governmental authorities both in the United States and abroad. In addition to testing and approval procedures, extensive regulations also govern marketing, manufacturing, distribution, labeling, and record keeping. If we do 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 our present or proposed products. Any change in legislation or regulations that govern the review and approval process relating to our current and future products could make it more difficult and costlier to obtain approval for new products, or to produce, market, and distribute existing products.

If our STREAMWAY System product is not accepted by our potential customers, it is unlikely we will ever become profitable.

The medical industry has historically used a variety of technologies for fluid waste management. Compared to these conventional technologies, our technology is relatively new, and the number of companies using our technology is limited. The commercial success of our product will depend upon the widespread adoption of our technology as a preferred method by hospitals and surgical centers. In order to be successful, our products 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;
- our ability to convince prospective strategic partners and customers that our technology is an attractive alternative to conventional methods used by the medical industry;
- our ability to select and execute agreements with effective distributors to market and sell our product; and
- our ability to assure customer use of the Skyline proprietary cleaning solution and in-line filter.

Because of these and other factors, our products may not gain market acceptance or become the industry standard for the health care industry. The failure of such companies to purchase our products would have a material adverse effect on our business, results of operations and financial condition.

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

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

We are dependent on a few key executive officers for our success. Our inability to retain those officers would impede our business plan and growth strategies, which would have a negative impact on our business and the value of an investment.

Precision's success depends on the skills, experience and performance of key members of its management team. Precision heavily depends on its management team: Carl Schwartz, Precision's Chief Executive Officer ("CEO"), and Bob Myers, Precision's Chief Financial Officer ("CFO"). Precision has entered into employment agreements with the CEO and the CFO of the senior management team and may expand the relatively small number of executives in its company. Were Precision 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 Precision's business plan and the diversion of its limited working capital. Precision can give no assurance that it can find satisfactory replacements for these key individuals at all, or on terms that are not unduly expensive or burdensome to Precision.

Our success is dependent on our ability to attract and retain technical personnel, sales and marketing personnel, and other skilled management.

Our success depends to a significant degree on our 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 our business. If we fail to attract, train and retain sufficient numbers of these highly-qualified people, our prospects, business, financial condition and results of operations will be materially and adversely affected.

Security breaches, loss of data and other disruptions to Precision or its third-party service providers could compromise sensitive information related to Precisions' business or prevent Precision from accessing critical information and expose it to liability, which could adversely affect Precisions' business and reputation.

Precisions' business requires that Precision collect and store sensitive data including credit card information, and Precisions' proprietary business and financial information. Precision faces a number of risks relative to Precisions' protection of, and Precisions' service providers' protection of, this critical information, including loss of access, inappropriate disclosure and inappropriate access, as well as risks associated with Precisions' ability to identify and audit such events. The secure processing, storage, maintenance and transmission of this critical information are vital to Precisions' operations and business strategy, and Precision devotes significant resources to protecting such information. Although Precision takes measures to protect sensitive information from unauthorized access or disclosure, Precisions' information technology and infrastructure may be vulnerable to attacks by hackers or viruses or otherwise breached due to employee error, malfeasance or other activities. While Precision has not experienced any such attack or breach, if such event would occur and cause interruptions in Precisions' operations, Precisions' networks would be compromised and the information Precision stores on those networks could be accessed by unauthorized parties, publicly disclosed, lost or stolen. Unauthorized access, loss or dissemination could disrupt Precisions' operations, including collecting, processing and preparing company financial information, manage the administrative aspects of Precisions' business and damage Precisions' reputation, any of which could adversely affect Precisions' business. In addition, the interpretation and application of consumer, health-related and data protection laws in the United States are often uncertain, contradictory and in flux. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with Precisions' practices. Complying with these various laws could cause Precision to incur substantial costs or require Precision to change its business practices, systems and compliance procedures in a manner adverse to Precisions' business.

Costs incurred because Precision is a public company may affect its profitability.

As a public company, Precision incurs significant legal, accounting, and other expenses and it is subject to the SEC's rules and regulations relating to public disclosure that generally involve 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. Full compliance with such rules and regulations requires significant legal and financial compliance costs and makes some activities more time-consuming and costlier, which may negatively impact its financial results. To the extent Precision's 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 its securities could be harmed.

Limitations on director and officer liability and indemnification of our officers and directors by us may discourage stockholders from bringing suit against a director.

Our 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 us or our 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 our behalf against a director. In addition, our certificate of incorporation and bylaws may provide for mandatory indemnification of directors and officers to the fullest extent permitted by governing state law.

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

We currently intend to retain any future earnings to support the development and expansion of our business and do not anticipate paying cash dividends in the foreseeable future. Our payment of any future dividends will be at the discretion of our Board of Directors after taking into account various factors, including but not limited to, our financial condition, operating results, cash needs, growth plans and the terms of any credit agreements that we may be a party to at the time. In addition, our ability to pay dividends on our 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 their 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 as in effect as of the date of this registration statement, a stockholder (or stockholders whose shares are aggregated) who has satisfied the applicable holding period and is not deemed to have been one of our 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 our common stock pursuant to Rule 144 or pursuant to any resale prospectus may have a material adverse effect on the market price of our securities.

We expect volatility in the price of our common stock, which may subject us to securities litigation.

When established, the market for our common stock may be characterized by significant price volatility when compared to seasoned issuers, and we expect that our share price will be more volatile than a seasoned issuer for the indefinite future. In addition, there is no assurance that the price of our 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. We 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.

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

Our authorized capital includes 20 million shares of preferred stock. Of this amount, 18,950 shares have been designated as Series B Convertible Preferred Stock, 1,213,819 shares have been designated as Series C Preferred Stock, 3,500,000 shares have been designated as Series D Convertible Preferred Stock and the remaining authorized shares are undesignated preferred stock. Our Board of Directors have 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, we are subject to provisions of the Delaware General Corporation Law regarding "business combinations." We may, in the future, consider adopting additional anti-takeover measures. The authority of our 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 us, may, in certain circumstances, delay, deter or prevent takeover attempts and other changes in control of the company not approved by our Board of Directors. As a result, our 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 our common stock or rights to purchase common stock could result in additional dilution of the percentage ownership of our stockholders and could cause our share price to fall.

We also expect that significant additional capital will be needed in the future to continue our planned operations. To the extent that we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities, or other equity securities in one or more transactions at prices and in a manner, we determine from time to time. If we sell 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 our existing stockholders, and new investors could gain rights superior to our existing stockholders. In addition, in the past, we have issued warrants to acquire shares of common stock. To the extent these warrants are ultimately exercised, you will sustain further dilution.

Acquisitions involve risks that could result in adverse changes to operating results, cash flows and liquidity.

Precision intends to make strategic acquisitions in addition to the Merger. However, Precision may not be able to identify suitable acquisition opportunities or may be unable to obtain the consent of Precision's stockholders and therefore, may not be able to complete such acquisitions. Precision may pay for acquisitions with its common stock or with convertible securities, which may dilute shareholders' investment in its common stock or it may decide to pursue acquisitions that investors may not agree with. In connection with potential Precision's acquisitions, Precision may agree to substantial earn-out arrangements. To the extent it defers the payment of the purchase price for any acquisition through a cash earn-out arrangement, it will reduce cash flows in subsequent periods. In addition, acquisitions may expose Precision to operational challenges and risks, including:

- the ability to profitably manage acquired businesses or successfully integrate the operations of acquired businesses, as well as the acquired business's financial reporting and accounting control systems into its existing platforms;
- increased indebtedness and contingent purchase price obligations associated with an acquisition;
- the ability to fund cash flow shortages that may occur if anticipated revenue is not realized or is delayed, whether by general economic or market conditions, or unforeseen internal difficulties;
- the availability of funding sufficient to meet increased capital needs;
- diversion of management's time and attention from existing operations; and
- the ability to retain or hire qualified personnel required for expanded operations.

Completing acquisitions may require significant management time and financial resources because Precision may need to assimilate widely dispersed operations with different corporate cultures. In addition, acquired companies may have liabilities that it failed to or were unable to discover in the course of performing due diligence investigations. Precision cannot assure the shareholders' that the indemnification granted by sellers of acquired companies will be sufficient in amount, scope or duration to fully offset the possible liabilities associated with businesses or properties it assumes upon consummation of an acquisition. Precision may learn additional information about its acquired businesses that could have a material adverse effect on Precision, such as unknown or contingent liabilities and liabilities related to compliance with applicable laws. Any such liabilities, individually or in the aggregate, could have a material adverse effect on its business. Failure to successfully manage the operational challenges and risks associated with, or resulting from, acquisitions could adversely affect Precision's results of operations, cash flows and liquidity. Borrowings or issuances of convertible securities associated with these acquisitions may also result in higher levels of indebtedness, which could adversely impact Precision's ability to service its debt within the scheduled repayment terms.

Our common stock could be delisted from The NASDAQ Capital Market, which delisting could hinder your ability to obtain accurate quotations on the price of our common stock or dispose of our common stock in the secondary market.

On November 16, 2018, we received a letter from the Listing Qualifications Department (the "Staff") of The Nasdaq Stock Market LLC ("Nasdaq") informing us that because the closing bid price for our common stock listed on Nasdaq was below $1.00 for 30 consecutive trading days, we do not comply with the minimum closing bid price requirement for continued listing on The Nasdaq Capital Market under Nasdaq Marketplace Rule 5550(a)(2), requiring a minimum bid price of $1.00 per share (the "Minimum Bid Price Requirement"). The notification has no immediate effect on the listing of our common stock.

In accordance with Nasdaq's Marketplace Rule 5810(c)(3)(A), we had a period of 180 calendar days, or until May 15, 2019, to regain compliance with the Minimum Bid Price Requirement. However, the bid price of the Company's common stock did not close at or above $1.00 per share for a minimum of 10 consecutive business days, and therefore we did not regain compliance with the Minimum Bid Price Requirement by May 15, 2019. However, we may be eligible for additional time. To qualify for additional time, we would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, with the exception of the bid price requirement, and would need to provide written notice of our intention to cure the deficiency during the second compliance period, by effecting a reverse stock split, if necessary. We have provided such notice to the Staff; however, if it appears to the Staff that we will not be able to cure the deficiency, or if we are otherwise not eligible, the Staff would notify us that our securities would be subject to delisting. In the event of such notification, we may appeal the Staff's determination to delist its securities, but there can be no assurance the Staff would grant our request for continued listing.

In the event our common stock is delisted from The NASDAQ Capital Market and we are also unable to maintain listing on another alternate exchange, trading in our common stock could thereafter be conducted in FINRA's OTC Bulletin Board or in the over-the-counter markets in the so-called pink sheets. In such event, the liquidity of our common stock would likely be impaired, not only in the number of shares which could be bought and sold, but also through delays in the timing of the transactions, and there would likely be a reduction in our coverage by security analysts and the news media, thereby resulting in lower prices for our common stock than might otherwise prevail.

Precision's ability to obtain and/or utilize financing to fund our ongoing operations may be limited by the terms of our certain outstanding Amended and Restated Senior Secured Promissory Notes.

Effective September 28, 2018, Precision issued one-year convertible promissory notes to each of two institutional investors (the "Investors") (together, the "Notes") in the original principal amount of an aggregate $2,297,728. The Notes accrue interest at a rate of 8% per annum (with twelve months of interest guaranteed). The Notes may be prepaid in any amount, provided that any amounts that are repaid from and after January 26, 2019 (including repayment at maturity and mandatory prepayments discussed below) will be subject to a 25% repayment penalty.

Effective February 7, 2019, Precision entered into a Forbearance Agreement with each of the Investors pursuant to which, among other things, the Investors agreed to forbear on their rights to accelerate the Notes based on an event of default and a claimed event of default. In connection with such forbearance, Precision issued Amended and Restated Senior Secured Promissory Notes that replaced the Notes and, among other things, increased the aggregate principal amount of our indebtedness to the Investors to $2,642,387.

As long as the Amended and Restated Notes remain outstanding, if Precision receives cash proceeds from any source other than (i) sales of our products or (ii) the first $2,000,000 of proceeds from securities offering transactions, Precision is required to inform the Investors of such receipt. Investor will have the right to require that Precision apply up to 50% of such proceeds to repay outstanding amounts owed under their Note. As a result, proceeds from future securities offering transactions will likely be subject to the Investors' repayment rights. The aforementioned criteria may negatively impact Precision's ability to obtain financing from securities offering transactions until repayment or conversion of the Notes. To the extent we are able to obtain such financing, this arrangement may limit Precision's ability to use the proceeds thereof to fund its operations. If we are unable to obtain financing or use the proceeds to fund its operations, Precision will be forced to limit its business activities, which will have a material adverse effect on Precision's results of operations and financial condition.

Precision may fail prevent further defaults under the Amended and Restated Notes, which could result in material penalties and acceleration of the Amended and Restated Notes, and the Investors could assert their rights as secured creditors.

Effective February 7, 2019, Precision entered into a Forbearance Agreement with each of the Investors in connection with (1) the Investors' claim that Precision failed to timely comply with the requirements of a registration rights agreement with the Investors and (2) a default resulting from Precision's failure to obtain stockholder approval on or before December 31, 2018 for Precision's pending Merger with Helomics. Under the Forbearance Agreements and the Amended and Restated Notes, Precision issued an aggregate of 166,667 shares to the Investors, and a total of $344,659 was added to the principal amount of Precision's indebtedness to the Investors, resulting in aggregate principal of $2,642,387. Interest on the Amended and Restated Notes accrued at a default rate of 18% beginning as of November 15, 2018 and continuing through the date of the Default Cure (as defined below).

Under the Forbearance Agreements, if (a) Precision obtains shareholder approval of the pending merger transaction with Helomics by March 31, 2019, (b) Precision maintains the effectiveness of its currently effective registration statement on Form S-3 that registers the resale of certain shares that we issued to the Investors as an inducement for their investment, and (c) there are no other defaults under the Amended and Restated Notes and related documents, then the above defaults will be considered cured (the "Default Cure"), the Amended and Restated Notes will not be accelerated and no additional default penalties will be paid. If Precision fails to satisfy these conditions, the forbearance will terminate, the Amended and Restated Notes will accelerate, and the Investors may assert all of their rights. The Company believes that, as a result of the effectiveness of such registration statement on February 13, 2019 and the stockholder approval of the Merger on March 22, 2019, the Default Cure has been achieved. However, there can be no assurance that there will not be additional defaults under terms of the Amended and Restated Notes. Upon a default, among other things, the Amended and Restated Notes become immediately due and payable, Precision is required to pay to the holder 135% (plus an additional 5% per each additional event of default) multiplied by the then outstanding balance of the Amended and Restated Notes plus default interest at 18%. Further, the Investors have a security interest in substantially all of Precision's assets and those of Helomics. In the event of a default, we may attempt to refinance the payment of the balance of the Amended and Restated Notes and applicable penalties; however, there is no assurance that such refinancing will be available. Therefore, defaults on the Amended and Restated Notes would have a material adverse effect on our financial condition, including the Investors' rights to seize our assets or those of Helomics in the event we cannot satisfy our obligations under the Amended and Restated Notes.

Risks Related to the Recent Merger with Helomics Holding Corporation (the "Merger")

On April 4, 2019 (the "Effective Date"), the Company completed the Merger and the Exchange Offer, as described in Note 10 to the Condensed Consolidated Financial Statements included herein, "Subsequent Events".

Completion of the Merger and the Exchange Offer resulted in the issuance of a large number of our shares and warrants, which significantly diluted and will significantly further dilute the percentage of stock held by existing holders of our common stock.

On the effective date of the pending Merger, we issued 4.0 million shares of our Common Stock and 3.5 million shares of Series D Preferred Stock to holders of Helomics capital stock. This issuance is in addition to the 1.1 million shares of Precision Common Stock previously issued to Helomics as consideration for Precision's prior acquisition of a twenty percent ownership interest in Helomics; these 1.1 million shares remained outstanding and were distributed to holders of Helomics capital stock. Each share of Precision Series D Preferred Stock is convertible into one share of Precision Common Stock starting one year after issuance, subject to adjustment. In the Exchange Offer, we issued: (1) approximately 8.6 million additional shares of our Common Stock, (2) approximately 14.2 warrants to purchase our Common Stock at an exercise price of $1.00 per share and (3) 0.6 million warrants to purchase Common Stock at an exercise price of $0.01 per share. Conversion of the Series D Preferred Stock and exercise of such warrants will significantly further dilute the percentage of stock held by existing holders of our common stock.

Costs associated with the Merger are difficult to estimate, may be higher than expected, and may harm the financial results of the combined company.

Both Precision and Helomics incurred substantial direct transaction costs associated with the Merger, and Precision will incur additional costs associated with consolidation and integration of operations. If the total costs of the Merger exceed estimates, or the benefits of the Merger do not exceed the total costs of the Merger, Precision's consolidated financial results could be adversely affected.

The Merger may result in disruption of Precision's existing business, distraction of management and diversion of other resources.

The integration of Precision's and Helomics' operations may divert management time and resources from the main historical businesses of both companies. After the Merger, management will likely be required to spend significant time integrating Precision's and Helomics' operations. This diversion of time and resources could cause the combined business to suffer.

The market price of Precision's common stock may decline as a result of the Merger.

The market price of Precision's common stock may decline as a result of the Merger if the integration of Precision's and Helomics' businesses is unsuccessful or if the costs of implementing the integration are greater than expected. The market price also may decline if Precision does not achieve the perceived benefits of the Merger as rapidly or to the extent anticipated by financial or industry analysts, or shareholders, or if the effect of the Merger on Precision's financial results is not consistent with the expectations of financial or industry analysts, or shareholders.

Each of Precision, Helomics and the combined company incurred substantial transaction-related costs relating to the Merger.

Precision and Helomics have incurred, and expect to continue to incur, significant non-recurring transaction-related costs associated with completing the Merger and combining the two companies. These fees and costs have been, and will continue to be, substantial. Non-recurring transaction costs include, but are not limited to, fees paid to legal, financial and accounting advisors, severance and benefit costs, filing fees and printing costs. Additional unanticipated costs may be incurred in the integration of the operations of Precision and Helomics, which may be higher than expected and could have a material adverse effect on the combined company's financial condition and operating results.

Precision's ability to use net operating loss and tax credit carryforwards and certain built-in losses to reduce future tax payments is limited by provisions of the Internal Revenue Code and may be subject to further limitation because of prior or future offerings of Precision's stock or other transactions.

Sections 382 and 383 of the United States Internal Revenue Code of 1986, as amended (the "Code") contain rules that limit the ability of a company that undergoes an ownership change, which is generally an increase in the ownership percentage of certain stockholders in the stock of a company by more than 50% over a three-year period, to utilize its net operating loss and tax credit carryforwards and certain built-in losses recognized in years after the ownership change. These rules generally operate by focusing on ownership changes involving stockholders owning directly or indirectly 5% or more of the stock of a company and any change in ownership arising from a new issuance of stock by the company. Generally, if an ownership change, as defined by Section 382 of the Code, occurs, the yearly taxable income limitation on the use of net operating loss and tax credit carryforwards and certain built-in losses is equal to the product of the applicable long-term tax-exempt rate and the value of the company's stock immediately before the ownership change. The Merger will result in such an ownership change. As a result, Precision will not be able to use its pre-Merger losses or credit carryovers or certain built-in losses to offset future taxable income in excess of the annual limitations imposed by Sections 382 and 383 of the Code, which may result in the expiration of a portion of Precision's tax attributes before utilization.

Precision will incur significantly increased costs as a result of the completion of the Merger.

In the periods following the completion of the Merger, Precision's operating expenses are likely to increase significantly as Helomics continues to develop and grow its business. These increases are most likely to be in the areas of sales and marketing, compensation and research and product development. There also may be increases in legal, accounting, insurance and compliance costs. As a result, the combined company is expected to report operating losses until Helomics can significantly increase its revenues. This may have a material adverse impact on the market price of Precision common stock following the Merger. Additionally, the integration of the operations of Precision and Helomics may result in unanticipated costs, which may be higher than expected and could have a material adverse effect on the combined company's financial condition and operating results.

The combined company will not be able to continue operating without additional financing.

Both Precision and Helomics have been operating at a loss. In order to continue operating and remain a going concern, the combined company will need to obtain additional financing, either through borrowings, public offerings, private offerings, or some type of business combination (e.g., merger, buyout, etc.), and there can be no assurance that it will be successful in such pursuits with terms satisfactory to management and Precision's board of directors. In the past, both companies have actively pursued a variety of funding sources including private offerings and have consummated certain transactions in order to address their respective capital requirements. Precision recently completed a private offering of securities and loaned a portion of the proceeds to Helomics. However, the combined company anticipates the need for additional capital beyond the recent offering and may not be able to acquire such additional funding. Accordingly, if the combined company is unable to generate adequate cash from operations, and if it is unable to find sources of funding, it may be necessary for it to sell one or more lines of business or all or a portion of its assets, enter into a business combination, reduce or eliminate operations, liquidate assets, or seek relief through a filing under the U.S. Bankruptcy Code. These possibilities, to the extent available, may be on terms that result in significant dilution to the combined company's existing shareholders or that result in its existing shareholders losing all of their investment in the combined company.

Precision may fail to realize the anticipated benefits of the Merger.

The success of the Merger will depend, in part, on Precision's ability to realize the anticipated growth opportunities and synergies from combining Precision and Helomics. The integration of Precision and Helomics will be a time consuming and expensive process and may disrupt their operations if it is not completed in a timely and efficient manner. In addition, Precision may not achieve anticipated synergies or other benefits of the Merger. Following the Merger, Precision and Helomics must operate as a combined organization utilizing common information and communication systems, operating procedures, financial controls and human resources practices. The combined company may encounter the following integration difficulties, resulting in costs and delays:

- failure to successfully manage relationships with customers and other important relationships;
- failure of customers to continue using the services of the combined company;
- difficulties in successfully integrating the management teams and employees of Precision and Helomics;
- challenges encountered in manager larger operations;

- losses of key employees;
- failure to manage the growth and growth strategies of Precision and Helomics;
- diversion of the attention of management from other ongoing business concerns;
- incompatibility of technologies and systems;
- impairment charges incurred to write down the carrying amount of intangible assets generated as a result of the Merger; and
- incompatibility of business cultures.

If the combined company's operations after the Merger do not meet the expectations of existing or prospective customers of Precision and Helomics, then these customers and prospective customers may cease doing business with the combined company altogether, which would harm its results of operations, financial condition and business prospects. If the management team is not able to develop strategies and implement a business plan that successfully addresses these difficulties, Precision may not realize the anticipated benefits of the Merger.

Risk Relating to Our Investment in or Acquisition of Helomics

Helomics molecular diagnostics business has limited revenue, and Helomics expects to incur net losses for the foreseeable future and Helomics may never achieve or sustain profitability.

The revenue generated from Helomics' molecular diagnostics business was $425,065, for the nine months ended September 30, 2018 and for the same fiscal period, Helomics' molecular diagnostics business had operating losses of approximately $3.8 million. Although Helomics expects the revenue generated from Helomics' molecular diagnostics business to grow in the future, there can be no assurance that Helomics will achieve revenue sufficient to offset expenses. Additionally, Helomics is engaged in activities to expand and diversify its revenue base. Helomics expects that a significant portion of Helomics revenue will come from certain service efforts being offered to pharmaceutical, diagnostic and biotech companies as well as academic institutions. Helomics' business may never achieve or sustain profitability, and Helomics' failure to achieve and sustain profitability in the future could have a material adverse effect on Helomics' business, financial condition and results of operations.

Helomics has a limited operating history as a molecular diagnostics company, which may make it difficult to evaluate the success of Helomics' business to date and to assess Helomics' future viability.

Helomics has operated as a molecular diagnostics company since the beginning of 2017. Helomics is building a new business foundation which may make it difficult to evaluate the success of Helomics' business to date and to assess its future viability.

If one or more significant payors stops providing reimbursement or decreases the amount of reimbursement for Helomics' molecular diagnostic tests, Helomics' revenue could decline.

Although Helomics has entered into contracts with certain third-party payors which establish in-network allowable rates of reimbursement for its molecular diagnostic tests, payors may suspend or discontinue reimbursement at any time, may require or increase co-payments from patients, or may reduce the reimbursement rates paid to Helomics. Any such actions could have a negative effect on Helomics' revenue.

If payors do not provide reimbursement, rescind or modify their reimbursement policies or delay payments for Helomics' tests, or if Helomics is unable to successfully negotiate additional reimbursement contracts, Helomics' commercial success could be compromised.

Physicians may not order Helomics' tests unless payors reimburse a substantial portion of the test price. There is uncertainty concerning third-party reimbursement of any test incorporating new molecular diagnostic technology. Reimbursement by a payor may depend on a number of factors, including a payor's determination that tests such as Helomics' molecular diagnostic tests are: (a) not experimental or investigational; (b) pre-authorized and appropriate for the patient; (c) cost-effective; (d) supported by peer-reviewed publications; and (e) included in clinical practice guidelines. Since each payor makes its own decision as to whether to establish a policy or enter into a contract to reimburse Helomics' tests, seeking these approvals is a time-consuming and costly process. Also, payor consolidation is underway and creates uncertainty as to whether coverage and contracts with existing payors will remain in effect. Finally, commercial payors may tie their allowable rates to Medicare rates, and should Medicare reduce their rates, Helomics may be negatively impacted. If Helomics fails to establish broad adoption of and reimbursement for its molecular diagnostic tests, or if Helomics is unable to maintain existing reimbursement from payors, its ability to generate revenue could be harmed and this could have a material adverse effect on Helomics' business, financial condition and results of operations.

Helomics may experience limits on its revenue if physicians decide not to order its molecular diagnostic tests.

If Helomics is unable to create or maintain demand for its molecular diagnostic tests in sufficient volume, it may not become profitable. To generate demand, Helomics will need to continue to educate physicians and the medical community on the value and benefits of its molecular diagnostic tests in order to change clinical practices through published papers, presentations at scientific conferences and one-on-one education by Helomics' internal sales force. In addition, Helomics' ability to obtain and maintain adequate reimbursement from third-party payors will be critical to generating revenue. In many cases, practice guidelines in the United States have recommended therapies or surgery to determine if a patient's condition is malignant or benign. Accordingly, physicians may be reluctant to order a diagnostic test that may suggest surgery is unnecessary. In addition, Helomics' molecular diagnostic tests are performed at Helomics' laboratories rather than by a pathologist in a local laboratory, so pathologists may be reluctant to support Helomics' molecular diagnostic tests. In addition, guidelines for the diagnosis and treatment of thyroid nodules may change to recommend another type of treatment protocol, and these changes may result in medical practitioners deciding not to use Helomics' molecular diagnostic tests. These facts may make physicians reluctant to convert to using Helomics' molecular diagnostic tests, which could limit Helomics' ability to generate revenue and achieve profitability which could have a material adverse effect on its business, financial condition and results of operations.

Helomics may experience limits on its revenue if patients decide not to use its molecular diagnostic tests.

Some patients may decide not to use Helomics' molecular diagnostic tests due to price, all or part of which may be payable directly by the patient if the patient's insurer denies reimbursement in full or in part. Many insurers seek to shift more of the cost of healthcare to patients in the form of higher co-payments or premiums. In addition, the current economic environment in the United States has and may continue to result in the loss of healthcare coverage. Implementation of provisions of the Patient Protection and Affordable Care Act, or PPACA (also known as the Affordable Care Act) also resulted in the loss of health insurance, and increases in premiums and reductions in coverage, for some patients. These events may result in patients delaying or forgoing medical checkups or treatment due to their inability to pay for Helomics' test, which could have an adverse effect on Helomics' revenue.

If Helomics' sales efforts are less successful than anticipated, its business expansion plans, including its service offerings, could suffer and its ability to generate revenues could be diminished. In addition, Helomics has limited history selling its molecular diagnostics tests on a direct basis and Helomics' limited history makes forecasting difficult.

If Helomics' sales efforts are not successful, or new additions to its sales initiatives fail to gain traction among customers, Helomics may not be able to increase market awareness and sales of its molecular diagnostic tests or its service offerings. If Helomics fails to establish its molecular diagnostic tests in the marketplace, it could have a negative effect on its ability to sell subsequent molecular diagnostic tests and hinder the desired expansion of its business. Helomics has limited historical experience forecasting the direct sales of its molecular diagnostics products and service offerings. Helomics' ability to produce product quantities that meet customer demand is dependent upon its ability to forecast accurately and plan production and processing accordingly.

Helomics relies on sole suppliers for some of the materials used in its molecular diagnostic tests, and it may not be able to find replacements or transition to alternative suppliers in a timely manner.

Helomics relies on sole suppliers for certain materials that it uses to perform its molecular diagnostic tests. Helomics also purchases reagents used in its molecular diagnostic tests from sole-source suppliers. While Helomics has developed alternate sourcing strategies for these materials and vendors, Helomics cannot be certain whether these strategies will be effective or the alternative sources will be available in a timely manner. If these suppliers can no longer provide Helomics with the materials it needs to perform its molecular diagnostic tests, if the materials do not meet its quality specifications, or if it cannot obtain acceptable substitute materials, an interruption in molecular diagnostic test processing could occur. Any such interruption may directly impact Helomics' revenue and cause it to incur higher costs.

Helomics may experience problems in scaling its operations, or in delays or reagent and supply shortages that could limit the growth of its revenue.

If Helomics encounters difficulties in scaling its operations as a result of, among other things, quality control and quality assurance issues and availability of reagents and raw material supplies, it will likely experience reduced sales of its molecular diagnostic tests, increased repair or re-engineering costs, and defects and increased expenses due to switching to alternate suppliers, any of which would reduce Helomics' revenues and gross margins. Although Helomics attempts to match its capabilities to estimates of marketplace demand, to the extent demand materially varies from Helomics' estimates, Helomics may experience constraints in its operations and delivery capacity, which could adversely impact revenue in a given fiscal period. Should Helomics' need for raw materials and reagents used in its molecular diagnostic tests fluctuate, Helomics could incur additional costs associated with either expediting or postponing delivery of those materials or reagents.

If Helomics is unable to support demand for its molecular diagnostic tests or any of its future tests or solutions, Helomics' business could suffer.

As demand for Helomics' molecular diagnostic tests grow, Helomics will need to continue to scale its testing capacity and processing technology, to expand its customer service, billing and systems processes and to enhance its internal quality assurance program. Helomics will also need additional certified laboratory scientists and other scientific and technical personnel to process higher volumes of its molecular diagnostic tests. Helomics cannot guarantee that increases in scale, related improvements and quality assurance will be implemented successfully or that appropriate personnel will be available. Failure to implement necessary procedures, transition to new processes or hire the necessary personnel could result in higher costs of processing tests or inability to meet demand. There can be no assurance that Helomics will be able to perform its testing on a timely basis at a level consistent with demand, or that Helomics' efforts to scale its operations will not negatively affect the quality of test results. If Helomics encounters difficulty meeting market demand or quality standards its reputation could be harmed, and its future prospects and business could suffer, causing a material adverse effect on Helomics' business, financial condition and results of operations.

If Helomics is unable to compete successfully, Helomics may be unable to increase or sustain its revenue or achieve profitability.

Helomics competes with physicians and the medical community who use traditional diagnostic methods. In many cases, practice guidelines in the United States have recommended therapies or surgery to determine if a patient's condition is malignant or benign. As a result, Helomics believes it will need to continue to educate physicians and the medical community on the value and benefits of its molecular diagnostic tests in order to change clinical practices. In addition, Helomics faces competition from other companies that offer diagnostic tests. It is also possible that Helomics faces future competition from laboratory-developed tests, or LDTs, developed by commercial laboratories such as Quest and/or other diagnostic companies developing new molecular diagnostic tests or technologies. Furthermore, Helomics may be subject to competition as a result of the new, unforeseen technologies that can be developed by Helomics' competitors in its diagnostic tests space.

To compete successfully Helomics must be able to demonstrate, among other things, that its molecular diagnostic test results are accurate and cost effective, and Helomics must secure a meaningful level of reimbursement for its tests. Many of Helomics' potential competitors have stronger brand recognition and greater financial capabilities than Helomics does. Others may develop tests with a lower price than Helomics that could be viewed by physicians and payors as functionally equivalent to Helomics' molecular diagnostic tests or offer a test at prices designed to promote market penetration, which could force Helomics to lower the price of its molecular diagnostic tests and affect its ability to achieve and maintain profitability. If Helomics is unable to compete successfully against current and future competitors, it may be unable to increase market acceptance of its molecular diagnostic tests and overall sales, which could prevent Helomics from increasing its revenue or achieving profitability and cause the market price of its common stock to decline. As Helomics adds new molecular diagnostic tests and services, it will face many of these same competitive risks for these new molecular diagnostic tests and services.

Developing new molecular diagnostic tests involves a lengthy and complex process, and Helomics may not be able to commercialize on a timely basis, or at all, other molecular diagnostic tests Helomics is developing. Developing new molecular diagnostic tests and solutions will require Helomics to devote considerable resources to research and development. Helomics may face challenges obtaining sufficient numbers of samples to validate a newly acquired or developed molecular diagnostic test. In order to develop and commercialize new molecular diagnostic tests, Helomics needs to:

- expend significant funds to conduct substantial research and development;
- conduct successful analytical and clinical studies;
- scale Helomics' laboratory processes to accommodate new molecular diagnostic tests; and
- build the commercial infrastructure to market and sell new molecular diagnostic tests.

Typically, few research and development projects result in commercial products, and success in early clinical studies often is not replicated in later studies. At any point, Helomics may abandon development of a molecular diagnostic test or Helomics may be required to expend considerable resources repeating clinical studies, which would adversely affect the timing for generating revenue from such test. If a clinical validation study fails to demonstrate the prospectively defined endpoints of the study or if Helomics fails to sufficiently demonstrate analytical validity, Helomics might choose to abandon the development of the molecular diagnostic test, which could harm its business. In addition, competitors may develop and commercialize new competing molecular diagnostic tests faster than Helomics or at a lower cost, which could have a material adverse effect on Helomics' business, financial condition and results of operations.

If Helomics is unable to develop or acquire molecular diagnostic tests to keep pace with rapid technological, medical and scientific change, its operating results and competitive position could be affected.

Recently, there have been numerous advances in technologies relating to diagnostics, particularly diagnostics that are based on genomic information. These advances require Helomics to continuously develop its technology and to work to develop new solutions to keep pace with evolving standards of care. Helomics' solutions could become obsolete unless it continually innovates and expands its product offerings to include new clinical applications. If Helomics is unable to develop or acquire new molecular diagnostic tests or to demonstrate the applicability of its molecular diagnostic tests for other diseases, Helomics' sales could decline and its competitive position could be harmed.

If the United States Food and Drug Administration ("FDA") begins to enforce regulation of Helomics' molecular diagnostic tests, Helomics could incur substantial costs and delays associated with trying to obtain pre-market clearance or approval and costs associated with complying with post-market requirements.

Clinical laboratory tests like Helomics' molecular diagnostic tests are regulated under CLIA as well as by applicable state laws. Most Laboratory Developed Tests ("LDTs") are currently not subject to the FDA's, regulation (although reagents, instruments, software or components provided by third parties and used to perform LDTs may be subject to regulation). In October 2014, the FDA issued two draft guidance documents: "Framework for Regulatory Oversight of Laboratory Developed Tests", which provides an overview of how the FDA would regulate LDTs through a risk-based approach, and "FDA Notification and Medical Device Reporting for Laboratory Developed Tests", which provides guidance on how the FDA intends to collect information on existing LDTs, including adverse event reports. On January 13, 2017, the FDA also issued a discussion paper on LDTs. Pursuant to the Framework for Regulatory Oversight draft guidance, LDT manufacturers would be subject to medical device registration, listing, and adverse event reporting requirements. The risk-based classification considers the LDT's intended use, technological characteristics, and the risk to patients if the LDT were to fail. The FDA has indicated in its guidance that screening devices for malignant cancers are LDTs of higher concern to the FDA and for which enforcement of pre-market and post-market review requirements would likely commence before other LDT types.

Pursuant to the Framework for Regulatory Oversight draft guidance, LDT manufacturers would be required to either submit a pre-market application and receive the FDA's approval before an LDT may be marketed or submit a pre-market notification in advance of marketing. These requirements would be phased in, starting with higher risk LDTs, following the issuance of the FDA's final guidance on this topic, which the FDA has identified as a priority. The draft guidance provides that LDTs that are already marketed at the time the final guidance is issued would not be withdrawn from the market during the FDA's review process. There is no timeframe within which the FDA must issue its final guidance, but issuance of this final guidance has been identified among a list of the FDA's priorities for 2016. As of the date of the filing of this proxy statement/prospectus/information statement, the FDA has not issued its final guidance. How the final guidance would affect Helomics' business is not yet known. Helomics cannot provide any assurance that the FDA regulation will not be required in the future for its tests, whether through additional guidance or regulations issued by the FDA, new enforcement policies adopted by the FDA or new legislation enacted by Congress. It is possible that legislation will be enacted into law, regulations could be promulgated, or guidance could be issued by the FDA which may result in increased regulatory burdens for Helomics to continue to offer its molecular diagnostic tests or to develop and introduce new tests. Helomics cannot predict the timing or content of future legislation enacted, regulations promulgated, or guidance issued regarding LDTs, or how it will affect Helomics' business.

If pre-market review is required by the FDA or if Helomics decides to voluntarily pursue the FDA's pre-market review of Helomics' tests, there can be no assurance that Helomics' molecular diagnostic tests or any tests Helomics may develop or acquire in the future will be cleared or approved on a timely basis, if at all, nor can there be assurance that labeling claims will be consistent with Helomics' current claims or adequate to support continued adoption of and reimbursement for its tests. If pre-market review is required, Helomics' business could be negatively impacted as a result of commercial delay that may be caused by the new requirements. The cost of conducting clinical trials and otherwise developing data and information to support pre-market applications may be significant. If Helomics is required to submit applications for its currently-marketed tests, Helomics may be required to conduct additional studies, which may be time-consuming and costly and could result in Helomics' currently-marketed tests being withdrawn from the market. If Helomics' tests are allowed to remain on the market but there is uncertainty in the marketplace about its tests, if Helomics is required by the FDA to label them investigational, or if labeling claims the FDA allows Helomics to make are limited, orders may decline, and reimbursement may be adversely affected. Continued compliance with the FDA's regulations would increase the cost of conducting Helomics' business, and subject Helomics to heightened regulation by the FDA and penalties for failure to comply with these requirements. Helomics cannot predict the timing or form of any such guidance or regulation, or the potential effect on Helomics' existing molecular diagnostic tests or Helomics' tests in development, or the potential impact of such guidance or regulation on Helomics' business, financial condition and results of operations.

If Helomics fails to comply with Federal, State and foreign laboratory licensing requirements, Helomics could lose the ability to perform its tests or experience disruptions to Helomics' business.

Helomics is subject to Clinical Laboratory Improvement Amendments ("CLIA"), a Federal law that regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. CLIA regulations mandate specific standards in the areas of personnel qualifications, administration, and participation in proficiency testing, patient test management and quality assurance. CLIA certification is also required in order for Helomics to be eligible to bill Federal and State healthcare programs, as well as many private third-party payors, for its molecular diagnostic tests. To renew these certifications, Helomics is subject to survey and inspection every two years. Moreover, CLIA inspectors may make random inspections of Helomics' clinical reference laboratories. Helomics is also required to maintain State licenses to conduct testing in its Pittsburgh, Pennsylvania laboratories. Pennsylvania laws require that Helomics maintain a license and establish standards for the day-to-day operation of Helomics' clinical reference laboratory in Pittsburgh, Pennsylvania. In addition, Helomics' Pittsburgh and New Haven laboratories are required to be licensed on a test-specific basis by certain other states. If Helomics were unable to obtain or lose its CLIA certificate or State licenses for its laboratories, whether as a result of revocation, suspension or limitation, Helomics would no longer be able to perform its molecular diagnostic tests, which could have a material adverse effect on Helomics' business, financial condition and results of operations. If Helomics were to lose its licenses issued by the States in which Helomics is required to hold licenses, Helomics would not be able to test specimens from those States. New molecular diagnostic tests Helomics may develop may be subject to new approvals by governmental bodies, and Helomics may not be able to offer its new molecular diagnostic tests to patients in such jurisdictions until such approvals are received.

Complying with numerous statutes and regulations pertaining to Helomics' molecular diagnostics business is an expensive and time-consuming process, and any failure to comply could result in substantial penalties.

Helomics is subject to regulation by both the Federal government and the States in which Helomics conducts its molecular diagnostics business, including:

- The Food, Drug and Cosmetic Act, as supplemented by various other statutes;
- The Prescription Drug Marketing Act of 1987, the amendments thereto, and the regulations promulgated thereunder and contained in 21 C.F.R. Parts 203 and 205, or the PDMA;
- CLIA and State licensing requirements;
- Manufacturing and promotion laws;
- Medicare billing and payment regulations applicable to clinical laboratories;
- The Federal Anti-Kickback Statute, which prohibits knowingly and willfully offering, paying, soliciting, or receiving remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing, arranging for, or recommending of an item or service that is reimbursable, in whole or in part, by a Federal healthcare program;
- The Federal Stark physician self-referral law (and state equivalents), which prohibits a physician from making a referral for certain designated health services covered by the Medicare program, including laboratory and pathology services, if the physician or an immediate family member has a financial relationship with the entity providing the designated health services, unless the financial relationship falls within an applicable exception to the prohibition;
- The Federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which established comprehensive federal standards with respect to the privacy and security of protected health information and requirements for the use of certain standardized electronic transactions, and amendments made in 2013 to HIPAA under the Health Information Technology for Economic and Clinical Health Act, which strengthen and expand HIPAA privacy and security compliance requirements, increase penalties for violators, extend enforcement authority to state attorneys general, and impose requirements for breach notification;
- The Federal Civil Monetary Penalties Law, which prohibits, among other things, the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception applies;
- The Federal False Claims Act, which imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment to the federal government;
- Other Federal and State fraud and abuse laws, prohibitions on self-referral, fee-splitting restrictions, prohibitions on the provision of products at no or discounted cost to induce physician or patient adoption, and false claims acts, which may extend to services reimbursable by any third-party payor, including private insurers;
- The prohibition on reassignment of Medicare claims, which, subject to certain exceptions, precludes the reassignment of Medicare claims to any other party;
- The rules regarding billing for diagnostic tests reimbursable by the Medicare program, which prohibit a physician or other supplier from marking up the price of the technical component or professional component of a diagnostic test ordered by the physician or other supplier and supervised or performed by a physician who does not "share a practice" with the billing physician or supplier; and
- State laws that prohibit other specified practices related to billing such as billing physicians for testing that they order, waiving coinsurance, co-payments, deductibles, and other amounts owed by patients, and billing a State Medicaid program at a price that is higher than what is charged to other payors.

Helomics has implemented policies and procedures designed to comply with these laws and regulations. Helomics periodically conducts internal reviews of its compliance with these laws. Helomics' compliance is also subject to governmental review. The growth of Helomics' business may increase the potential of violating these laws, regulations or Helomics' internal policies and procedures. The risk of Helomics being found in violation of these or other laws and regulations is further increased by the fact that many have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Violations of Federal or State regulations may incur investigation or enforcement action by the FDA, Department of Justice, State agencies, or other legal authorities, and may result in substantial civil, criminal, or other sanctions. Any action brought against Helomics for violation of these or other laws or regulations, even if Helomics successfully defend against it, could cause Helomics to incur significant legal expenses and divert Helomics' managements' attention from the operation of its business. If Helomics' operations are found to be in violation of any of these laws and regulations, Helomics may be subject to civil and criminal penalties, damages and fines, Helomics could be required to refund payments received by it, Helomics could face possible exclusion from Medicare, Medicaid and other Federal or State healthcare programs and Helomics could even be required to cease its operations. Any of the foregoing consequences could have a material adverse effect on Helomics' business, financial condition and results of operations.

If Helomics uses hazardous materials in a manner that causes contamination or injury, Helomics could be liable for resulting damages.

Helomics is subject to Federal, State and local laws, rules and regulations governing the use, discharge, storage, handling and disposal of biological material, chemicals and waste. Helomics cannot eliminate the risk of accidental contamination or injury to employees or third parties from the use, storage, handling or disposal of these materials. In the event of contamination or injury, Helomics could be held liable for any resulting damages, remediation costs and any related penalties or fines, and any liability could exceed Helomics' resources or any applicable insurance coverage Helomics may have. The cost of compliance with these laws and regulations may become significant, and Helomics' failure to comply may result in substantial fines or other consequences, and either could have a significant impact on Helomics' operating results.

Security breaches, loss of data and other disruptions to Helomics or its third-party service providers could compromise sensitive information related to Helomics' business or prevent Helomics from accessing critical information and expose it to liability, which could adversely affect Helomics' business and reputation.

Helomics' business requires that Helomics and its third-party service providers collect and store sensitive data, including legally protected health information, personally identifiable information about patients, credit card information, and Helomics' proprietary business and financial information. Helomics faces a number of risks relative to Helomics' protection of, and Helomics' service providers' protection of, this critical information, including loss of access, inappropriate disclosure and inappropriate access, as well as risks associated with Helomics' ability to identify and audit such events. The secure processing, storage, maintenance and transmission of this critical information are vital to Helomics' operations and business strategy, and Helomics devotes significant resources to protecting such information. Although Helomics takes measures to protect sensitive information from unauthorized access or disclosure, Helomics' information technology and infrastructure may be vulnerable to attacks by hackers or viruses or otherwise breached due to employee error, malfeasance or other activities. While Helomics has not experienced any such attack or breach, if such event would occur and cause interruptions in Helomics' operations, Helomics' networks would be compromised and the information Helomics stores on those networks could be accessed by unauthorized parties, publicly disclosed, lost or stolen. Unauthorized access, loss or dissemination could disrupt Helomics' operations, including Helomics' ability to process tests, provide test results, bill payors or patients, process claims, provide customer assistance services, conduct research and development activities, collect, process and prepare company financial information, provide information about Helomics' solution and other patient and physician education and outreach efforts, manage the administrative aspects of Helomics' business and damage Helomics' reputation, any of which could adversely affect Helomics' business. In addition, the interpretation and application of consumer, health-related and data protection laws in the United States are often uncertain, contradictory and in flux. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with Helomics' practices. Complying with these various laws could cause Helomics to incur substantial costs or require Helomics to change its business practices, systems and compliance procedures in a manner adverse to Helomics' business.

If Helomics is sued for product liability or errors and omissions liability, Helomics could face substantial liabilities that exceed its resources.

The marketing, sale and use of Helomics' molecular diagnostic tests could lead to product liability claims if someone were to allege that the molecular diagnostic test failed to perform as it was designed. Helomics may also be subject to liability for errors in the results Helomics provides to physicians or for a misunderstanding of, or inappropriate reliance upon, the information Helomics provides. A product liability or errors and omissions liability claim could result in substantial damages and be costly and time consuming for Helomics to defend. Although Helomics maintains product liability and errors and omissions insurance, Helomics cannot be certain that its insurance would fully protect it from the financial impact of defending against these types of claims or any judgments, fines or settlement costs arising out of such claims. Any product liability or errors and omissions liability claim brought against Helomics, with or without merit, could increase its insurance rates or prevent it from securing insurance coverage in the future. Additionally, any product liability lawsuit could cause injury to Helomics' reputation or cause Helomics to suspend sales of its products and solutions. The occurrence of any of these events could have a material adverse effect on Helomics' business, financial condition and results of operations.

Billing for Helomics' diagnostic solutions is complex, and Helomics must dedicate substantial time and resources to the billing process to be paid for its molecular diagnostic tests.

Billing for clinical laboratory testing services is complex, time consuming and expensive. Depending on the billing arrangement and applicable law, Helomics bills various payors, including Medicare, insurance companies and patients, all of which have different billing requirements. To the extent laws or contracts require Helomics to bill patient co-payments or co-insurance, Helomics must also comply with these requirements. Helomics may also face increased risk in its collection efforts, including write-offs of doubtful accounts and long collection cycles, which could have a material adverse effect on Helomics' business, results of operations and financial condition. Among others, the following factors make the billing process complex:

- differences between the list price for Helomics' molecular diagnostic tests and the reimbursement rates of payors;
- compliance with complex Federal and State regulations related to billing Medicare;
- disputes among payors as to which party is responsible for payment;
- differences in coverage among payors and the effect of patient co-payments or co-insurance;
- differences in information and billing requirements among payors;
- incorrect or missing billing information; and
- the resources required to manage the billing and claims appeals process.

As Helomics introduces new molecular diagnostic tests, it will need to add new codes to the billing process as well as to Helomics' financial reporting systems. Failure or delays in effecting these changes in external billing and internal systems and processes could negatively affect Helomics' revenue and cash flow. Additionally, Helomics' billing activities require it to implement compliance procedures and oversight, train and monitor its employees, challenge coverage and payment denials, assist patients in appealing claims, and undertake internal audits to evaluate compliance with applicable laws and regulations as well as internal compliance policies and procedures. Payors also conduct external audits to evaluate payments, which add further complexity to the billing process. These billing complexities, and the related uncertainty in obtaining payment for Helomics' diagnostic solution, could negatively affect Helomics' revenue and cash flow, Helomics' ability to achieve profitability, and the consistency and comparability of Helomics' results of operations.

Helomics relies on a third-party to process and transmit claims to payors, and any delay in either could have an adverse effect on Helomics' revenue.

Helomics relies on a third-party provider to provide overall processing of claims and to transmit the actual claims to payors based on the specific payor billing format. If claims for Helomics' molecular diagnostic tests are not submitted to payors on a timely basis, or if Helomics is required to switch to a different provider to handle claim submissions, Helomics may experience delays in its ability to process these claims and receipt of payments from payors, which could have a material adverse effect on Helomics' business, financial condition and results of operations.

Enacted healthcare reform legislation may increase Helomics' costs, impair Helomics' ability to adjust its pricing to match any such increased costs, and therefore could materially and adversely affect its business, financial condition and results of operations.

PPACA entails sweeping healthcare reforms with staggered effective dates from 2010 through 2018, although certain of these effective dates have been delayed by action of the current administration. While some guidance has been issued under PPACA over the past several years, many provisions in PPACA require the issuance of additional guidance from the U.S. Department of Labor, the Internal Revenue Service, the U.S. Department of Health & Human Services, and State governments. This reform includes, but is not limited to: the implementation of a small business tax credit; required changes in the design of Helomics' healthcare policy including providing insurance coverage to part-time workers working on average thirty (30) or more hours per week; "grandfathering" provisions for existing policies; "pay or play" requirements; a "Cadillac plan" excise tax; and specifically required "essential benefits," that must be included in "qualified plans," which benefits include coverage for laboratory tests.

Effective January 1, 2014, each State was required to participate in the PPACA marketplace and make health insurance coverage available for purchase by eligible individuals through a website. While these websites were subject to significant administrative issues leading up to their inception dates (and, in some cases, thereafter), it is currently estimated that in excess of 11 million individuals nationwide had enrolled in health insurance coverage through these exchanges as of the end of 2015. It is unclear, however, how many of these individuals are becoming insured after previously not having health insurance coverage, versus maintaining their plans purchased on the exchanges in 2014 or switching from other health insurance plans.

PPACA also requires "Applicable Manufacturers" to disclose to the Secretary of the Department of Health & Human Services drug sample distributions and certain payments or transfers of value to covered recipients (physicians and teaching hospitals) on an annual basis. "Applicable Manufacturers" and "Applicable Group Purchasing Organizations" must also disclose certain physician ownership or investment interests. The data submitted will ultimately be made available on a public website. Based upon the structure of Helomics' relationship with its clients, Helomics may be included in the definition of "Applicable Manufacturer" for purposes of the disclosure requirements or may provide services that include the transfer of drug samples and/or other items of value to covered recipients. As such, Helomics may be required to disclose or provide information that is subject to disclosure. There may be certain risks and penalties associated with the failure to properly make such disclosures, including but not limited to the specific civil liabilities set forth in PPACA, which allows for a maximum civil monetary penalty per "Applicable Manufacturer" of $1,150,000 per year. There may be additional risks and claims made by third parties derived from an improper disclosure that are difficult to ascertain at this time.

While PPACA may increase the number of patients who have insurance coverage, its cost containment measures could also adversely affect reimbursement for any of Helomics' molecular diagnostic tests. Cost control initiatives also could decrease the price that Helomics' receives for any molecular diagnostic tests Helomics may develop in the future. If Helomics' molecular diagnostic tests are not considered cost-effective or if Helomics is unable to generate adequate third-party reimbursement for the users of its molecular diagnostic tests, then Helomics may be unable to maintain revenue streams sufficient to realize its targeted return on investment for its molecular diagnostic tests.

Helomics is currently unable to determine the long-term, direct or indirect impact of such legislation on its business. Since the effect of many of the provisions of PPACA may not be determinable for a number of years, Helomics does not expect PPACA to have a material adverse impact on its near-term results of operations. However, healthcare reform as mandated and implemented under PPACA and any future Federal or State mandated healthcare reform could materially and adversely affect its business, financial condition and operations by increasing Helomics' operating costs, including its costs of providing health insurance to Helomics' employees, decreasing Helomics' revenue, impeding Helomics' ability to attract and retain customers, requiring changes to Helomics' business model, or causing Helomics to lose certain current competitive advantages.

Changes in governmental regulation could negatively impact Helomics' business operations and increase its costs.

The pharmaceutical, biotechnology and healthcare industries are subject to a high degree of governmental regulation. Significant changes in these regulations affecting Helomics' business could result in the imposition of additional restrictions on Helomics' business, additional costs to Helomics in providing Helomics' molecular diagnostic tests to its customers or otherwise negatively impact Helomics' business operations. Changes in governmental regulations mandating price controls and limitations on patient access to Helomics' products could also reduce, eliminate or otherwise negatively impact Helomics' sales.

If Helomics does not increase its revenues and successfully manage the size of its operations, Helomics' business, financial condition and results of operations could be materially and adversely affected.

The majority of Helomics' operating expenses are personnel-related costs such as employee compensation and benefits, reagents and disposable supplies as well as the cost of infrastructure to support Helomics' operations, including facility space and equipment. Helomics continuously reviews its personnel to determine whether they are fully utilizing their services. If Helomics is unable to achieve revenue growth in the future or fail to adjust its cost infrastructure to the appropriate level to support its revenues, Helomics' business, financial condition and results of operations could be materially and adversely affected.

If Helomics research and development (R&D) efforts for its TruTumor and D-CHIP artificial intelligence platform take longer than expected the commercial revenues from the service offerings that use these platforms could also be delayed.

Helomics CRO business offers various services to pharma, diagnostics and biotech companies. These services use its TruTumor Patient derived tumor platform and its D-CHIP AI platform. These platforms are the subject of active R&D to further improve and validate them for commercial use in order to help Helomics' clients in their drug discovery, biomarker and clinical trial activities. Helomics could face delays in this R&D, for example; Helomics may not be able to secure access to and approval to use clinical data from academic hospital partners required to validate the D-CHIP platform in a timely manner; clinical testing volume (number of specimens coming to Helomics for testing) may not grow sufficiently to drive data generation for D-CHIP as well as further development of the TruTumor platform; patient consent to use the patient's data and tumor material for R&D may not be sufficient to support Helomics R&D; Helomics may not be able to attract and retain the appropriately qualified staff to perform the necessary R&D. Helomics has a limited operating history with the CRO and Informatics business which makes it difficult to forecast the revenue of these business units. While Helomics is committed to the buildout of both the CRO and D-CHIP services for the long term, the company cannot predict at this time, with any certainty, the future viability of either business unit.

If Helomics' information technology and communications systems fail or Helomics experiences a significant interruption in its operation, its reputation, business and results of operations could be materially and adversely affected.

The efficient operation of Helomics' business is dependent on Helomics' information technology and communications systems. The failure of these systems to operate as anticipated could disrupt its business and result in decreased revenue and increased overhead costs. In addition, Helomics does not have complete redundancy for all of its systems and its disaster recovery planning cannot account for all eventualities. Helomics' information technology and communications systems, including the information technology systems and services that are maintained by third party vendors, are vulnerable to damage or interruption from natural disasters, fire, terrorist attacks, malicious attacks by computer viruses or hackers, power loss or failure of computer systems, Internet, telecommunications or data networks. If these systems or services become unavailable or suffer a security breach, Helomics may expend significant resources to address these problems, and Helomics' reputation, business and results of operations could be materially and adversely affected.

If Helomics is unable to protect its intellectual property effectively, Helomics' business would be harmed.

Helomics relies on patent protection as well as trademark, trade secret and other intellectual property rights protection and contractual restrictions to protect Helomics' proprietary technology. If Helomics' fails to protect its intellectual property, third parties may be able to compete more effectively against it and Helomics may incur substantial litigation costs in its attempts to recover or restrict use of its intellectual property. While Helomics applies for patents covering its products and technologies and uses thereof, Helomics may fail to apply for patents on important products and technologies in a timely fashion or at all, or Helomics may fail to apply for patents in relevant jurisdictions. Others could seek to design around Helomics' current or future patented technologies. Helomics may not be successful in defending any challenges made against Helomics' patents or patent applications. Any successful third-party challenge to Helomics' patents could result in the unenforceability or invalidity of such patents and increased competition to Helomics' business. The outcome of patent litigation can be uncertain and any attempt by Helomics to enforce its patent rights against others may not be successful, or, if successful, may take substantial time and result in substantial cost, and may divert Helomics' efforts and attention from other aspects of its business.

Monitoring unauthorized disclosure is difficult, and Helomics does not know whether the steps Helomics has taken to prevent such disclosure are, or will be, adequate. If Helomics were to enforce a claim that a third-party had illegally obtained and was using its trade secrets, it would be expensive and time consuming, and the outcome would be unpredictable. Further, competitors could willfully infringe Helomics' intellectual property rights, design around its protected technology or develop their own competitive technologies that arguably fall outside of Helomics' intellectual property rights. Others may independently develop similar or alternative products and technologies or replicate any of Helomics' products and technologies. If Helomics' intellectual property does not adequately protect it against competitors' products and methods, Helomics' competitive position could be adversely affected, as could Helomics' business and the results of its operations. To the extent Helomics' intellectual property offers inadequate protection, or is found to be invalid or unenforceable, Helomics would be exposed to a greater risk of competition. If Helomics' intellectual property does not provide adequate coverage of its competitors' products, Helomics' competitive position could be adversely affected, as could its overall business. Both the patent application process and the process of managing patent disputes can be time consuming and expensive.

Helomics may be involved in litigation related to intellectual property, which could be time-intensive and costly and may adversely affect its business, operating results or financial condition.

Helomics may receive notices of claims of direct or indirect infringement or misappropriation or misuse of other parties' proprietary rights from time to time and some of these claims may lead to litigation. Helomics cannot assume that it will prevail in such actions, or that other actions alleging misappropriation or misuse by Helomics of third-party trade secrets, infringement by Helomics of third-party patents and trademarks or other rights, or the validity of Helomics' patents, trademarks or other rights, will not be asserted or prosecuted against it. Helomics might not have been the first to make the inventions covered by each of Helomics' pending patent applications and Helomics might not have been the first to file patent applications for these inventions. No assurance can be given that other patent applications will not have priority over Helomics' patent applications. If third parties bring these proceedings against Helomics' patents, Helomics could incur significant costs and experience management distraction. Litigation may be necessary for Helomics to enforce its patents and proprietary rights or to determine the scope, coverage and validity of the proprietary rights of others. The outcome of any litigation or other proceeding is inherently uncertain and might not be favorable to Helomics, and Helomics might not be able to obtain licenses to technology that it requires on acceptable terms or at all. In addition, if Helomics resorts to legal proceedings to enforce its intellectual property rights or to determine the validity, scope and coverage of the intellectual property or other proprietary rights of others, the proceedings could be burdensome and expensive, even if Helomics were to prevail. Any litigation that may be necessary in the future could result in substantial costs and diversion of resources and could have a material adverse effect on Helomics' business, financial condition and operating results.

In the event of a successful claim of infringement against Helomics, Helomics may be required to pay damages and ongoing royalties, and obtain one or more licenses from third parties, or be prohibited from selling its products. Helomics may not be able to obtain these licenses on acceptable terms, if at all. Helomics could incur substantial costs related to royalty payments for licenses obtained from third parties, which could negatively affect Helomics' financial results. In addition, Helomics' agreements with some of its customers, suppliers or other entities with whom Helomics' does business require it to defend or indemnify these parties to the extent they become involved in infringement claims, including the types of claims described above. If Helomics is required or agrees to defend or indemnify third parties in connection with any infringement claims, Helomics could incur significant costs and expenses that could have a material adverse effect on Helomics' business, financial condition, and results of operations.

ITEM 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

ITEM 3. Defaults Upon Senior Securities

None.

ITEM 4. Mine Safety Disclosures

Not applicable.

ITEM 5. Other Information

Loan from CEO

On May 9, 2019, Dr. Schwartz advanced $75,000 to the Company. The loan earns 8% interest and is due in 60 days.

ITEM 6. Exhibits

See the attached exhibit index.

SIGNATURES:

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

PRECISION THERAPEUTICS INC.

Date: May 15, 2019

By: /s/ Carl Schwartz
Carl Schwartz
Chief Executive Officer

Date: May 15, 2019

By: /s/ Bob Myers
Bob Myers
Chief Financial Officer

EXHIBIT INDEX

PRECISION THERAPEUTICS INC.
Form 10-Q

The quarterly period ended March 31, 2019

Exhibit No.		Description
1.1		Placement Agency Agreement dated February 27, 2019 (1)
1.2		Placement Agency Agreement dated March 27, 2019 (2)
4.1		Amended and Restated Common Stock Purchase Warrant issued to Carl Schwartz dated January 8, 2019 (4)
4.2		Form of Warrant (March 1, 2019 closing) (1)
4.3		Form of Unit Purchase Option (March 1, 2019 closing)(1)
4.4		Form of Warrant (March 29, 2019 closing) (2)
4.5		Form of Unit Purchase Option (March 29, 2019 closing) (2)
10.1		Second Amended and Restated Promissory Note issued to Carl Schwartz dated February 6, 2019 (5)
10.2		Forbearance Agreement by and between L2 Capital, LLC and the Company dated February 7, 2019 (5)
10.3		Forbearance Agreement by and between Peak One Opportunity Fund, LP and the Company dated February 7, 2019 (5)
10.4		Amended and Restated Senior Secured Promissory Note issued to L2 Capital, LLC dated February 7, 2019 (5)
10.5		Amended and Restated Senior Secured Promissory Note issued to Peak One Opportunity Fund, LP dated February 7, 2019 (5)
10.6		Amended and Restated Promissory Note issued to Carl Schwartz dated January 8, 2019 (4)
10.7		Subscription Agreement by and between Carl Schwartz and the Company dated January 8, 2019 (4)
31.1*		Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*		Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*		Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

101.INS*	XBRL Instance Document**
101.SCH*	XBRL Extension Schema Document**
101.CAL*	XBRL Extension Calculation Linkbase Document**
101.DEF*	XBRL Extension Definition Linkbase Document**
101.LAB*	XBRL Extension Labels Linkbase Document**
101.PRE*	XBRL Extension Presentation Linkbase Document**

* Filed herewith.

(1) Filed on March 1, 2019 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.

(2) Filed on April 2, 2019 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.

(3) Filed on October 30, 2018 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.

(4) Filed on January 14, 2019 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.

(5) Filed on February 12, 2019 as an exhibit to our Current Report on Form 8-K and incorporated herein by reference.

** In accordance with Rule 406T of Regulation S-T, this information is deemed not “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

Exhibit 31.1

CERTIFICATION
PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, Carl Schwartz, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Precision Therapeutics Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principals;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 15, 2019

/s/ Carl Schwartz
Carl Schwartz
Chief Executive Officer

Exhibit 31.2

CERTIFICATION
PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, Bob Myers, certify that:

1. I have reviewed the quarterly report on Form 10-Q of Precision Therapeutics Inc.;

2. Based on my knowledge, this report does not contain any untrue statements of a material fact or omit to state a material fact necessary to make the statements in light of the circumstances under which some statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principals;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report (that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date May 15, 2019

/s/ Bob Myers
Bob Myers
Chief Financial Officer

Exhibit 32.1

CERTIFICATION
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Precision Therapeutics Inc. (the "Company") for the quarter ended March 31, 2019 as filed with the Securities and Exchange Commission (the "Report"), I, Carl Schwartz, Chief Executive Officer (Principal Executive Officer) and, I, Bob Myers, Chief Financial Officer (Principal Financial Officer) of the Company, hereby certify as of the date hereof, solely for purposes of § 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. § 1350, that to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company at the dates and for the periods indicated.

Date: May 15, 2019

/s/ Carl Schwartz
Carl Schwartz
Chief Executive Officer

Date: May 15, 2019

/s/ Bob Myers
Bob Myers
Chief Financial Officer