SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 8-K

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

Date of Report (Date of earliest event reported): **February 26, 2019**

Precision Therapeutics Inc.

(Exact name of registrant as specified in charter)

Delaware	**001-36790**	**33-1007393**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

2915 Commers Drive, Suite 900
Eagan, Minnesota 55121
(Address of principal executive offices)

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

Not Applicable
(Former name or former address, if changed from last report)

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

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

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

Emerging growth company o

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. o

Item 8.01 Other Events.

The Company is filing the risk factors attached hereto as Exhibit 99.1 for the purpose of supplementing and updating the risk factor disclosures contained in its prior public filings, including those discussed under the heading “Item 1A. Risk Factors” in the Company’s Annual Report on Form 10-K for the year ended December 31, 2017, filed with the SEC on April 2, 2018. The updated risk factor disclosures are filed herewith as Exhibit 99.1 and are incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Risk Factors

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 hereunto duly authorized.

Date: February 26, 2019

PRECISION THERAPEUTICS INC.

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Risk Factors

Item 1A. Risk Factors

Our operations and financial results are subject to various risks and uncertainties, including those described below. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties we are unaware of, or we currently believe are not material, may also become important factors affecting us. If any of the following risks occur, our business, financial condition, operating results and prospects could be materially and adversely affected. In that event, the price of our stock could decline.

RISKS RELATING TO THE PRECISION, ITS BUSINESS AND ITS STOCK

Precision will require additional financing to finance operating expenses and fulfill its business plan. Such financing will be dilutive. Precision's independent public accounting firm has indicated in their audit opinion, contained in Precision's financial statements, that they have substantial doubt about Precision's ability to remain a going concern.

Precision has not achieved profitability and anticipates that it will continue to incur net losses at least through the remainder of 2018. Precision had revenues of $655,000 in 2017, but Precision had negative operating cash flows of $4.5 million. In January 2017, Precision received proceeds of $3.9 million because of its public offering. In November 2017, Precision received proceeds of $1.3 million because of its private placement. Precision's cash and cash equivalents balance was $0.8 million as of December 31, 2017, and its accounts payable and accrued expenses were an aggregate $0.9 million. Precision is currently incurring negative operating cash flows of approximately $452,000 per month. Although Precision is attempting to curtail its expenses, there is no guarantee that Precision will be able to reduce these expenses significantly, and expenses for some periods may be higher as Precision prepares its products for broader sales, increases its sales efforts and maintains adequate inventories.

On January 9, 2018, Precision received net proceeds of $2.5 million because of an S-3 public offering. Subsequently, the underwriter exercised its over-allotment option and Precision received additional net proceeds of $188,000 on February 20, 2018. Precision's cash and cash equivalents balance on January 31, 2018 was approximately $2.8 million.

Precision recently completed a private offering of securities and loaned a portion of the proceeds to Helomics. The proceeds from these investments will provide capital to Precision and Helomics. For more information about the investment transaction, see *"Precision Management's Discussion and Analysis of Financial Condition and Results of Operations – Recent Developments."*

In addition to the recent private offering, Precision may require additional funding to finance operating expenses and to invest in its sales organization and new product development and to enter the international marketplace. Precision will attempt to raise these funds through equity or debt financing, alternative offerings or other means. If Precision is successful in securing adequate funding it plans to make significant capital or equipment investments, and it 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, Precision will be forced to limit Precision's business activities, which will have a material adverse effect on Precision's results of operations and financial condition.

Because of the above factors, Precision's independent registered public accounting firm has indicated in their audit opinion, contained in Precision's financial statements included in this proxy statement/prospectus/information statement, that they have serious doubts about Precision's ability to continue as a going concern. The financial statements have been prepared assuming Precision will continue as a going concern. See *"Precision Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources."*

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

Precision has committed significant capital and management resources to developing its CRO business and other new business areas, and Precision intends to continue to devote significant and management resources to new businesses. In 2017, Precision provided $668,000 in financing to Helomics, of which $500,000 in principal amount has been converted into an equity interest in Helomics and $168,000 in principal amount is subject to secured notes that remain outstanding. In connection with its private offering, in 2018, Precision loaned to Helomics an additional $907,500 in exchange for an additional secured promissory note. See *"Precision Management's Discussion and Analysis of Financial Condition and Results of Operations – Recent Developments."* In December 2018 and January 2019 Precision loaned to Helomics an additional $235,000 that addends to the original promissory note. In addition, in August 2017, Precision entered into a merger agreement with CytoBioscience, which was subsequently terminated in November 2017. From July 2017 through November 2017, Precision advanced $1,070,000 to CytoBioscience in the form of secured notes, which are still outstanding. CytoBioscience has indicated in its most recent Form 10-Q filings that they have defaulted on the note; CytoBioscience is seven months in arrears on interest payments. Precision has issued a Demand Notice to CytoBioscience and filed a complaint to recover the debt. The companies are negotiating repayment terms. It is likely that Precision will make further investments and advances in other businesses as it develops its CRO business and other business models. There can be no assurance that any of the outstanding balances of these existing promissory notes or future advances will be repaid. Further, there is no assurance that Precision's equity investments in new businesses will result in significant value for Precision. Therefore, Precision could invest significant capital in other business enterprises with no certainty when or whether Precision will realize a return on these investments. Investments in cash will deplete Precision's capital resources, meaning that Precision will be required to raise significant amounts of new capital. There is no assurance that Precision will be successful in raising sufficient capital, and the terms of any such financing will be dilutive to its stockholders. Precision 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 its stockholders. Further, the energy and resources of Precision's 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, Precision's business may fail regardless of the level of success of Precision's STREAMWAY business.

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

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

- be successful in uncertain markets;
- respond effectively to competitive pressures;
- successfully address intellectual property issues of others;
- protect and expand Precision's intellectual property rights; and
- continue to develop and upgrade Precision's products.

STREAMWAY Business Risk Factors

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

Precision relies on a combination of patent, trade secret and other intellectual property rights and measures to protect its intellectual property. Precision currently owns and may in the future own or license additional patent rights or trade secrets in the U.S., with non-provisional patents elsewhere in the world that cover certain of Precision's products. Precision relies on patent laws and other intellectual property laws, nondisclosure and other contractual provisions and technical measures to protect its products and intangible assets. These intellectual property rights are important to Precision's ongoing operations and no assurance can be given that any measure Precision implements will be sufficient to protect its intellectual property rights. Also, with respect to Precision's trade secrets and proprietary know-how, Precision cannot be certain that the confidentiality agreements entered into with employees will not be breached, or that Precision will have adequate remedies for any breach. Precision may lose the protection afforded by these rights through patent expirations, legal challenges or governmental action. If Precision cannot protect its rights, Precision may lose its competitive advantage if these patents were found to be invalid in the jurisdictions in which Precision sells or plans to sell its products. The loss of Precision's intellectual property rights could have a material adverse effect on its business.

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

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

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

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

Precision's competitors include Cardinal Health, Inc., a medical manufacturer and distributor, and Stryker Instruments, a wholly owned subsidiary of Stryker Corporation, which has a leading position in Precision's market. Both of these competitors are substantially larger than Precision and are better capitalized than Precision.

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

Precision believes that its ability to compete successfully depends on a number of factors, including its technical innovations of unlimited suction and unlimited capacity capabilities, its innovative and advanced research and development capabilities, strength of its intellectual property rights, sales and distribution channels and advanced manufacturing capabilities. Precision plans to employ these and other elements as it develops its products and technologies, but there are many other factors beyond its control. Precision 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 its development and marketing of new products, which could adversely impact the trading price of the shares of Precision's common stock.

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

The production, marketing, and research and development of Precision's product 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 Precision does not comply with applicable regulatory requirements, violations could result in warning letters, non-approvals, suspensions of regulatory approvals, civil penalties and criminal fines, product seizures and recalls, operating restrictions, injunctions, and criminal prosecution.

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

If Precision's products are not accepted by its potential customers, it is unlikely that Precision will ever become profitable.

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

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

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

If demand for Precision's products are unexpectedly high, there is no assurance that there will not be supply interruptions or delays.

Precision is currently manufacturing the STREAMWAY System, following GMP compliance regulations of the FDA, at its own facility and anticipates the capability of producing the STREAMWAY System in sufficient quantities for future near-term sales. Precision has contracted with a manufacturing company that can manufacture products at higher volumes. However, if demand for Precision's product is unexpectedly high, there is no assurance that Precision or its 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 Precision's results of operations.

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

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, and Bob Myers, Precision's Chief Financial Officer. Precision has entered into employment agreements with the CEO and the CFO of the senior management team and it may expand the relatively small number of executives in its company. Were Precision to lose one or more of these key individuals, Precision 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 you 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.

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

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

Costs incurred because 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 costly, 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 Precision's officers and directors by it may discourage stockholders from bringing suit against a director.

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

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

Precision currently intends to retain any future earnings to support the development and expansion of its business and does not anticipate paying cash dividends in the foreseeable future. Precision's payment of any future dividends will be at the discretion of its Board of Directors after taking into account various factors, including but not limited to, Precision's financial condition, operating results, cash needs, growth plans and the terms of any credit agreements that Precision may be a party to at the time. In addition, Precision's ability to pay dividends on its common stock may be limited by state law. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize certain returns on their investment. As a result, investors must rely on stock appreciation and a liquid trading market for any return on investment in Precision'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 Precision 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 proxy statement/prospectus/information 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 Precision's affiliates at the time of sale, or at any time during the three months preceding a sale, may sell their shares of Precision common stock. Any substantial sale, or cumulative sales, of Precision common stock pursuant to Rule 144 or pursuant to any resale prospectus may have a material adverse effect on the market price of Precision's securities.

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

If established, the market for Precision common stock may be characterized by significant price volatility when compared to seasoned issuers, and Precision expects that its share price will be more volatile than a seasoned issuer for the indefinite future. In addition, there is no assurance that the price of Precision common stock will not be volatile. In the past, plaintiffs have often initiated securities class action litigation against a company following periods of volatility in the market price of its securities. Precision 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.

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

Precision's authorized capital includes 20 million shares of preferred stock. Of this amount, 18,950 shares have been designated as Series B Convertible Preferred Stock, 1,213,819 shares have been designated as Series C Preferred Stock, 3,500,000 shares will be designated as Series D Preferred Stock in connection with the Merger, and the remaining authorized shares are undesignated preferred stock. Precision's Board of Directors has the power to issue any or all of the shares of undesignated preferred stock, including the authority to establish one or more series and to fix the powers, preferences, rights and limitations of such class or series, without seeking stockholder approval. Further, as a Delaware corporation, Precision is subject to provisions of the Delaware General Corporation Law regarding "business combinations." Precision may, in the future, consider adopting additional anti-takeover measures. The authority of Precision's 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 Precision, may, in certain circumstances, delay, deter or prevent takeover attempts and other changes in control of Precision not approved by Precision's Board of Directors. As a result, Precision's stockholders may lose opportunities to dispose of their shares at favorable prices generally available in takeover attempts or that may be available under a merger proposal and the market price, voting and other rights of the holders of common stock may also be affected.

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

Precision also expects that significant additional capital will be needed in the future to continue its planned operations. To the extent that Precision raises additional capital by issuing equity securities, its stockholders may experience substantial dilution. Precision may sell common stock, convertible securities, or other equity securities in one or more transactions at prices and in a manner, it determines from time to time. If Precision sells common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to Precision's existing stockholders, and new investors could gain rights superior to its existing stockholders. In addition, in the past, Precision has 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 your investment in its common stock, or it may decide to pursue acquisitions that investors may not agree with. In connection with most of Precision's acquisitions, Precision also agreed 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 distinct corporate cultures. In addition, acquired companies may have liabilities that it failed, or were unable, to discover in the course of performing due diligence investigations. Precision cannot assure you 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 have a period of 180 calendar days, or until May 15, 2019, to regain compliance with the Minimum Bid Price Requirement. If at any time before May 18, 2019 the bid price of the Company's common stock closes at or above $1.00 per share for a minimum of 10 consecutive business days, Nasdaq will provide written notification that the Company has achieved compliance with the Minimum Bid Price Requirement. However, the Company has been advised that Nasdaq has discretion to extend this required period to 20 consecutive business days or to impose other requirements.

The letter also disclosed that in the event we do not regain compliance with the Minimum Bid Price Requirement by May 15, 2019, 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. 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 as of 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 $2,297,727.50. 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 as of 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, following which each Investor has the right to require that Precision apply up to 50% of such proceeds to repay outstanding amounts owed under their note. Precision has already received $1,620,000 in aggregate cash proceeds from securities offering transactions as of February 26, 2019. As a result, proceeds from future securities offering transactions may be subject to the Investors' repayment rights. This arrangement 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 to cure a default and claimed default on the Amended and Restated Notes, or to prevent further defaults, 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 as of 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 agreements 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 accrues at a default rate of 18% beginning as of November 15, 2018 and continuing through the date of the Default Cure (as defined below), at which time the rate returns to the original rate of 8%.

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. 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. There can be no assurance that Precision will achieve the Default Cure or that there will not be additional defaults under terms of the Amended and Restated Notes. In such an event, 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 PENDING MERGER TRANSACTION WITH HELOMICS HOLDING CORPORATION

On October 26, 2018, Precision entered into an Amended and Restated Agreement and Plan of Merger with Helomics Acquisition, Inc. ("Merger Sub"), a wholly owned subsidiary of Precision, and Helomics Holding Corporation ("Helomics") (the "Merger Agreement"). Under the Merger Agreement, Helomics will merge with and into Merger Sub, with Merger Sub, to be renamed Helomics Holding Corporation, surviving as a wholly-owned subsidiary of Precision (the "Merger"). The following risks relate to the Merger. The Merger is more fully described in Amendment No. 2 to Precision's Registration Statement on Form S-4, filed with the Securities and Exchange Commission on January 24, 2019 (SEC File no. 333-228031) (the "Form S-4 Registration Statement").

Precision may not complete the Merger, which could negatively impact Precision's stock price and future operations.

If the Merger is not completed for any reason, including approval of the listing of the common stock by NASDAQ, Precision and Helomics may each be subjected to a number of material risks. The price of Precision common stock may decline to the extent that the current market price of the Precision's common stock reflects a market assumption that the Merger will be completed. Some costs related to the Merger, such as legal, accounting, filing, printing and mailing, must be paid and expended even if the Merger is not completed. In addition, if the Merger is not completed and the Precision's Board of Directors determines to seek another merger or business combination, there can be no assurance that the Board of Directors will be able to find a partner willing to agree to more attractive terms than those which have been negotiated for in the Merger.

The Merger Consideration is not adjustable based on the market price of Precision common stock so the consideration received (a) in connection with the Merger at the Closing of the Merger and/or (b) in connection with the Exchange Offer may have a greater or lesser value than at the time the Merger Agreement was signed.

Changes in the market price of Precision common stock before the completion of the Merger will not affect the number of shares Helomics security holders will be entitled to receive pursuant to the Merger Agreement (the "Merger Consideration") and/or the related exchange offer (the "Exchange Offer"). Therefore, if, before the completion of the Merger, the market price of Precision common stock declines from the market price on the date of the Merger Agreement, then Helomics security holders could receive consideration with substantially lower value in connection with the Merger, the Exchange Offer or both. Similarly, if before the completion of the Merger, the market price of Precision common stock increases from the market price on the date of the Merger Agreement, then Helomics security holders could receive consideration with substantially more value for their shares of Helomics capital stock than the parties had anticipated.

If the conditions to the Merger are not met, the Merger may not occur.

Even if the Merger is approved by the stockholders of both Precision and Helomics, specified conditions must be satisfied or waived to complete the Merger. These conditions are set forth in the Merger Agreement and described in the section titled "*The Merger Agreement — Conditions to the Completion of the Merger*" in the Form S-4 Registration Statement. Neither Precision nor Helomics can assure you that all the conditions will be satisfied or waived. If the conditions are not satisfied or waived, the Merger may not occur or may be delayed, and Precision and Helomics each may lose some or all the intended benefits of the Merger.

The Merger may be completed even though material adverse changes may result from the announcement of the Merger, industry-wide changes and other causes.

In general, either Precision or Helomics can refuse to complete the Merger if there is a material adverse change affecting the other party between October 26, 2018, the date of the Merger Agreement, and the closing of the Merger. However, certain types of changes do not permit either party to refuse to complete the Merger, even if such change could be said to have a material adverse effect on Precision or Helomics, including:

1. conditions generally affecting the industries in which Helomics or Precision participates or the U.S. or global economy as a whole, to the extent that such conditions do not have a disproportionate impact on Precision or Helomics and their respective subsidiaries, taken as a whole, as compared to other industry participants;

2. general conditions in the financial markets, and any changes therein (including any changes arising out of acts of terrorism, war, weather conditions or other force majeure events), to the extent that such conditions do not have a disproportionate impact on Precision or Helomics and their respective subsidiaries, taken as a whole, as compared to other industry participants; and

3. any change in accounting requirements or principles or any change in applicable legal requirements.

If material adverse changes occur and Precision and Helomics still complete the Merger, the stock price of the combined company may suffer. This in turn may reduce the value of the Merger and/or the Exchange Offer to the stockholders of Precision, Helomics or both.

The Merger may not occur if either Precision or Helomics or both is not satisfied with the results of due diligence.

Both (a) Precision's satisfaction with the results of its due diligence regarding Helomics and its subsidiary entities and (b) Helomics' satisfaction with the results of its due diligence regarding Precision are conditions that must be satisfied or waived to complete the Merger. Neither Precision nor Helomics can assure you that these conditions will be satisfied or waived. If the conditions are not satisfied or waived, the Merger may not occur or may be delayed, and Precision and Helomics each may lose some or all the intended benefits of the Merger.

Precision stockholders may not realize a benefit from the Merger commensurate with the ownership dilution they will experience in connection with the Merger.

If the combined organization is unable to realize the full strategic and financial benefits currently anticipated from the Merger, Precision stockholders will have experienced substantial dilution of their ownership interests without receiving any commensurate benefit, or only receiving part of the commensurate benefit to the extent the combined organization is able to realize only part of the strategic and financial benefits currently anticipated from the Merger.

Prior to the Merger, each of Helomics and Precision is obligated pursuant to the Merger Agreement to conduct their respective business and operations in the ordinary course and in accordance in all material respects with past practices, which could limit favorable opportunities available to Helomics and/or Precision, which could adversely affect their respective businesses.

Covenants in the Merger Agreement requires each of Helomics and Precision to conduct their respective business and operations in the ordinary course, which may impede the ability of each of Helomics and Precision to enter into other transactions that are not in the ordinary course of business, pending completion of the Merger. As a result, if the Merger is not completed, the parties may be at a relative disadvantage to their competitors during that period.

Certain provisions of the Merger Agreement may discourage third parties from submitting competing proposals, including proposals that may be superior to the arrangements contemplated by the Merger Agreement.

The terms of the Merger Agreement prohibit Helomics from soliciting competing proposals or cooperating with persons making unsolicited takeover proposals, including proposals that may be superior to the arrangements contemplated by the Merger Agreement.

Because the lack of a public market for Helomics' capital stock makes it difficult to evaluate the fairness of the Merger, the stockholders of Helomics may receive consideration (a) in the Merger and/or (b) the Exchange Offer that is less than the fair market value of Helomics' capital stock and/or Precision may pay more than the fair market value of Helomics' capital stock.

The outstanding capital stock of Helomics is privately held and is not traded in any public market. The lack of a public market makes it extremely difficult to determine the fair market value of Helomics' capital stock. Because the percentage of Precision equity to be issued to Helomics stockholders was determined based on negotiations between the parties, it is possible that the value of the Precision common stock to be received by Helomics stockholders will be less than the fair market value of Helomics' capital stock, or Precision may pay more than the aggregate fair market value for Helomics' capital 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 will incur substantial direct transaction costs associated with the Merger and 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 and Helomics' existing businesses, distraction of their management and diversion of other resources.

The integration of Precision's and Helomics' operations may divert management time and resources from the main 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.

Any delay in completion of the Merger may significantly reduce the benefits expected to be obtained from the Merger.

The Merger is subject to approval of Helomics' shareholders, and subject to a number of other conditions beyond the control of Precision and Helomics that may prevent, delay or otherwise materially adversely affect its completion. Precision and Helomics cannot predict whether or when these other conditions will be satisfied. Any delay in completing the Merger may significantly reduce the synergies and other benefits that Precision and Helomics expect to achieve if they successfully complete the Merger within the expected timeframe and integrate their respective businesses.

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

Following 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.

RISKS RELATED TO 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 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 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 generally 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 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, expand customer service, billing and systems processes and 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 that 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 a test 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, Helomics will need to add new codes to Helomics' billing process as well as 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 it 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 (AI) 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.