

Precipio, Inc.
Form S-1/A
June 14, 2018

As filed with the Securities and Exchange Commission on 14 June, 2018

Registration No. 333-224297

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

AMENDMENT NO. 1

TO

FORM S-1

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

PRECIPIO, INC.

(Exact name of Registrant as specified in its charter)

Delaware

(State or other jurisdiction of

3826

(Primary Standard Industrial

91-1789357

(I.R.S.

Employer

**incorporation or organization) Classification Code Number) Identification
No.)**

4 Science Park

New Haven, Connecticut 06511

(203) 787-7888

(Address, including zip code and telephone number, including area code, of Registrant's principal executive offices)

Ilan Danieli

Chief Executive Officer

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Approximate date of commencement of proposed sale to the public: As soon as practicable after this Registration Statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box:

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering:

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering:

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering:

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

Large Accelerated Filer	<input type="checkbox"/>	Accelerated Filer	<input type="checkbox"/>
Non-Accelerated Filer	<input type="checkbox"/>	Smaller Reporting Company	<input checked="" type="checkbox"/>
Emerging Growth Company	<input type="checkbox"/>		

(Do not check if a smaller reporting company)

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act.

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price(1)	Amount of Registration Fee(2)
Common Stock, \$0.01 par value per share	\$ 3,290,000	\$ 409.60

(1) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended.

(2) Calculated pursuant to Rule 457(o) based on an estimate of the proposed maximum aggregate offering price.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to Completion

Preliminary Prospectus dated [____], 2018

PROSPECTUS

Shares

Common Stock

Our common stock is listed on The NASDAQ Capital Market under the symbol “PRPO.” The last reported sale price of our common stock on _____, 2018 was \$ _____ per share.

This prospectus relates to shares of common stock of Precipio Inc. that may be sold by the selling stockholder identified in this prospectus. The shares of common stock offered under this prospectus by the selling stockholder are issuable to Leviston Resources LLC (“Leviston”) or the Investor pursuant to a certain Equity Purchase Agreement dated February 8, 2018 with Leviston and ourselves (the “Equity agreement”) in accordance with which we may offer and sell shares of our common stock having an aggregate offering price of up to \$8,000,000 from time to time to the Investor.

We will not receive any of the proceeds from the sale of shares by the selling stockholder. This registration statement covers only approximately 41% of the \$8,000,000 of shares of our common stock issuable pursuant to the Equity Agreement. We will file subsequent registration statements covering the resale of additional shares of our common

stock issuable pursuant to the Equity Agreement with the Investor beginning approximately 30 days after we have substantially completed the sale to the Investor under the Equity Agreement of the shares subject to this registration statement.

Sales of our common stock, if any, under this prospectus may be made in sales deemed to be “at-the-market” equity offerings as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, or the Securities Act, at a purchase price equal to 97.25% of the volume weighted average sales price of the common stock reported on the date that the Investor receives a capital call from us.

The selling stockholder may sell the shares of common stock described in this prospectus in a number of different ways and at varying prices. We provide more information about how the selling stockholder may sell its shares of common stock in the section titled “Plan of Distribution.” Leviston is an “underwriter” within the meaning of the Securities Act of 1933, as amended, in connection with sales of shares offered pursuant to this prospectus. We will pay the expenses incurred in registering the shares, including legal and accounting fees.

Investing in our common stock involves a high degree of risk. See “Risk Factors” in this prospectus to read about the factors you should consider before buying shares of our common stock.

We may amend or supplement this prospectus from time to time by filing amendments or supplements as required. You should read the entire prospectus and any amendments or supplements carefully before you make your investment decision.

Neither the Securities and Exchange Commission nor any other regulatory body has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is June 14, 2018

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You should rely only on the information contained in this prospectus or in any free writing prospectus we file with the Securities and Exchange Commission. We have not authorized anyone to provide you with information different from that contained in this prospectus or any free writing prospectus. We take no responsibility for, and can provide no assurance, as to the reliability of any other information that others may give you. We are offering to sell and seeking offers to buy, shares of our common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date on the front cover of this prospectus, or other earlier date stated in this prospectus, regardless of the time of delivery of this prospectus or of any sale of our common stock. Our business, financial condition, results of operations and prospects may have changed since such date.

For investors outside of the United States: we have not done anything that would permit this offering outside the United States or to permit the possession or distribution of this prospectus outside the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside of the United States.

PROSPECTUS SUMMARY

This summary does not contain all of the information you should consider before buying shares of our common stock. You should read the entire prospectus carefully, especially the “Risk Factors” and on our Quarterly report on form 10-Q for the first quarter ended March 31, 2018, filed with the SEC on May 21, 2018 and our financial statements and the related notes our Annual Report on Form 10-K for the fiscal year ended December 31, 2017, filed with the SEC on April 13, 2018, before deciding to invest in shares of our common stock.

Overview

We are a cancer diagnostics company providing diagnostic products and services to the oncology market. We have built and continue to develop a platform designed to eradicate the problem of misdiagnosis by harnessing the intellect, expertise and technology developed within academic institutions and delivering quality diagnostic information to physicians and their patients worldwide. We operate a cancer diagnostic laboratory located in New Haven, Connecticut and have partnered with the Yale School of Medicine to capture the expertise, experience and technologies developed within academia so that we can provide a better standard of cancer diagnostics and solve the growing problem of cancer misdiagnosis. We also operate a research and development facility in Omaha, Nebraska which will focus on further development of ICE-COLD-PCR, or ICP, the patented technology described further below, which was exclusively licensed by us from Dana-Farber Cancer Institute, Inc., or Dana-Farber, at Harvard University. The research and development center will focus on the development of this technology, which we believe will enable us to commercialize other technologies developed by our current and future academic partners. Our platform connects patients, physicians and diagnostic experts residing within academic institutions. Launched in 2017, the platform facilitates the following relationships:

- **Patients:** patients may search for physicians in their area and consult directly with academic experts that are on the platform. Patients may also have access to new academic discoveries as they become commercially available.

- **Physicians:** physicians can connect with academic experts to seek consultations on behalf of their patients and may also provide consultations for patients in their area seeking medical expertise in that physician’s relevant specialty. Physicians will also have access to new diagnostic solutions to help improve diagnostic accuracy.

- **Academic Experts:** academic experts on the platform can make themselves available for patients or physicians seeking access to their expertise. Additionally, these experts have a platform available to commercialize their research discoveries.

We intend to continue updating our platform to allow for patient-to-patient communications and allow individuals to share stories and provide support for one another, to allow physicians to consult with their peers to discuss and share challenges and solutions, and to allow academic experts to interact with others in academia on the platform to discuss

their research and cross-collaborate.

ICP was developed at Harvard and is licensed exclusively by us from Dana-Farber. The technology enables the detection of genetic mutations in liquid biopsies, such as blood samples. The field of liquid biopsies is a rapidly growing market, aimed at solving the challenge of obtaining genetic information on disease progression and changes from sources other than a tumor biopsy.

Gene sequencing is performed on tissue biopsies taken surgically from the tumor site in order to identify potential therapies that will be more effective in treating the patient. There are several limitations to this process. First, surgical procedures have several limitations, including:

- Cost: surgical procedures are usually performed in a costly hospital environment. For example, according to a recent study the mean cost of lung biopsies is greater than \$14,000; surgery also involves hospitalization and recovery time.
- Surgical access: various tumor sites are not always accessible (e.g. brain tumors), in which cases no biopsy is available for diagnosis.
- Risk: patient health may not permit undergoing an invasive surgery; therefore, a biopsy cannot be obtained at all.
- Time: the process of scheduling and coordinating a surgical procedure often takes time, delaying the start of patient treatment.

Second, there are several tumor-related limitations that provide a challenge to obtaining such genetic information from a tumor:

- Tumors are heterogeneous by nature: a tissue sample from one area of the tumor may not properly represent the tumor's entire genetic composition; thus, the diagnostic results from a tumor may be incomplete and non-representative.

- Metastases: in order to accurately test a patient with metastatic disease, ideally an individual biopsy sample should be taken from each site (if those sites are even known). These biopsies are very difficult to obtain; therefore, physicians often rely on biopsies taken only from the primary tumor site.

The advent of technologies enabling liquid biopsies as an alternative to tumor biopsy and analysis is based on the fact that tumors (both primary and metastatic) shed cells and fragments of DNA into the blood stream. These blood samples are called “liquid biopsies” that contain circulating tumor DNA, or ctDNA, which hold the same genetic information found in the tumor(s). That tumor DNA is the target of genetic analysis. However, since the quantity of tumor DNA is very small in proportion to the “normal” (or “healthy”) DNA within the blood stream, there is a need to identify and separate the tumor DNA from the normal DNA.

ICP is an enrichment technology that enables the laboratory to focus its analysis on the tumor DNA by enriching, and thereby “multiplying” the presence of, tumor DNA, while maintaining the normal DNA at its same level. Once the enrichment process has been completed, the laboratory genetic testing equipment is able to identify genetic abnormalities presented in the ctDNA, and an analysis can be conducted at a higher level of sensitivity, to enable the detection of such genetic abnormalities. The technology is encapsulated into a chemical that is provided in the form of a kit and sold to other laboratories who wish to conduct these tests in-house. The chemical within the kit is added to the specimen preparation process, enriching the sample for the tumor DNA so that the analysis will detect those genetic abnormalities.

Risks Associated with Our Business

Our ability to implement our business strategy is subject to numerous risks that you should be aware of before making an investment decision. These risks are described more fully in the section entitled “Risk Factors” immediately following this prospectus summary. These risks include, among others:

• We will require additional capital in order to continue our operations, and may have difficulty raising additional capital;

- We have a history of recurring losses, and we can provide no assurance as to our future operating results;

• We have a history of recurring losses and an accumulated deficit, which, among other factors, raise doubt about our ability to continue as a going concern, which in turn may hinder our ability to obtain future financing;

• Our stock price has experienced price fluctuations and may continue to do so, thereby adversely affecting our business;

• Our common stock could be further diluted as the result of the issuance of additional shares of common stock, convertible securities, warrants or options.

Recent Developments

On April 20, 2018, the Company entered into a securities purchase agreement (“Debt Financing Agreement”) with certain investors, pursuant to which the Company will issue up to approximately \$3.3M in 8% Senior Secured Convertible Promissory Notes with 100% common stock warrant coverage. The initial closing provided the Company with \$1,660,000 of gross proceeds for the issuance of Notes with an aggregate principal of \$1,824,176. The Note is payable by the Company on the earlier of (i) the one year anniversary after the initial closing date or (ii) upon the closing of a qualified offering, namely the Company raising gross proceeds of at least \$7,000,000. The obligations under the Notes are secured, subject to certain exceptions and other permitted payments by a perfected security interest on the assets of the Company.

During May 2018, holders of Series B and Series C warrants exercised 2,398,143 warrants for 2,398,143 shares of the Company’s common stock as a result of the provisions contained in the Debt Financing Agreement. The Company received approximately \$720,000 from the warrant exercises.

Merger Transaction

On June 29, 2017, the Company (then known as Transgenomic, Inc., or Transgenomic), completed its merger, or the Merger, with Precipio Diagnostics, LLC (Precipio), a privately held Delaware limited liability company, in accordance with the terms of the Agreement and Plan of Merger (Merger Agreement), dated October 12, 2016, as amended on February 2, 2017 and June 29, 2017. Pursuant to the Merger Agreement, a newly formed subsidiary of Transgenomic merged with and into Precipio, with Precipio surviving the Merger as a wholly-owned subsidiary of the combined company. In connection with the Merger, the Company changed its name from Transgenomic, Inc. to Precipio, Inc. and effected a 1-for-30 reverse stock split of its common stock.

Corporate Information

We were incorporated under the laws of the State of Delaware in March 1997. Our principal executive office is located at 4 Science Park, New Haven, Connecticut, 06511, and our telephone number is (203) 787-7888. Our website address is www.precipiodx.com. We do not incorporate the information on or accessible through our website into this prospectus, and you should not consider any information on, or that can be accessed through, our website as part of this prospectus. Our current and future annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and other filings with the SEC are available, free of charge, through our website as soon as reasonably practicable after we electronically file such materials with, or furnish them to, the SEC. Our SEC filings can be accessed through the investors section of our website. The information contained on, or accessible through, our website is not intended to be part of this prospectus or any report we file with, or furnish to, the SEC and incorporated by reference herein. Our common stock trades on the NASDAQ Capital Market, or NASDAQ, under the symbol "PRPO."

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below together with all of the other information contained in this prospectus, including our financial statements and the related notes on our Quarterly report on form 10Q for the first quarter ended March 31, 2018, filed with the SEC on May 21, 2018 and our Annual Report on Form 10-K for the fiscal year ended December 31, 2017, filed with the SEC on April 13, 2018, before deciding to invest in our common stock. If any of the following risks actually occur, our business, prospects, operating results and financial condition could suffer materially, the trading price of our common stock could decline and you could lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may also adversely affect our business.

Risks Related to Our Business and Strategy

There is substantial doubt about our ability to continue as a going concern.

Our Independent Registered Public Accounting Firm has issued an opinion on our Consolidated Financial Statements included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017, filed with the SEC on April 13, 2018, that states that the Consolidated Financial Statements were prepared assuming we will continue as a going concern. Our consolidated financial statements have been prepared using accounting principles generally accepted in the United States of America applicable for a going concern, which assume that we will realize our assets and discharge our liabilities in the ordinary course of business. We have incurred substantial operating losses and have used cash in our operating activities for the past few years. For the year ended December 31, 2017, we had a net loss of \$20.7 million, negative working capital of \$8.3 million and net cash used in operating activities of \$6.7 million. We are not current in making payments to all lenders and vendors. Our consolidated financial statements do not include any adjustments to the amounts and classification of assets and liabilities that may be necessary should we be unable to continue as a going concern. We also cannot be certain that additional financing, if needed, will be available on acceptable terms, or at all, and our failure to raise capital when needed could limit our ability to continue our operations.

To date, we have experienced negative cash flow from development of our diagnostic technology, as well as from the costs associated with establishing a laboratory and building a sales force to market our products and services. We expect to incur substantial net losses for the foreseeable future to further develop and commercialize our diagnostic technology. We also expect that our selling, general and administrative expenses will continue to increase due to the additional costs associated with market development activities and expanding our staff to sell and support our products. Our ability to achieve or, if achieved, sustain profitability is based on numerous factors, many of which are beyond our control, including the market acceptance of our products, competitive product development and our

market penetration and margins. We may never be able to generate sufficient revenue to achieve or, if achieved, sustain profitability.

Because of the numerous risks and uncertainties associated with further development and commercialization of our diagnostic technology and any future tests, we are unable to predict the extent of any future losses or when we will become profitable, if ever. We may never become profitable and you may never receive a return on an investment in our securities. An investor in our securities must carefully consider the substantial challenges, risks and uncertainties inherent in the development and commercialization of tests in the medical diagnostic industry. We may never successfully commercialize our diagnostic technology or any future tests, and our business may fail.

We will need to raise substantial additional capital to commercialize our diagnostic technology, and our failure to obtain funding when needed may force us to delay, reduce or eliminate our product development programs or collaboration efforts or force us to restrict or cease operations.

As of March 31, 2018, we had cash of \$0.3 million and our working capital was approximately negative \$7.5 million. Due to our recurring losses from operations and the expectation that we will continue to incur losses in the future, we will be required to raise additional capital to complete the development and commercialization of our current product candidates and to pay off our obligations. To date, to fund our operations and develop and commercialize our products, we have relied primarily on equity and debt financings. When we seek additional capital, we may seek to sell additional equity and/or debt securities or to obtain a credit facility, which we may not be able to do on favorable terms, or at all. Our ability to obtain additional financing will be subject to a number of factors, including market conditions, our operating performance and investor sentiment. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue the development and/or commercialization of one or more of our product candidates, restrict or cease our operations or obtain funds by entering into agreements on unattractive terms. Due to the timing of the filing of our Quarterly Report on Form 10-Q for the quarter ended June 30, 2017, we will not be eligible to file a new Form S-3 registration statement until September 1, 2018. Our existing Form S-3 registration statement expired in February 2018. This may have an adverse impact on our ability to raise additional capital.

We have incurred losses since our inception and expect to incur losses for the foreseeable future. We cannot be certain that we will achieve or sustain profitability.

We have incurred losses since our inception and expect to incur losses in the future. As of March 31, 2018, we had a net loss of \$2.4 million, negative working capital of \$7.5 million and net cash used in operating activities of \$1.1 million. To date, we have experienced negative cash flow from development of our diagnostic technology, as well as from the costs associated with establishing a laboratory and building a sales force to market our products and services. We expect to incur substantial net losses for the foreseeable future to further develop and commercialize our diagnostic technology. We also expect that our selling, general and administrative expenses will continue to increase due to the additional costs associated with market development activities and expanding our staff to sell and support our products. Our ability to achieve or, if achieved, sustain profitability is based on numerous factors, many of which are beyond our control, including the market acceptance of our products, competitive product development and our market penetration and margins. We may never be able to generate sufficient revenue to achieve or, if achieved, sustain profitability.

Because of the numerous risks and uncertainties associated with further development and commercialization of our diagnostic technology and any future tests, we are unable to predict the extent of any future losses or when we will become profitable, if ever. We may never become profitable and you may never receive a return on an investment in our securities. An investor in our securities must carefully consider the substantial challenges, risks and uncertainties inherent in the development and commercialization of tests in the medical diagnostic industry. We may never successfully commercialize our diagnostic technology or any future tests, and our business may fail.

We are continuing to integrate legacy internal controls over financial reporting into our financial reporting framework.

Such changes have resulted, and may continue to result in changes in our internal control over financial reporting results that materially affect our internal control over financial reporting. We continue to integrate the business processes and information systems in effect prior to the reverse merger, including internal controls. If we cannot provide reliable financial reports or detect and prevent fraud, our business and operating results could be harmed, investors could lose confidence in our reporting financial information, and the trading price of our common stock could drop significantly.

We have been, and may continue to be, subject to costly litigation.

We have been, and may continue to be, subject to legal proceedings. Due to the nature of our business and our lack of sufficient capital resources to pay our obligations on a timely basis, we may be subject to a variety of regulatory investigations, claims, lawsuits and other proceedings in the ordinary course of our business. The results of these legal proceedings cannot be predicted with certainty due to the uncertainty inherent in litigation, including the effects of discovery of new evidence or advancement of new legal theories, the difficulty of predicting decisions of judges and juries and the possibility that decisions may be reversed on appeal. Such litigation has been, and in the future, could be, costly, time-consuming and distracting to management, result in a diversion of resources and could materially adversely affect our business, financial condition and operating results.

The commercial success of our product candidates will depend upon the degree of market acceptance of these products among physicians, patients, health care payors and the medical community and on our ability to successfully market our product candidates.

Our products may never gain significant acceptance in the marketplace and, therefore, may never generate substantial revenue or profits for us. Our ability to achieve commercial market acceptance for our existing and future products will depend on several factors, including:

our ability to convince the medical community of the clinical utility of our products and their potential advantages over existing diagnostics technology;

- the willingness of physicians and patients to utilize our products; and

the agreement by commercial third-party payors and government payors to reimburse our products, the scope and amount of which will affect patients' willingness or ability to pay for our products and will likely heavily influence physicians' decisions to recommend our products.

In addition, physicians may rely on guidelines issued by industry groups, such as the National Comprehensive Cancer Network, medical societies, such as the College of American Pathologists, or CAP, or other key oncology-related organizations before utilizing any diagnostic test. Although we have a study underway to demonstrate the clinical utility of our existing products, none of our products are, and may never be, listed in any such guidelines.

We believe that publications of scientific and medical results in peer-reviewed journals and presentations at leading conferences are critical to the broad adoption of our products. Publication in leading medical journals is subject to a peer-review process, and peer reviewers may not consider the results of studies involving our products sufficiently novel or worthy of publication. The failure to be listed in physician guidelines or to be published in peer-reviewed journals could limit the adoption of our products. Failure to achieve widespread market acceptance of our products would materially harm our business, financial condition, and results of operations.

If we cannot compete successfully with our competitors, including new entrants in the market, we may be unable to increase or sustain our revenue or achieve and sustain profitability.

The medical diagnostic industry is intensely competitive and characterized by rapid technological progress. We face significant competition from competitors ranging in size from diversified global companies with significant research and development resources to small, specialized firms whose narrower product lines may allow them to be more effective in deploying related PCR technology in the genetic diagnostic industry. Our closest competitors fall largely into two groups, consisting of companies that specialize in oncology and offer directly competing services to our diagnostic services, offering their services to oncologists and pathology departments within hospitals, as well as large commercial companies that offer a wide variety of laboratory tests that range from simple chemistry tests to complex genetic testing. The technologies associated with the molecular diagnostics industry are evolving rapidly and there is intense competition within such industry. Certain molecular diagnostics companies have established technologies that may be competitive to our product candidates and any future tests that we develop. Some of these tests may use different approaches or means to obtain diagnostic results, which could be more effective or less expensive than our tests for similar indications. Moreover, these and other future competitors have or may have considerably greater resources than we do in terms of technology, sales, marketing, commercialization and capital resources. These competitors may have substantial advantages over us in terms of research and development expertise, experience in clinical studies, experience in regulatory issues, brand name exposure and expertise in sales and marketing as well as in operating central laboratory services. Many of these organizations have financial, marketing and human resources greater than ours; therefore, there can be no assurance that we can successfully compete with present or potential competitors or that such competition will not have a materially adverse effect on our business, financial position or results of operations.

In July 2017, we commenced a study to demonstrate the impact of academic pathology expertise on diagnostic accuracy. There is no assurance that this study, or other studies or trials we may conduct, will demonstrate favorable results. If the results of this study, or other studies or trials we may conduct, demonstrate unfavorable or inconclusive results, customers may choose our competitors' products over our products and our commercial opportunities may be reduced or eliminated.

We believe that many of our competitors spend significantly more on research and development-related activities than we do. Our competitors may discover new diagnostic tools or develop existing technologies to compete with our diagnostic technology. Our commercial opportunities will be reduced or eliminated if these competing products are more effective, are more convenient or are less expensive than our product candidates.

We may not be able to develop new products or enhance the capabilities of our systems to keep pace with rapidly changing technology and customer requirements, which could have a material adverse effect on our business and operating results.

Our success depends on our ability to develop new products and applications for our diagnostic technology in existing and new markets, while improving the performance and cost-effectiveness of our systems. New technologies, techniques or products could emerge that might offer better combinations of price and performance than our current or future products and systems. Existing or future markets for our products, as well as potential markets for our diagnostic product candidates, are characterized by rapid technological change and innovation. It is critical to our success that we anticipate changes in technology and customer requirements and successfully introduce new, enhanced and competitive technologies to meet our customers' and prospective customers' needs on a timely and cost-effective basis. At the same time, however, we must carefully manage the introduction of new products. If customers believe that such products will offer enhanced features or be sold for a more attractive price, they may delay purchases until such products are available. We may also have excess or obsolete inventory of older products as we transition to new products and our experience in managing product transitions is very limited. If we do not successfully innovate and introduce new technology into our product lines or effectively manage the transitions to new product offerings, our revenues and results of operations will be adversely impacted.

Competitors may respond more quickly and effectively than we do to new or changing opportunities, technologies, standards or customer requirements. We anticipate that we will face increased competition in the future as existing companies and competitors develop new or improved products and as new companies enter the market with new technologies.

We currently depend on the services of pathologists at a single academic partner and the loss of the services of these pathologists would adversely impact our ability to develop, commercialize and deliver our products.

We currently depend on the services of pathologists at a single academic partner to review and render their diagnostic interpretation of our test results and to prepare the final diagnostic results that we integrate into our final report for our customers. Although we are in the process of adding new academic partners, it would be difficult to replace the services provided by the pathologists at our current partner if their services became unavailable to us for any reason prior to adding other academic partners. If this academic partner does not successfully carry out its contractual duties or obligations and meet expected deadlines; if this partner needs to be replaced, or if the quality or accuracy of the services provided by the pathologists at this partner were compromised for any reason, we would likely not be able to provide our services in a manner expected by our customers, and our financial results and the commercial prospects for our products could be harmed. The loss of the services of these pathologists would severely harm our ability to develop, commercialize and deliver our products, and our business, financial condition and operating results would be materially adversely affected.

We may experience temporary disruptions and delays in processing biological samples at our facilities.

We may experience delays in processing biological samples caused by software and other errors. Any delay in processing samples could have an adverse effect on our business, financial condition and results of operations.

We depend upon a limited number of key personnel, and if we are not able to retain them or recruit additional qualified personnel, the commercialization of our product candidates and any future tests that we develop could be delayed or negatively impacted.

Our success is largely dependent upon the continued contributions of our officers and employees. Our success also depends in part on our ability to attract and retain highly qualified scientific, commercial and administrative personnel. In order to pursue our test development and commercialization strategies, we will need to attract and hire additional personnel with specialized experience in a number of disciplines, including assay development, laboratory and clinical operations, sales and marketing, billing and reimbursement. There is intense competition for personnel in the fields in which we operate. If we are unable to attract new employees and retain existing employees, the development and commercialization of our product candidates and any future tests could be delayed or negatively impacted. If any of them becomes unable or unwilling to continue in their respective positions, and we are unable to find suitable replacements, our business and financial results could be materially negatively affected.

We will need to increase the size of our organization, and we may experience difficulties in managing growth.

We are a small company with 31 full-time employees as of December 31, 2017. Future growth will impose significant added responsibilities on members of management, including the need to identify, attract, retain, motivate and integrate highly skilled personnel. We may increase the number of employees in the future depending on the progress of our development of diagnostic technology. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to:

- integrate additional management, administrative, manufacturing and regulatory personnel;
- maintain sufficient administrative, accounting and management information systems and controls; and
 - hire and train additional qualified personnel.

We may not be able to accomplish these tasks, and our failure to accomplish any of them could harm our financial results.

We currently have limited experience in marketing products. If we are unable to establish marketing and sales capabilities and retain the proper talent to execute on our sales and marketing strategy, we may not be able to generate product revenue.

We have developed limited experience in marketing our products and services. We intend to continue to develop our in-house marketing organization and sales force, which will require significant capital expenditures, management resources and time. We will have to compete with other diagnostic companies to recruit, hire, train and retain marketing and sales personnel.

If we are unable to further grow our internal sales, marketing and distribution capabilities, we may pursue collaborative arrangements regarding the sales and marketing of our product candidates or future products, however, we may not be able to establish or maintain such collaborative arrangements, or if we are able to do so, they may not have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates.

We may not realize the anticipated benefits of our merger with Transgenomic, Inc.

In June 2017, we completed our merger with Transgenomic, Inc, or Transgenomic. Integrating the operations of the businesses of Precipio Diagnostics successfully or otherwise realizing any of the anticipated benefits of the merger with Precipio, including anticipated cost savings and additional revenue opportunities, involves a number of potential challenges. The failure to meet these integration challenges could seriously harm our results of operations and the market price of our common stock may decline as a result.

Realizing the benefits of the merger will depend in part on the integration of information technology, operations and personnel. These integration activities are complex and time-consuming and we may encounter unexpected difficulties or incur unexpected costs, including:

our inability to achieve the cost savings and operating synergies anticipated in the merger, including synergies relating to increased purchasing efficiencies and a reduction in costs associated with the merger;

- diversion of management attention from ongoing business concerns to integration matters;
- difficulties in consolidating and rationalizing information technology platforms and administrative infrastructures;
- complexities associated with managing the geographic separation of the combined businesses and consolidating multiple physical locations where management may determine consolidation is desirable;
- difficulties in integrating personnel from different corporate cultures while maintaining focus on providing consistent, high quality customer service;
- challenges in demonstrating to our customers that the merger will not result in adverse changes in customer service standards or business focus; and
- possible cash flow interruption or loss of revenue as a result of change of ownership transitional matters.

We may not successfully integrate the operations of the businesses in a timely manner and may not realize the anticipated net reductions in costs and expenses and other benefits and synergies of the merger with Transgenomic to the extent, or in the timeframe, anticipated. In addition to the integration risks discussed above, our ability to realize these net reductions in costs and expenses and other benefits and synergies could be adversely impacted by practical or legal constraints on our ability to combine operations.

Cybersecurity risks could compromise our information and expose us to liability, which may harm our ability to operate effectively and may cause our business and reputation to suffer.

Cybersecurity refers to the combination of technologies, processes and procedures established to protect information technology systems and data from unauthorized access, attack, or damage. We rely on our information systems to provide security for processing, transmission and storage of confidential information about our patients, customers and personnel, such as names, addresses and other individually identifiable information protected by HIPAA and other privacy laws. Cyber-attacks are increasingly more common, including in the health care industry. The regulatory environment surrounding information security and privacy is increasingly demanding, with the frequent imposition of new and changing requirements. Compliance with changes in privacy and information security laws and with rapidly evolving industry standards may result in our incurring significant expense due to increased investment in technology and the development of new operational processes.

We have not experienced any known attacks on our information technology systems that compromised any confidential information. We maintain our information technology systems with safeguard protection against cyber-attacks including passive intrusion protection, firewalls and virus detection software. However, these safeguards

do not ensure that a significant cyber-attack could not occur. Although we have taken steps to protect the security of our information systems and the data maintained in those systems, it is possible that our safety and security measures will not prevent the systems' improper functioning or damage or the improper access or disclosure of personally identifiable information such as in the event of cyber-attacks.

Security breaches, including physical or electronic break-ins, computer viruses, attacks by hackers and similar breaches can create system disruptions or shutdowns or the unauthorized disclosure of confidential information. If personal information or protected health information is improperly accessed, tampered with or disclosed as a result of a security breach, we may incur significant costs to notify and mitigate potential harm to the affected individuals, and we may be subject to sanctions and civil or criminal penalties if we are found to be in violation of the privacy or security rules under HIPAA or other similar federal or state laws protecting confidential personal information. In addition, a security breach of our information systems could damage our reputation, subject us to liability claims or regulatory penalties for compromised personal information and could have a material adverse effect on our business, financial condition and results of operations.

Our ability to use net operating loss carryforwards to offset future taxable income for U.S. federal tax purposes is subject to limitation and risk that could further limit our ability to utilize our net operating losses.

Under U.S. federal income tax law, a corporation's ability to utilize its net operating losses, or NOLs, to offset future taxable income may be significantly limited if it experiences an "ownership change" as defined in Section 382 of the Internal Revenue Code, as amended. In general, an ownership change will occur if there is a cumulative change in a corporation's ownership by "5-percent shareholders" that exceeds 50 percentage points over a rolling three-year period. A corporation that experiences an ownership change will generally be subject to an annual limitation on the use of its pre-ownership change NOLs equal to the value of the corporation immediately before the ownership change, multiplied by the long-term tax-exempt rate (subject to certain adjustments). The annual limitation for a taxable year generally is increased by the amount of any "recognized built-in gains" for such year and the amount of any unused annual limitation in a prior year. On December 22, 2017, a law commonly known as the Tax Cuts and Jobs Act, or the TCJ Act, was enacted in the United States. Certain provisions of the TCJ Act impact the ability to utilize NOLs generated in 2018 and forward; any limitation to our annual use of NOLs could require us to pay a greater amount of U.S. federal (and in some cases, state) income taxes, which could reduce our after-tax income from operations for future taxable years and adversely impact our financial condition.

Reimbursement and Regulatory Risks Relating to Our Business

Governmental payers and health care plans have taken steps to control costs.

Medicare, Medicaid and private insurers have increased their efforts to control the costs of health care services, including clinical testing services. They may reduce fee schedules or limit/exclude coverage for certain types of tests that we perform. Medicaid reimbursement varies by state and is subject to administrative and billing requirements and budget pressures. We expect efforts to reduce reimbursements, impose more stringent cost controls and reduce utilization of testing services will continue. These efforts, including changes in laws or regulations, may have a material adverse impact on our business.

Changes in payer mix could have a material adverse impact on our net sales and profitability.

Testing services are billed to physicians, patients, government payers such as Medicare, and insurance companies. Tests may be billed to different payers depending on a particular patient's medical insurance coverage. Government payers have increased their efforts to control the cost, utilization and delivery of health care services as well as reimbursement for laboratory testing services. Further reductions of reimbursement for Medicare and Medicaid services or changes in policy regarding coverage of tests or other requirements for payment, such as prior authorization or a physician or qualified practitioner's signature on test requisitions, may be implemented from time to time. Reimbursement for the laboratory services component of our business is also subject to statutory and regulatory reduction. Reductions in the reimbursement rates and changes in payment policies of other third party payers may occur as well. Such changes in the past have resulted in reduced payments as well as added costs and have decreased test utilization for the clinical laboratory industry by adding more complex new regulatory and administrative requirements. As a result, increases in the percentage of services billed to government payers could have an adverse impact on our net sales.

Our laboratories require ongoing CLIA certification.

The Clinical Laboratory Improvement Amendments of 1988, or CLIA, extended federal oversight to virtually all clinical laboratories by requiring that they be certified by the federal government or by a federally-approved accreditation agency. The CLIA requires that all clinical laboratories meet quality assurance, quality control and personnel standards. Laboratories must also undergo proficiency testing and are subject to inspections.

The sanctions for failure to comply with the CLIA requirements include suspension, revocation or limitation of a laboratory's CLIA certificate, which is necessary to conduct business, cancellation or suspension of the laboratory's approval to receive Medicare and/or Medicaid reimbursement, as well as significant fines and/or criminal penalties. The loss or suspension of a CLIA certification, imposition of a fine or other penalties, or future changes in the CLIA law or regulations (or interpretation of the law or regulations) could have a material adverse effect on us.

We believe that we are in compliance with all applicable laboratory requirements, but no assurances can be given that our laboratories will pass all future certification inspections.

Failure to comply with HIPAA could be costly.

The Health Insurance Portability and Accountability Act, or HIPAA, and associated regulations protect the privacy and security of certain patient health information and establish standards for electronic health care transactions in the United States. These privacy regulations establish federal standards regarding the uses and disclosures of protected health information. Our laboratories are subject to HIPAA and its associated regulations. If we fail to comply with these laws and regulations we could suffer civil and criminal penalties, fines, exclusion from participation in governmental health care programs and the loss of various licenses, certificates and authorizations necessary to operate our patient testing business. We could also incur liabilities from third party claims.

Our failure to comply with any applicable government laws and regulations or otherwise respond to claims relating to improper handling, storage or disposal of hazardous chemicals that we use may adversely affect our results of operations.

Our research and development and commercial activities involve the controlled use of hazardous materials and chemicals. We are subject to federal, state, local and international laws and regulations governing the use, storage, handling and disposal of hazardous materials and waste products. If we fail to comply with applicable laws or regulations, we could be required to pay penalties or be held liable for any damages that result and this liability could exceed our financial resources. We cannot be certain that accidental contamination or injury will not occur. Any such accident could damage our research and manufacturing facilities and operations, resulting in delays and increased costs.

We may become subject to the Anti-Kickback Statute, Stark Law, False Claims Act, Civil Monetary Penalties Law and may be subject to analogous provisions of applicable state laws and could face substantial penalties if we fail to comply with such laws.

There are several federal laws addressing fraud and abuse that apply to businesses that receive reimbursement from a federal health care program. There are also a number of similar state laws covering fraud and abuse with respect to, for example, private payors, self-pay and insurance. Currently, we receive a substantial percentage of our revenue from private payors and from Medicare. Accordingly, our business is subject to federal fraud and abuse laws, such as the Anti-Kickback Statute, the Stark Law, the False Claims Act, the Civil Monetary Penalties Law and other similar laws. Moreover, we are already subject to similar state laws. We believe we have operated, and intend to continue to operate, our business in compliance with these laws. However, these laws are subject to modification and changes in interpretation, and are enforced by authorities vested with broad discretion. Federal and state enforcement entities have significantly increased their scrutiny of healthcare companies and providers which has led to investigations, prosecutions, convictions and large settlements. We continually monitor developments in this area. If these laws are interpreted in a manner contrary to our interpretation or are reinterpreted or amended, or if new legislation is enacted with respect to healthcare fraud and abuse, illegal remuneration, or similar issues, we may be required to restructure our affected operations to maintain compliance with applicable law. There can be no assurances that any such restructuring will be possible or, if possible, would not have a material adverse effect on our results of operations, financial position, or cash flows.

Anti-Kickback Statute

A federal law commonly referred to as the “Anti-Kickback Statute” prohibits the knowing and willful offer, payment, solicitation or receipt of remuneration, directly or indirectly, in return for the referral of patients or arranging for the referral of patients, or in return for the recommendation, arrangement, purchase, lease or order of items or services that

are covered, in whole or in part, by a federal healthcare program such as Medicare or Medicaid. The term “remuneration” has been broadly interpreted to include anything of value such as gifts, discounts, rebates, waiver of payments or providing anything at less than its fair market value. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or the PPACA, amended the intent requirement of the Anti-Kickback Statute such that a person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate the statute. Further, the PPACA now provides that claims submitted in violation of the Anti-Kickback Statute constitute false or fraudulent claims for purposes of the federal False Claims Act, or FCA, including the failure to timely return an overpayment. Many states have adopted similar prohibitions against kickbacks and other practices that are intended to influence the purchase, lease or ordering of healthcare items and services reimbursed by a governmental health program or state Medicaid program. Some of these state prohibitions apply to remuneration for referrals of healthcare items or services reimbursed by any third-party payor, including commercial payors and self-pay patients.

Stark Law

Section 1877 of the Social Security Act, or the Stark Law, prohibits a physician from referring a patient to an entity for certain “designated health services” reimbursable by Medicare if the physician (or close family members) has a financial relationship with that entity, including an ownership or investment interest, a loan or debt relationship or a compensation relationship, unless an exception to the Stark Law is fully satisfied. The designated health services covered by the law include, among others, laboratory and imaging services. Some states have self-referral laws similar to the Stark Law for Medicaid claims and commercial claims.

Violation of the Stark Law may result in prohibition of payment for services rendered, a refund of any Medicare payments for services that resulted from an unlawful referral, \$15,000 civil monetary penalties for specified infractions, criminal penalties, and potential exclusion from participation in government healthcare programs, and potential false claims liability. The repayment provisions in the Stark Law are not dependent on the parties having an improper intent; rather, the Stark Law is a strict liability statute and any violation is subject to repayment of all amounts arising out of tainted referrals. If physician self-referral laws are interpreted differently or if other legislative restrictions are issued, we could incur significant sanctions and loss of revenues, or we could have to change our arrangements and operations in a way that could have a material adverse effect on our business, prospects, damage to our reputation, results of operations and financial condition.

False Claims Act

The FCA prohibits providers from, among other things, (1) knowingly presenting or causing to be presented, claims for payments from the Medicare, Medicaid or other federal healthcare programs that are false or fraudulent; (2) knowingly making, using or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the federal government; or (3) knowingly making, using or causing to be made or used, a false record or statement to avoid, decrease or conceal an obligation to pay money to the federal government. The “qui tam” or “whistleblower” provisions of the FCA allow private individuals to bring actions under the FCA on behalf of the government. These private parties are entitled to share in any amounts recovered by the government, and, as a result, the number of “whistleblower” lawsuits that have been filed against providers has increased significantly in recent years. Defendants found to be liable under the FCA may be required to pay three times the actual damages sustained by the government, plus civil penalties ranging between \$5,500 and \$11,000 for each separate false claim.

There are many potential bases for liability under the FCA. The government has used the FCA to prosecute Medicare and other government healthcare program fraud such as coding errors, billing for services not provided, and providing care that is not medically necessary or that is substandard in quality. The PPACA also provides that claims submitted in connection with patient referrals that result from violations of the Anti-Kickback Statute constitute false claims for the purpose of the FCA, and some courts have held that a violation of the Stark law can result in FCA liability, as well. In addition, a number of states have adopted their own false claims and whistleblower provisions whereby a private party may file a civil lawsuit in state court. We are required to provide information to our employees and certain contractors about state and federal false claims laws and whistleblower provisions and protections.

Civil Monetary Penalties Law

The Civil Monetary Penalties Law prohibits, among other things, the offering or giving of remuneration to a Medicare or Medicaid beneficiary that the person or entity knows or should know is likely to influence the beneficiary’s selection of a particular provider or supplier of items or services reimbursable by a federal or state healthcare program. This broad provision applies to many kinds of inducements or benefits provided to patients, including complimentary items, services or transportation that are of more than a nominal value. This law could affect how we have to structure our operations and activities.

Intellectual Property Risks Related to Our Business