Precipio, Inc.
Form 10-Q
August 22, 2017
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)
x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended June 30, 2017
OR
o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____
Commission File Number: 001-36439

PRECIPIO, INC.
(Exact name of registrant as specified in its charter)

Delaware	91-1789357
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
4 Science Park, New Haven, CT	06511
(Address of principal executive offices)	(Zip Code)

(203) 787-7888
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No o
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	o	Accelerated filer	o
Non-accelerated filer	o (Do not check if a smaller reporting company)	Smaller reporting company	x
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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No x

As of August 16, 2017, the number of shares of common stock outstanding was 6,407,860.

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PART I. FINANCIAL INFORMATION
Item 1. Condensed Consolidated Financial Statements
PRECIPIO, INC. AND SUBSIDIARY
CONDENSED CONSOLIDATED BALANCE SHEETS
(Dollars in thousands, except share data)

	June 30, 2017 (unaudited)	December 31, 2016
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 967	$ 51
Accounts receivable, net	569	388
Inventories	108	100
Other current assets	154	13
Total current assets	1,798	552
PROPERTY AND EQUIPMENT, NET	262	280
OTHER ASSETS:		
Goodwill	13,832	—
Intangibles, net	21,100	—
Other assets	18	10
	$ 37,010	$ 842
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES:		
Current maturities of long-term debt	$ 513	$ 395
Convertible bridge notes, less debt discounts and debt issuance costs	166	695
Accounts payable	10,328	1,084
Current maturities of capital leases	48	46
Accrued expenses	3,521	700
Deferred revenue	210	92
Other current liabilities	1,528	—
Total current liabilities	16,314	3,012
LONG TERM LIABILITIES:		
Long-term debt, less current maturities and discounts	—	4,127
Common stock warrant liability	618	—
Capital leases, less current maturities	138	163
Other long-term liabilities	171	—
Total liabilities	17,241	7,302
STOCKHOLDERS' EQUITY (DEFICIT):		
Preferred stock - $0.01 par value, 15,000,000 and 1,294,434 shares authorized at June 30, 2017 and December 31, 2016, respectively, 1,712,901 and 780,105 shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively	17	8
Common stock, $0.01 par value, 150,000,000 and 1,806,850 shares authorized at June 30, 2017 and December 31, 2016, respectively, 6,407,860 and 449,175 shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively	64	4
Additional paid-in capital	34,975	4,376
Accumulated deficit	(15,287)	(10,848)
Total stockholders' equity (deficit)	19,769	(6,460)

$ 37,010	$ 842

See notes to unaudited condensed consolidated financial statements.

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PRECIPIO, INC. AND SUBSIDIARY
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Dollars in thousands, except per share data)

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2017	2016	2017	2016
SALES				
Patient service revenue, net	$316	$615	$619	$1,271
less provision for bad debts	(56)	(111)	(111)	(229)
Net sales	260	504	508	1,042
COST OF DIAGNOSTIC SERVICES	284	241	466	479
Gross profit (loss)	(24)	263	42	563
OPERATING EXPENSES	777	548	1,440	1,076
OPERATING LOSS	(801)	(285)	(1,398)	(513)
OTHER INCOME (EXPENSE):				
Interest expense, net	(220)	(160)	(382)	(242)
Warrant revaluation	(3)	1	(3)	—
Loss on extinguishment of debt	(53)	—	(53)	—
Merger advisory fees	(2,603)	—	(2,603)	—
Other, net	—	—	—	3
	(2,879)	(159)	(3,041)	(239)
LOSS BEFORE INCOME TAXES	(3,680)	(444)	(4,439)	(752)
INCOME TAX EXPENSE	—	—	—	—
NET LOSS	(3,680)	(444)	(4,439)	(752)
DEEMED DIVIDENDS ON ISSUANCE OR EXCHANGE OF PREFERRED UNITS	(5,248)	—	(5,248)	(1,422)
PREFERRED DIVIDENDS	—	—	—	(433)
TOTAL DIVIDENDS	(5,248)	—	(5,248)	(1,855)
NET LOSS AVAILABLE TO COMMON STOCKHOLDERS	$(8,928)	$(444)	$(9,687)	$(2,607)
BASIC AND DILUTED LOSS PER COMMON SHARE	$(15.35)	$(1.03)	$(18.77)	$(6.10)
BASIC AND DILUTED WEIGHTED-AVERAGE SHARES OF COMMON STOCK OUTSTANDING	581,481	429,819	515,968	427,217

See notes to unaudited condensed consolidated financial statements.

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PRECIPIO, INC. AND SUBSIDIARY
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
Six Months Ended
June 30, 2017
(Dollars in thousands)

	Preferred Stock		Common Stock				
	Outstanding Shares	Par Value	Outstanding Shares	Par Value	Additional Paid-in Capital	Accumulated Deficit	Total
Balance, January 1, 2017	780,105	$ 8	449,175	$ 4	$ 4,376	$ (10,848)	$ (6,460)
Net loss	—	—	—	—	—	(4,439)	(4,439)
Conversion of warrants into preferred stock	8,542	—	—	—	25	—	25
Conversion of warrants into common stock	—	—	1,958,166	20	(20)	—	—
Conversion of preferred stock into common stock	(788,647)	(8)	788,647	8	—	—	—
Conversion of Senior and Junior debt into preferred stock and common stock	802,920	8	1,414,700	14	4,749	—	4,771
Conversion of bridge notes into common stock	—	—	155,639	2	885	—	887
Issuance of common stock for consulting services in connection with the merger	—	—	321,821	3	2,186	—	2,189
Shares issued in connection with business combination	802,925	8	1,255,119	12	20,078	—	20,098
Issuance of preferred stock	107,056	1	—	—	399	—	400
Issuance of warrants in conjunction with issuance of side agreement	—	—	—	—	414	—	414
Beneficial conversion feature on issuance of bridge notes	—	—	—	—	1,856	—	1,856
Non-cash stock-based compensation and vesting of restricted units			64,593	1	27	—	28
Balance, June 30, 2017	1,712,901	$ 17	6,407,860	$ 64	$ 34,975	$ (15,287)	$ 19,769

See notes to unaudited condensed consolidated financial statements.

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PRECIPIO, INC. AND SUBSIDIARY
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Dollars in thousands)

	Six Months Ended June 30,	
	2017	2016
CASH FLOWS USED IN OPERATING ACTIVITIES:		
Net loss	$(4,439)	$(752)
Adjustments to reconcile net loss to net cash flows used in operating activities:		
Depreciation and amortization	48	55
Amortization of deferred financing costs and debt discount	57	18
Loss on extinguishment of debt	53	—
Stock-based compensation and change in liability of stock appreciation rights	23	7
Merger advisory fees	2,603	—
Provision for losses on doubtful accounts	111	229
Capitalized PIK interest on convertible bridge notes	—	81
Warrant revaluation	3	—
Changes in operating assets and liabilities:		
Accounts receivable	(136)	(340)
Inventories	7	(18)
Other assets	(1)	1
Accounts payable	290	91
Accrued expenses and other liabilities	484	238
Net cash used in operating activities	(897)	(390)
CASH FLOWS PROVIDED BY INVESTING ACTIVITIES:		
Cash acquired in business combination	101	—
Net cash provided by investing activities	101	—
CASH FLOWS PROVIDED BY FINANCING ACTIVITIES:		
Principal payments on capital lease obligations	(23)	(19)
Issuance of preferred stock	400	—
Payment of deferred financing costs	(25)	(10)
Proceeds from exercise of warrants	25	—
Proceeds from long-term debt	315	—
Proceeds from convertible bridge notes	1,365	455
Principal payments on long-term	(345)	(74)
Net cash flows provided by financing activities	1,712	352
NET CHANGE IN CASH AND CASH EQUIVALENTS	916	(38)
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	51	235
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$967	$197
SUPPLEMENTAL CASH FLOW INFORMATION		
Cash paid during the period for interest	$30	$18
SUPPLEMENTAL DISCLOSURE OF NON-CASH INFORMATION		
Purchases of equipment financed through capital lease	—	49
Preferred unit dividend financed through exchange agreement	—	433
Convertible bridge notes exchanged for long-term debt	—	1,120
Series A and B preferred exchanged for long-term debt	—	1,715
Conversion of bridges loans plus interest into common stock	877	—

Conversion of senior and junior notes plus interest into preferred stock and common stock	4,771	—
Deferred debt issuance cost	64	—
Beneficial conversion feature on issuance of bridge notes	1,856	—
Accrued merger cost	10	—
Issuance of warrants in conjunction with issuance of side agreement	414	—

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See notes to unaudited condensed consolidated financial statements.

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PRECIPIO, INC. AND SUBSIDIARY
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
Three and Six Months Ended June 30, 2017 and 2016

1. BUSINESS DESCRIPTION
Business Description

Precipio, Inc., and Subsidiary, ("we", "us", "our", the "Company" or "Precipio") is 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 ("ICP"), the patented technology which was exclusively licensed by us from Dana-Farber Cancer Institute, Inc. ("Dana-Farber") at Harvard University ("Harvard"). 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 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.

Merger Transaction

On June 29, 2017, the Company (then known as "Transgenomic, Inc.", or "Transgenomic"), completed a reverse merger (the "Merger") with Precipio Diagnostics, LLC, a privately held Delaware limited liability company ("Precipio Diagnostics") in accordance with the terms of the Agreement and Plan of Merger (the "Merger Agreement"), dated October 12, 2016, as amended on February 2, 2017 and June 29, 2017, by and among Transgenomic, Precipio Diagnostics and New Haven Labs Inc. ("Merger Sub") a wholly-owned subsidiary of Transgenomic. Pursuant to the Merger Agreement, Merger Sub merged with and into Precipio Diagnostics, with Precipio Diagnostics surviving the Merger as a wholly-owned subsidiary of the combined company (See Note 3 - Reverse Merger). In connection with the Merger, the Company changed its name from Transgenomic, Inc. to Precipio, Inc., relisted its common stock under Precipio, Inc. on the National Association of Securities Dealers Automated Quotations ("NASDAQ"), and effected a 1-for-30 reverse stock split of its common stock. Upon the consummation of the Merger, the historical financial statements of Precipio Diagnostics become the Company's historical financial statements. Accordingly, the historical financial statements of Precipio Diagnostics are included in the comparative prior periods. As a result of the Merger, historical preferred stock, common stock, restricted units, warrants and additional paid-in capital, including share and per share amounts, have been retroactively adjusted to reflect the equity structure of the combined company, including the effect of the Merger exchange ratio. Pursuant to the Merger Agreement, each outstanding share of capital stock of Precipio Diagnostic was exchanged for 10.2502 pre-reverse stock split shares of Company Common Stock (the "Exchange Ratio"). See Note 3 - Reverse Merger for additional discussion of the Merger.

Going Concern

The condensed consolidated financial statements have been prepared using accounting principles generally accepted in the United States of America ("GAAP") applicable for a going concern, which assume that the Company will realize its assets and discharge its liabilities in the ordinary course of business. The Company has incurred substantial operating losses and has used cash in its operating activities for the past several years. As of June 30, 2017, the Company had a net loss of $4.4 million and negative working capital of $14.5 million. The Company's ability to continue as a going concern is dependent upon a combination of achieving its business plan, including generating additional revenue, and raising additional financing to meet its debt obligations and paying liabilities arising from normal business operations when they come due.

Precipio is currently in discussions with certain investors to raise additional capital. There can be no assurance such capital is or will be available at terms favorable or agreeable to management, if at all, or that the Company will successfully complete the proposed capital raise. Since the outcome of these matters cannot be predicted with any certainty at this time, there is substantial doubt that the Company will be able to continue as a going concern.

Notwithstanding the aforementioned circumstances, there remains substantial doubt about the Company's ability to continue as a going concern. There can be no assurance that the Company will be able to successfully achieve its initiatives summarized above in order to continue as a going concern. The accompanying financial statements have been prepared assuming the Company will continue as a going concern and do not include any adjustments that might result should the Company be unable to continue as a going concern as a result of the outcome of this uncertainty.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation.

The accompanying condensed consolidated financial statements are presented in conformity with GAAP. We have evaluated events occurring subsequent to June 30, 2017 for potential recognition or disclosure in the condensed consolidated financial statements and concluded that, other than what is disclosed in Note 12 - Subsequent Events, there were no other subsequent events that required recognition or disclosure.

The condensed consolidated balance sheet as of December 31, 2016 was derived from our audited balance sheet as of that date. There has been no change in the balance sheet from December 31, 2016. The accompanying condensed consolidated financial statements as of and for the three and six months ended June 30, 2017 and 2016 are unaudited and reflect all adjustments (consisting of only normal recurring adjustments) that are, in the opinion of management, necessary for a fair presentation of the financial position and operating results for the interim periods. These unaudited condensed consolidated financial statements and notes should be read in conjunction with the audited financial statements and notes thereto of Precipio Diagnostics for the year ended December 31, 2016 contained in our current report on Form 8-K/A, filed with the Securities and Exchange Commission (the "SEC") on July 31, 2017. The results of operations for the interim periods presented are not necessarily indicative of the results for fiscal year 2017.

Principles of Consolidation.

The condensed consolidated financial statements include the accounts of Precipio, Inc. and our wholly owned subsidiary. All inter-company balances and transactions have been eliminated in consolidation.

Use of Estimates.

The preparation of condensed consolidated financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of net sales and expenses during the reporting period. In addition, estimates and assumptions associated with the determination of the fair value of certain assets and related impairments require considerable judgment by management. Actual results could differ from the estimates and assumptions used in preparing these condensed consolidated financial statements.

Risks and Uncertainties.

Certain risks and uncertainties are inherent in our day-to-day operations and in the process of preparing our financial statements. The more significant of those risks are presented below and throughout the notes to the unaudited condensed consolidated financial statements.

The Company operates in the healthcare industry which is subject to numerous laws and regulations of federal, state and local governments. These laws and regulations include, but are not necessarily limited to, matters such as licensure, accreditation, government healthcare program participation requirements, reimbursement for patient services, and Medicare and Medicaid fraud and abuse. Government activity has increased with respect to investigations and allegations concerning possible violations of fraud and abuse statutes and regulations by healthcare providers. Violations of these laws and regulations could result in expulsion from government healthcare programs together with the imposition of significant fines and penalties, as well as significant repayments for patient services previously billed. Management believes that the Company is in compliance with fraud and abuse regulations, as well

as other applicable government laws and regulations. While no material regulatory inquiries have been made, compliance with such laws and regulations can be subject to future government review and interpretation as well as regulatory actions unknown or unasserted at this time.

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PRECIPIO, INC. AND SUBSIDIARY
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)
Three and Six Months Ended June 30, 2017 and 2016

Fair Value.
Unless otherwise specified, book value approximates fair value. The common stock warrant liability is recorded at fair value. See Note 10 - Fair Value for additional information.
Cash and Cash Equivalents and Other Current Assets.
Cash and cash equivalents include cash and investments with original maturities at the date of acquisition of three months or less. Other current assets as of June 30, 2017 of $0.2 million includes prepaid assets of $0.1 million and other receivables of $0.1 million and consisted of primarily prepaid assets as of December 31, 2016.
Concentrations of Risk.
From time to time, we may maintain a cash position with financial institutions in amounts that exceed Federal Deposit Insurance Corporation insured limits. We have not experienced any losses on such accounts as of June 30, 2017.
Service companies in the health care industry typically grant credit without collateral to patients. The majority of these patients are insured under third-party insurance agreements. The services provided by the Company are routinely billed utilizing the Current Procedural Terminology (CPT) code set designed to communicate uniform information about medical services and procedures among physicians, coders, patients, accreditation organizations, and payers for administrative, financial, and analytical purposes. CPT codes are currently identified by the Centers for Medicare and Medicaid Services and third-party payors. The Company utilizes CPT codes for Pathology and Laboratory Services contained within codes 80000-89398.

Property and Equipment.
Depreciation expense related to property and equipment was less than $0.1 million for the six months ended June 30, 2017 and 2016. Depreciation expense during each period includes depreciation related to equipment acquired under capital leases.
Goodwill and Intangible Assets.
As a result of the Merger, the Company recorded goodwill and intangible assets as part of its allocation of the purchase consideration. See Note 3 - Reverse Merger for the amounts recorded.

Goodwill

Goodwill is tested for impairment annually. We perform this impairment analysis during the fourth quarter of each year or when a significant event occurs that may impact goodwill. Impairment occurs when the carrying value is determined to be not recoverable, thereby causing the carrying value of the goodwill to exceed its fair value. If impaired, the asset’s carrying value is reduced to its fair value. No events have transpired in the six months ended June 30, 2017 that would require an impairment analysis prior to our scheduled review.

Intangibles

We review our amortizable long-lived assets for impairment annually or whenever events indicate that the carrying amount of the asset (group) may not be recoverable. An impairment loss may be needed if the sum of the future undiscounted cash flows is less than the carrying amount of the asset (group). The amount of the loss would be determined by comparing the fair market value of the asset to the carrying amount of the asset (group). There were no impairment charges during the six months ended June 30, 2017.
In-process research and development (“IPR&D”) represents the fair value assigned to research and development assets that were not fully developed at the date of the Merger. Until the IPR&D projects are completed, the assets are accounted for as indefinite-lived intangible assets and subject to impairment testing. For the six months ended June 30, 2017, there was no impairment of IPR&D.

Stock-Based Compensation.

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PRECIPIO, INC. AND SUBSIDIARY
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)
Three and Six Months Ended June 30, 2017 and 2016

All stock-based awards to date have exercise prices equal to the market price of our common stock on the date of grant and have ten-year contractual terms. Unvested awards as of June 30, 2017 had vesting periods of up to three years from the date of grant. None of the awards outstanding at June 30, 2017 are subject to performance or market-based vesting conditions.

During the six months ended both June 30, 2017 and 2016, we recorded compensation expense for all stock awards of less than $0.1 million within operating expense. As of June 30, 2017, the unrecognized compensation expense related to unvested stock awards was less than $0.1 million, which is expected to be recognized over a weighted-average period of one year.

Included in our stock awards outstanding as of June 30, 2017 were fully vested stock appreciation rights (“SARs”) to purchase 2,777 shares of our common stock. The SARs were issued solely to a former executive officer and vested over three years from the date of grant.

Net Sales Recognition.

Revenue is realized and earned when all of the following criteria are met:

- Persuasive evidence of an arrangement exists;
- Delivery has occurred or services have been rendered;
- The seller’s price to the buyer is fixed or determinable; and
- Collectability is reasonably assured.

In our New Haven, Connecticut laboratory, we primarily recognize revenue for services rendered upon completion of the testing process. Net patient service revenue is reported at the estimated net realizable amounts from patients, third-party payors and others for services rendered, including retroactive adjustment under reimbursement agreements with third-party payors. Revenue under third-party payor agreements is subject to audit and retroactive adjustment. Provisions for third-party payor settlements are provided in the period in which the related services are rendered and adjusted in the future periods, as final settlements are determined.

In our Omaha, Nebraska laboratory, we perform services on a project by project basis. When we receive payment in advance, we initially defer the revenue and recognize it when we deliver the service. These projects typically do not extend beyond one year.

At each of June 30, 2017 and December 31, 2016, deferred net sales included in the balance sheet in deferred revenue were $0.2 million and $0.1 million, respectively.

Taxes collected from customers and remitted to government agencies for specific net sales producing transactions are recorded net with no effect on the income statement.

Presentation of Insurance Claims and Related Insurance Recoveries.

The Company accounts for its insurance claims and related insurance recoveries at their gross values as standards for health care entities do not allow the Company to net insurance recoveries against the related claim liabilities. There were no insurance claims or insurance recoveries recorded during the three and six months ended June 30, 2017 and 2016.

Income Taxes.

Deferred tax assets and liabilities are determined based on the differences between the financial reporting and tax basis of assets and liabilities at each balance sheet date using tax rates expected to be in effect in the year the differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance to the extent that it is

more likely than not that they will not be realized.

Beneficial Conversion Features.

The intrinsic value of a beneficial conversion feature ("BCF") inherent to a convertible note payable, which is not bifurcated and accounted for separately from the convertible note payable and may not be settled in cash upon conversion, is treated as a discount to the convertible note payable. This discount is amortized over the period from the date of issuance to the first conversion date using the effective interest method. If the note payable is retired prior to the end of its contractual term, the unamortized discount is expensed in the period of retirement to interest expense. In general, the BCF is measured by comparing the effective

conversion price, after considering the relative fair value of detachable instruments included in the financing transaction, if any, to the fair value of the common shares at the commitment date to be received upon conversion.

Deemed dividends are also recorded for the intrinsic value of conversion options embedded in preferred shares based upon the differences between the fair value of the underlying common stock at the commitment date of the transaction and the effective conversion price embedded in the preferred shares. When the preferred shares are non-redeemable the BCF is fully amortized into additional paid-in capital and preferred discount. If the preferred shares are redeemable, the discount is amortized from the commitment date to the first conversion date.

Loss Per Share.

Basic loss per share is calculated based on the weighted-average number of common shares outstanding during each period. Diluted loss per share includes shares issuable upon exercise of outstanding stock options, warrants or conversion rights that have exercise or conversion prices below the market value of our common stock. Options, warrants and conversion rights pertaining to 2,545,463 and 2,771,149 shares of our common stock have been excluded from the computation of diluted loss per share at June 30, 2017 and 2016, respectively, because the effect is anti-dilutive due to the net loss.

Recent Accounting Pronouncements.

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2014-09, Revenue from Contracts with Customers. This guidance requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to a customer. ASU No. 2014-09 will replace most existing revenue recognition guidance in generally accepted accounting principles in the U.S. when it becomes effective. In July 2015, the FASB decided to defer the effective date of this new accounting guidance by one year. As a result, ASU No. 2014-09 will be effective for us for all annual and interim reporting periods beginning after December 15, 2017 and early adoption would be permitted as of the original effective date. The new standard permits the use of either the retrospective or cumulative effect transition method. We do not expect to early adopt this guidance and we have not selected a transition method. We are currently evaluating the impact this guidance will have on our financial condition, results of operations and cash flows.

In February 2016, the FASB issued ASU No. 2016-02, Leases. The new standard amends the recognition of lease assets and lease liabilities by lessees for those leases currently classified as operating leases and amends disclosure requirements associated with leasing arrangements. The new standard is effective for fiscal years and interim periods within those fiscal years beginning after December 15, 2018. Early adoption is permitted. The new standard must be adopted using a modified retrospective transition, and provides for certain practical expedients. Transition will require application of the new guidance at the beginning of the earliest comparative period presented. We are currently assessing the impact that the adoption of this ASU will have on our consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-09, Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting. The new standard simplifies several aspects related to the accounting for share-based payment transactions, including the accounting for income taxes, statutory tax withholding requirements, forfeitures and classification on the statement of cash flows. This guidance is effective for fiscal years and interim periods within those fiscal years beginning after December 15, 2016. The Company adopted ASU No. 2016-09 as of January 1, 2017. The adoption of this guidance does not have a material effect on the Company’s financial position and results of operations.

In August 2016, FASB issued ASU No. 2016-15, Classification of Certain Cash Receipts and Cash Payments. ASU No. 2016-15 eliminates the diversity in practice related to the classification of certain cash receipts and payments in the statement of cash flows by adding or clarifying guidance on eight specific cash flow issues. ASU No. 2016-15 is

effective for fiscal years beginning after December 15, 2017, and for interim periods within that fiscal year. We do not believe ASU No. 2016-15 will have a material effect on our financial position and results of operations.

In January 2017, FASB issued ASU No. 2017-01, Business Combinations (Topic 805): Clarifying the Definition of a Business. ASU No. 2017-01 adds guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. The new guidance is effective for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. The Company does not believe ASU No. 2017-01 will have a material effect on its financial position and results of operations.

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In January 2017, FASB issued ASU No. 2017-04, Intangibles — Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment, which removes Step 2 from the goodwill impairment test. It is effective for annual and interim periods beginning after December 15, 2019. Early adoption is permitted for interim or annual goodwill impairment test performed with a measurement date after January 1, 2017. The Company has adopted this standard and there was no impact on its consolidated financial statements because a goodwill impairment has not occurred after January 1, 2017.

In July 2017, FASB issued ASU No. 2017-11, Earning Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480) and Derivatives and Hedging (Topic 815), which was issued in two parts, Part I, Accounting for Certain Financial Instruments with Down Round Features and Part II, Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception. Part I of ASC No. 2017-11 addresses the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features. When determining whether certain financial instruments should be classified as liabilities or equity instruments, a down round feature no longer precludes equity classification when assessing whether the instrument is indexed to an entity’s own stock. The amendments also clarify existing disclosure requirements for equity-classified instruments. As a result, a freestanding equity-linked financial instrument (or embedded conversion option) no longer would be accounted for as a derivative liability at fair value as a result of the existence of a down round feature. For freestanding equity classified financial instruments, the amendments require entities that present earnings per share (EPS) in accordance with Topic 260 to recognize the effect of the down round feature when it is triggered. That effect is treated as a dividend and as a reduction of income available to common shareholders in basic EPS. The amendments in Part II of ASU 2017-11 recharacterize the indefinite deferral of certain provisions of Topic 480 that now are presented as pending content in the codification, to a scope exception. Part II amendments do not have an accounting effect. The ASU 2017-11 is effective for annual and interim periods beginning after December 15, 2018, with early adoption permitted. The Company has early adopted this standard as of January 1, 2017 with the only impact being that the warrants with down round provisions entered into in June 2017 were treated as equity classification. (See Note 5 - Convertible Bridge Notes).

3. REVERSE MERGER

On June 29, 2017 (the “Closing Date”), the Company completed the Merger with Precipio Diagnostics, in accordance with the terms of the Merger Agreement. Upon the consummation of the Merger, the historical financial statements of Precipio Diagnostics become the Company's historical financial statements. Accordingly, the historical financial statements of Precipio Diagnostics are included in the comparative prior periods.
On the Closing Date, the outstanding common and preferred units of Precipio Diagnostics and certain debt of Precipio Diagnostics were converted into (i) 5,352,847 shares of Precipio common stock, together with cash in lieu of fractional units, and (ii) 802,920 shares of Precipio preferred stock with an aggregate face amount equal to $3 million.
In connection with the Merger, on the Closing Date, Precipio also issued promissory notes and shares of Precipio preferred and common stock in a number of transactions, whereby:

- Holders of certain secured indebtedness of Transgenomic received in exchange for such indebtedness 802,925 shares of Precipio preferred stock in an amount equal to $3.0 million stated value, and 352,630 shares of Precipio common stock;

- Holders of Transgenomic preferred stock converted it into 7,155 shares of Precipio common stock; and

- Precipio issued 107,056 shares of Precipio preferred stock to certain investors in exchange for $400,000 in a private placement. Precipio also completed the sale of an aggregate of $800,000 of promissory notes pursuant to a securities purchase agreement.

Purchase Consideration
The preliminary estimated purchase consideration based on the value of the equity of Transgenomic, the accounting acquiree, is as follows:

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(dollars in thousands)	
Legacy Transgenomic common stock	$6,088
Fair value of preferred stock converted to common stock	49
Fair value of debt converted to common stock	2,398
Fair value of debt converted to preferred stock	9,796
Fair value of existing bridge notes	1,275
Fair value of warrants	1,996
Purchase consideration	$21,602

In estimating the preliminary purchase consideration above, Transgenomic used its closing stock price of $6.80 as of the Closing Date. Transgenomic had 895,334 common shares outstanding prior to the Merger. In connection with the Merger, Transgenomic preferred stock converted into 7,155 shares of Precipio common stock and certain of Transgenomic debt and accrued interest converted into 352,630 shares of Precipio common stock and 802,925 shares of Precipio preferred stock, face value $3.0 million with an 8% annual dividend. At the Closing Date, the preferred stock had a fair value of $12.20 per share.

Allocation of Purchase Consideration

The following table sets forth an allocation of the purchase consideration to the identifiable tangible and intangible assets of Transgenomic, the accounting acquiree, based on fair values as of the Closing Date with the excess recorded as goodwill:

(dollars in thousands)	
Current and other assets	$419
Property and equipment	29
Goodwill	13,832
Other intangible assets[(1)]	21,100
Total assets	35,380
Current liabilities	13,604
Other liabilities	174
Total liabilities	13,778
Net assets acquired	$21,602

(1) Other intangible assets consist of:

(dollars in thousands)	
Acquired technology	$18,990
Customer relationships	250
Non-compete agreements	30
Trademark and trade name	40
Backlog	200
In-process research and development	1,590
Total intangibles	$21,100

We determined the estimated fair value of the acquired technology but using the multi-period excess earnings method of the income approach. The estimated fair value of the remaining identifiable intangible assets acquired were

determined primarily by using the income approach.

Unaudited pro forma information

The operating results of Transgenomic for the period after the Closing Date to June 30, 2017 have been included in the Company's condensed consolidated financial statements as of and for the three and six months ended June 30, 2017.

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The following unaudited pro forma information presents the Company's financial results as if the acquisition of Transgenomic had occurred on January 1, 2016:

Dollars in thousands, except per share amounts

	Six months ended June 30,	
	2017	2016
Net sales	$1,472	$1,783
Net loss available to common stockholders	(13,864)	(13,266)
Loss per common share	$(2.16)	$(2.07)

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4. LONG-TERM DEBT

Long-term debt consists of the following:

	Dollars in Thousands	
	June 30, 2017	December 31, 2016
Senior Notes	$ —	$ 3,270
Senior Note debt issuance costs	—	(9)
Junior Notes	—	584
Connecticut Innovations - line of credit	162	162
Department of Economic and Community Development (DECD)	226	243
DECD debt issuance costs	—	(30)
Webster Bank	—	328
Webster Bank debt discounts and issuance costs	—	(26)
Convertible promissory notes	125	—
Total long-term debt	513	4,522
Current portion of long-term debt	(513)	(395)
Long-term debt, net of current maturities	$ —	$ 4,127

Senior and Junior Notes

During 2016, the Company raised $525,000 from members through the issuance of senior notes which accrue interest at a rate of 12% and are payable at the sooner of the closing of a qualified public offering, as outlined in the note agreement, or five years from date of issuance.

Also during 2016, the Company restructured equity through a redemption and exchange agreement by exchanging Member Equity comprised of Series A and Series B Convertible Preferred Units in the amount of $2,147,716 (members' initial investment of $1,715,000, plus declared dividends on these preferred units of $432,716), and Convertible Bridge Notes of $1,120,000, plus accrued interest of $61,073 for new senior notes of $2,744,968 ("Senior Notes") and new junior notes of $583,821 ("Junior Notes"). The Senior and Junior Notes accrue interest at a rate of 12% and 15%, respectively, and have maturity dates ranging from March 2021 to September 2021, or earlier based on certain qualifying events as outlined in the note agreements.

During the six months ended June 30, 2017, the Company raised $315,000 from members through the issuance of Senior Notes at a rate of 12% interest that are payable at the sooner of the closing of a qualified public offering, as outlined in the note agreement, or five years from date of issuance.

On the Closing Date of the Merger, the outstanding balance of $3,584,968 in Senior Notes and $583,821 in Junior Notes, plus accrued interest of $602,373, were converted into 802,920 shares of Precipio preferred stock and 1,414,700 shares of Precipio common stock. There were no Senior or Junior Notes outstanding as June 30, 2017.

As of December 31, 2016, the outstanding balance of Senior and Junior Notes was $3,269,968 and $583,821, respectively, with accrued interest included within the accrued expenses on the accompanying condensed consolidated balance sheet of $279,740 and $71,258, respectively.

Connecticut Innovations, Incorporated

The Company entered into a line of credit on April 1, 2012 with Connecticut Innovations, Incorporated (Connecticut Innovations), an entity affiliated with a director of the Company, for up to $500,000 with interest paid monthly at 8%, due on September 1, 2018. Principal and interest payments began February 1, 2013 and ranged from $7,436 to $12,206 until September 2016, when the Company entered into a forbearance agreement to 1) defer monthly principal payments until October 2017 and 2) make interest-only payments totaling $1,041 per month through October 2017. Pursuant to the forbearance agreement, the

Company was also restricted from any additional borrowings under the line of credit. The line was secured by substantially all of the Company's assets.

In connection with the Merger, the Company was to pay in full its loan obligations with Connecticut Innovations. The outstanding balance was $162,066 at both June 30, 2017 and December 31, 2016. The outstanding principal and accrued interest balance was paid in full in July 2017.

Department of Economic and Community Development.

The Company entered into a 10-year term loan with the Department of Economic and Community Development ("DECD") on May 1, 2013 for $300,000, with interest paid monthly at 3%, due on April 23, 2023. The loan was secured by substantially all of the Company's assets but was subordinate to the term loan with Webster Bank and the Connecticut Innovations line of credit. In connection with the Merger, the Company was to pay in full its loan obligations with DECD. The outstanding balance was $225,714 and $243,287 as of June 30, 2017 and December 31, 2016, respectively. The outstanding principal and accrued interest balance was paid in full in July 2017.

Webster Bank.

The Company entered into a 3.5-year term loan with Webster Bank on December 1, 2014 for $500,000, with interest paid monthly at the one month LIBOR rate (1.16% at June 30, 2017) plus 500 basis points, due on May 31, 2018. The line was secured by substantially all of the Company's assets and had first priority over all other outstanding debt.

The term loan with Webster Bank was subject to financial covenants relating to maintaining adequate cash runway, as defined in the term loan agreement. As of December 31, 2016 the Company was not in compliance with these covenants and, as such, the Webster Bank debt has all been presented as current in the accompanying condensed consolidated financial statements.

On June 29, 2017, the closing date of the Merger, the Company paid in full its loan obligations (including principal and interest) with Webster Bank. The outstanding balance was zero and $328,000 as of June 30, 2017 and December 31, 2016, respectively.

During the three and six months ended June 30, 2017, the Company incurred a loss on extinguishment of debt in the approximate amount of $53,000, related to the extinguishment of the Connecticut Innovations, DECD and Webster Bank loans.

Convertible Promissory Notes.

The Company, as part of the merger, assumed an Unsecured Convertible Promissory Note (the "Note") with an accredited investor (the "Investor") in the aggregate principal amount of $125,000 and interest accrues at a rate of 6% per year. The Note provided that two-thirds of the outstanding principal amount of the Note was due upon the earlier to occur of the close of the Merger or June 17, 2017 (such applicable date, the "Maturity Date"). The remaining one-third of the principal amount outstanding on the Note was to be paid on the six month anniversary of the Maturity Date.

On the Maturity Date, the then outstanding aggregate amount owed on the Note of $143,041 ($125,000 in principal amount and $18,041 of accrued interest which is included within accrued expenses on the accompanying consolidated condensed balance sheet) became due. Pursuant to the terms of the Note, the Company's failure to pay any principal or interest within 10 days of the date such payment is due will constitute an event of default (the "Prospective Event of Default"). On June 21, 2017, the Investor agreed to waive the Prospective Event of Default and agreed to further extend the Maturity Date of the Note pursuant to a side letter to the Note (the "Side Letter"). The Side Letter provides that two-thirds of the outstanding principal amount of the Note must be paid upon the earlier to occur of (1) the closing of a public offering by the Company of either common stock, convertible preferred stock or convertible preferred notes or (2) August 16, 2017 (such applicable date, the "Deferred Maturity Date"). As of August 21, 2017, the Company has not made any payment related to amounts that were due on August 16, 2017. Pursuant to the terms of the Notes, the Company's failure to pay any principal or interest within 10 days of the date such payment is due will constitute an event of default. The Company is attempting to negotiate a resolution with the Investor so that the Company will not default on such payment; however, there is no guarantee that the Company will be able to work out a satisfactory resolution. The remaining one-third of the principal amount outstanding on the Note must be paid on the six month anniversary of the Deferred Maturity Date (the "Extended Maturity Date"). All accrued and unpaid interest on the outstanding principal amount of the Note will be due and immediately payable on the Extended Maturity Date, unless the Note is converted in which case such interest will be payable in shares of the Company's common stock as part of the conversion.

5. CONVERTIBLE BRIDGE NOTES.

Convertible Bridge Notes.

During the year ended December 31, 2016, the Company had outstanding $695,000 of unsecured convertible bridge notes. The notes accrued interest at a rate of 14% and were payable on the extended maturity date of December 31, 2016. During January 2017, the holders of the convertible bridge notes agreed to waive the maturity date of December 31, 2016 and change it to payable on demand and accrue interest until paid.

The convertible bridge notes had conversion terms of (i) convertible into Series C Preferred Units of the Company (at a 30% discount) upon a Qualified Series C Financing (as defined in the note agreement), (ii) at the option of the holders of a majority of the then-outstanding principal amount of the notes, convertible into Series C Preferred Units of the Company (at a 30% discount) upon any other Series C Financing, or (iii) if no such Qualified Series C Financing occurs, or no such optional conversion takes place by the maturity date (as hereinafter defined), the convertible notes will be fully repaid by Company or the notes and accrued and unpaid interest shall convert into Preferred Series B Units (at a 30% discount) of the Preferred Series B conversion Price as defined in the operating agreement provided that notice is given to the Company at least one day prior to maturity. In the event a Deemed Liquidity Event (merger, sale, IPO, or transaction with exchange of 50% or more of voting power) the holders of the notes at their sole discretion can (a) require the Company to pay an amount equal to two times the principal and accrued and unpaid interest or (b) convert all unpaid principal and interest at a rate of 70% of the applicable security. These notes were subordinated to Connecticut Innovations, DECD and Webster Bank.

In connection with the Merger, on the Closing Date, convertible bridge notes of $695,000, plus $192,000 of accrued interest, were converted into 155,639 shares of Precipio common stock.

2017 New Bridge Notes I.

Prior to the Merger, the Company (then Transgenomic) completed the sale of an aggregate of $1.2 million of non-convertible promissory notes (the “2017 Bridge Notes”) in a bridge financing pursuant to a securities purchase agreement (the “Purchase Agreement”), for which $561,500 was then given to Precipio Diagnostics through the issuance of a promissory note and is eliminated in consolidation. The financing was intended to help facilitate the completion of the Merger. The 2017 Bridge Notes had an annual interest rate of 4% and a 90-day maturity. The 2017 Bridge Notes may be repaid by the Company at any time in cash upon payment of a 20% premium. In connection with the issuance of the 2017 Bridge Notes, the Company issued warrants (the “2017 Bridge Warrants”) to acquire 40,000 shares of the Company's common stock at an exercise price of $15.00 per share, subject to anti-dilution protection. The Purchase Agreement provides certain piggyback registration rights for the holders of the 2017 Bridge Warrants for a period of six months after the closing of the bridge financing. Aegis Capital Corp. acted as placement agent for the bridge financing and received a placement agent fee of $84,000 and warrants (the “Aegis Warrants”) to acquire 5,600 shares of the Company's common stock at an exercise price of $15.00 per share. The Aegis Warrants are identical to the 2017 Bridge Warrants except that the Aegis Warrants do not have anti-dilution protection.

At the time of the Merger, the 2017 Bridge Notes were extinguished and replaced with convertible promissory notes (the “2017 New Bridge Notes I”) with an original principal amount of $1.2 million in the aggregate pursuant to an Exchange Agreement (the “Exchange Agreement”) entered into on the Closing Date. The 2017 New Bridge Notes I have an annual interest rate of 8.0% and are due and payable upon the earlier to occur of (i) October 1, 2017 or (ii) the closing of a Qualified Offering (as defined in the 2017 New Bridge Notes I). The 2017 New Bridge Notes I are

convertible into shares of our common stock at an initial conversion price of $3.736329 per share, subject to adjustment, and may be convertible into shares of our preferred stock at the holder’s option if the Company does not complete a Qualified Offering (as defined in the 2017 New Bridge Notes I) by October 1, 2017. The Company may redeem the 2017 New Bridge Notes I at any time in cash upon payment of a 20% premium, or $240,000. As the convertible promissory notes were convertible into the Company's common stock at a conversion rate lower than the fair market value of the common stock at the time of issuance, the Company recorded $989,000 as a beneficial conversion feature, which was recorded as a debt discount in the balance sheet. The discount will be amortized using the effective interest method through the first conversion date of the 2017 New Bridge Notes I.

Pursuant to the Exchange Agreement, the 2017 Bridge Warrants were canceled and replaced with new warrants to acquire 45,600 shares of our common stock (the “2017 New Bridge Warrants”). The initial exercise price of the 2017 New Bridge Warrants is $7.50 (subject to adjustments). If the Company completes a Qualified Offering (as defined in the 2017 New Bridge warrants), the exercise price of the 2017 New Bridge Warrants will become the lower of (i) $7.50, or (ii) 110% of the per share offering price in the Qualified Offering, but in no event lower than $1.50 per share, which has been considered a down round provision. At issuance, the 2017 New Bridge Warrants had a fair value of $211,000 and were recorded as a debt discount to the related 2017 New Bridge Notes I, with the corresponding entry to additional paid in capital as the warrants were considered classified as equity in accordance with GAAP. As discussed in Note 2 of the accompanying unaudited condensed consolidated financial statements,

the Company early adopted ASU 2017-11, which allowed the Company to treat the warrants as equity classified, despite the down round provision.

2017 New Bridge Note II.

In connection with the Merger, on the Closing Date and pursuant to a Securities Purchase Agreement (the "Bridge Purchase Agreement"), the Company completed the sale of an aggregate of $800,000 of a convertible promissory note (the "2017 New Bridge Note II"). The Company received net proceeds of $721,000 from the sale of the 2017 New Bridge Note II, which will be used for working capital purposes. The 2017 New Bridge Note II has an annual interest rate of 8.0% and are due and payable upon the earlier to occur of (i) October 1, 2017 or (ii) the closing of a Qualified Offering (as defined in the 2017 New Bridge Note II). The 2017 New Bridge Note II is convertible into shares of our common stock at an initial conversion price of $3.736329 per share, subject to adjustment, and may be convertible into shares of our preferred stock at the holder's option if the Company does not complete a Qualified Offering (as defined in the 2017 New Bridge Note II) by October 1, 2017. The Company may redeem the 2017 New Bridge Note II at any time in cash upon payment of a 20% premium, or $160,000.

As the 2017 New Bridge Note II was convertible into the Company's common stock at a conversion rate lower than the fair market value of the common stock at the time of issuance, the Company recorded $656,000 as a beneficial conversion feature, which was recorded as a debt discount in the balance sheet. The discount will be amortized using the effective interest method through the first conversion date of the 2017 New Bridge Note II.

In connection with the bridge financing and the assumption of certain obligations by an entity controlled by Mark Rimer (a director of the Company), the Company issued to that entity warrants (the "Side Warrants") to purchase an aggregate of 91,429 shares of the Company's common stock at an exercise price of $7.00 per share (subject to adjustment), with a fair value of $487,000 at the date of issuance. The Side Warrants have a term of 5 years and are exercisable as to 22,857 shares of the Company's common stock upon grant and as to 68,572 shares of the Company's common stock upon the entity's performance of the assumed obligations. The Company has recorded merger advisory expense of $414,000 related to the Side Warrants during the three and six months ended June 30, 2017. The remaining fair value of $73,000 will be recorded as expense at the time the performance obligations are met.

In addition, upon the Company consummating one or more rounds of equity financing following July 1, 2017, with aggregate gross proceeds of at least $7 million, the Company will use a portion of the proceeds from such financing to repay the principal amount of the 2017 New Bridge Notes, together with any premium and interest.

As of June 30, 2017, the outstanding convertible notes balance was $2.0 million, net of debt discounts of $1.7 million and debt issuance cost of $0.1 million. Accrued interest of approximately $10,000 is included within accrued expenses on the accompanying condensed consolidated balance sheet.

6. ACCRUED EXPENSES.

Accrued expenses consist of the following:

	June 30,	December 31, 2016

	2017	
Accrued expenses	$2,560	$ 50
Accrued compensation	791	155
Accrued interest	170	495
	$3,521	$ 700

7. CONTINGENCIES

The Company is involved in legal proceedings related to matters, which are incidental to its business. The Company has also assumed a number of claims as a result of the Merger. See below for a discussion on these matters.

The healthcare industry is subject to numerous laws and regulations of federal, state and local governments. These laws and regulations include, but are not necessarily limited to, matters such as licensure, accreditation, government healthcare program

participation requirement, reimbursement for patient services and Medicare and Medicaid fraud and abuse. Government activity has increased with respect to investigations and allegations concerning possible violations of fraud and abuse statutes and regulations by healthcare providers.

Violations of these laws and regulations could result in expulsion from government healthcare programs together with the imposition of significant fines and penalties, as well as significant repayments for patient services previously billed. Management believes that the Company is in compliance with fraud and abuse regulations, as well as other applicable government laws and regulations. While no material regulatory inquiries have been made, compliance with such laws and regulations can be subject to future government review and interpretation, as well as regulatory actions unknown or unasserted at this time.

The outcome of legal proceedings and claims brought against us are subject to significant uncertainty. Therefore, although management considers the likelihood of such an outcome to be remote, if one or more of these legal matters were resolved against us in the same reporting period for amounts in excess of management’s expectations, our financial statements for such reporting period could be materially adversely affected. In general, the resolution of a legal matter could prevent us from offering our services or products to others, could be material to our financial condition or cash flows, or both, or could otherwise adversely affect our operating results.

Claims assumed in the Merger

The Company assumed a number of claims as a result of the Merger. In addition to the claims described below, we are delinquent on the payment of outstanding accounts payable certain of our vendors and suppliers who have taken or have threatened to take legal action to collect such outstanding amounts.

On February 25, 2016, the Board of Regents of the University of Nebraska (“UNMC”) filed a lawsuit against us in the District Court of Douglas County, Nebraska, for breach of contract and seeking recovery of $0.7 million owed by us to UNMC. A $0.4 million liability has been recorded and is reflected in accrued expenses at March 31, 2017 and December 31, 2016. We and UNMC entered into a settlement agreement dated February 6, 2017, which included, among other things, a mutual general release of claims, and our agreement to pay $0.4 million to UNMC in installments over a period of time. As of March 15, 2017, the initial payment due to UNMC under the settlement agreement is delinquent. We and UNMC are currently in discussions to extend the date of the initial payment due to UNMC. A $0.4 million liability has been recorded and is reflected in accrued expenses at June 30, 2017.

On April 13, 2016, Fox Chase Cancer Center (“Fox Chase”) filed a lawsuit against Transgenomic in the Court of Common Pleas of Philadelphia County, First Judicial District of Pennsylvania Civil Trial Division (the “Court of Common Pleas”), alleging, among other things, breach of contract, tortious interference with present and prospective contractual relations, unjust enrichment, fraudulent conversion and conspiracy and seeking punitive damages in addition to damages and other relief. This lawsuit relates to a license agreement Transgenomic entered into with Fox Chase in August 2000, as amended (the “License Agreement”), as well as the assignment of certain of Transgenomic's rights under the License Agreement to Integrated DNA Technologies, Inc. (“IDT”) pursuant to the Surveyor Kit Patent, Technology and Inventory Purchase Agreement Transgenomic entered into with IDT effective as of July 1, 2014 (the “IDT Agreement”). Pursuant to the terms of the IDT Agreement, Transgenomic agreed to indemnify IDT with respect to certain of the claims asserted in the Fox Chase proceeding. On July 8, 2016, the Court of Common Pleas sustained Transgenomic's preliminary objections to several of Fox Chase’s claims and dismissed the claims for tortious interference, fraudulent conversion, conspiracy, punitive damages and attorney’s fees. Accordingly, the case has been

narrowed so that only certain contract claims and an unjust enrichment claim remained pending against Transgenomic.

During June 2017, prior to the Merger, Transgenomic entered into a settlement agreement with Fox Chase (the "Agreement") which will resolve all outstanding claims in the litigation brought in April 2016 by Fox Chase against Transgenomic in the Court of Common Pleas of Philadelphia County (the "Action"). The case will remain pending with the Court until all settlement payments to Fox Chase have been made. Under the Agreement the Company will make three (3) payments to Fox Chase totaling $175,000. The last payment is to be made on or before September 30, 2017, and once received Fox Chase is obligated to cause the Action to be formally dismissed with prejudice. Also, on July 13, 2017 the Company entered into an agreement with its co-Defendant, IDT, regarding the Company's indemnity obligations to IDT for legal fees and expenses incurred in the Action pursuant to the terms of the IDT Agreement. The IDT Agreement provides for monthly payments of $27,800 from the Company to IDT, in the total amount of $139,000, commencing on August 15, 2017 and concluding on December 15, 2017. A $0.3 million liability has been recorded and is reflected in accrued expenses at June 30, 2017.

On June 23, 2016, the Icahn School of Medicine at Mount Sinai ("Mount Sinai") filed a lawsuit against us in the Supreme Court of the State of New York, County of New York, alleging, among other things, breach of contract and, alternatively, unjust enrichment and quantum merit, and seeking recovery of $0.7 million owed by us to Mount Sinai for services rendered. We and Mount Sinai entered into a settlement agreement dated October 27, 2016, which included, among other things, a mutual general release of claims, and our agreement to pay approximately $0.7 million to Mount Sinai in installments over a period of time. A $0.7 million liability has been recorded and is reflected in accrued expenses at June 30, 2017. Effective as of February 1, 2017, we and Mount Sinai agreed to amend the terms of our settlement agreement to extend the date of the initial payment due to Mount Sinai.

On December 19, 2016, Todd Smith ("Smith") filed a lawsuit against us in the District Court of Douglas County Nebraska, alleging breach of contract and seeking recovery of $2.2 million owed by us to Smith for costs and damages arising from a breach of our obligations pursuant to a lease agreement between the parties. On April 7, 2017, we entered into a settlement agreement with Smith related to the early termination of our lease for our Omaha, Nebraska facility. The agreement included, among other things, a mutual general release of claims, and our agreement to pay approximately $0.6 million to Smith in installments over a period of time. A $0.6 million liability has been recorded and is reflected in accrued expenses at June 30, 2017.

On February 21, 2017, XIFIN, Inc. ("XIFIN") filed a lawsuit against us in the District Court for the Southern District of California alleging breach of written contract and seeking recovery of approximately $0.27 million owed by us to XIFIN for damages arising from a breach of our obligations pursuant to a Systems Services Agreement between us and XIFIN, dated as of February 22, 2013, as amended and restated on September 1, 2014. On April 5, 2017, the court clerk entered default against us. On May 5, 2017, XIFIN filed an application for entry of default judgment against us. A $0.3 million liability has been recorded and is reflected in accrued expenses at June 30, 2017.

We and Science Park Development Corporation ("SPDC") entered into that certain Lease dated as of December 31, 2011, as modified by the First Amendment to Lease dated as of June 18, 2013, as further modified by a letter agreement dated as of February 2, 2015, as modified by the Second Amendment to Lease dated as of June 26, 2015 (the " SPDC Lease"). In November 2016, SPDC alleged that we defaulted on our obligations under the SPDC Lease. Specifically, SPDC alleges that we failed to pay approximately $0.4 million in rental payments due under the SPDC Lease and that we vacated a portion of the leased premises in violation of the terms of the SPDC Lease. We and SPDC entered into a settlement agreement dated March 6, 2017, which included, among other things, a mutual general release of claims, and our agreement to pay approximately $0.4 million to SPDC in installments over a period of time. This liability has been recorded and is reflected in accrued expenses at June 30, 2017.

CPA Global provides us with certain patent management services. On February 6, 2017, CPA Global claimed that we owe approximately $0.2 million for certain patent maintenance services rendered. CPA Global has not filed claims against us in connection with this allegation. A liability of approximately $0.2 million has been recorded and is reflected in accrued expenses at June 30, 2017.

On March 9, 2016, counsel for Edge BioSystems, Inc. ("EdgeBio") sent a demand letter on behalf of EdgeBio to us in connection with the terms of that certain Asset Purchase Agreement dated September 8, 2015 (the "EdgeBio Agreement"). EdgeBio alleges, among other things, that certain customers of EdgeBio erroneously remitted payments to us, that such payments should have been paid to EdgeBio and that we failed to remit these funds to EdgeBio in violation of the terms of the EdgeBio Agreement. On September 13, 2016, we received a demand for payment letter from EdgeBio's counsel alleging that the balance due to EdgeBio is approximately $0.1 million. A liability of approximately $0.1 million has been recorded and is reflected in accrued expenses at June 30, 2017.

On February 17, 2017, Jesse Campbell ("Campbell") filed a lawsuit individually and on behalf of others similarly situated against us in the District Court for the District of Nebraska alleging we have a materially incomplete and misleading proxy relating to a potential merger and that the merger agreement's deal protection provisions deter superior offers. As a result, he alleges that we have violated Sections 14(a) and 20(a) of the Exchange Act and Rule

14a-9 promulgated thereafter. Although we intend to defend the lawsuit, there can be no assurance regarding the ultimate outcome of this case. Given the uncertainty of litigation, the legal standards that must be met for, among other things, class certification and success on the merits, we are unable to estimate the amount of loss, or range of possible loss, at this time that may result from this action. In the event that a settlement is reached related to these matters, the amount of such settlement may be material to our results of operations and financial condition and may have a material adverse impact on our liquidity.

8. INCOME TAXES

We file a US federal consolidated income tax return and state income tax returns in various jurisdictions. We have statutes of limitation open for federal & state income tax returns related to tax years 2014 through 2016.

Income tax expense for both the three months and six months ended June 30, 2017 was zero as a result of recording a full valuation allowance against the deferred tax asset generated predominantly by net operating losses. For the three and six months ended June 30, 2016, the Company was organized as a limited liability company and operated under the default classification as a partnership until July 31, 2016. Consequently, prior to August 1, 2016, income tax expense or benefits were calculated at the members' level.

We had no material interest or penalties during fiscal 2017 or fiscal 2016, and we do not anticipate any such items during the next twelve months. Our policy is to record interest and penalties directly related to uncertain tax positions as income tax expense in the condensed consolidated statements of operations.

As a result of the merger, there was a change in ownership as defined in IRS § 382. Because of this change, use of a portion of the accumulated net operating losses and tax credit carryforwards will be limited in future periods. Further, a portion of the carryforwards will expire before being applied to reduce future income tax liabilities. Since the net deferred tax assets have a full valuation allowance recorded, any limitation generated from this calculation would not effect the current financial statements.

9. STOCKHOLDERS' EQUITY (DEFICIT)

Common Stock.

Pursuant to our Third Amended and Restated Certificate of Incorporation, as amended, we currently have 150,000,000

shares of common stock authorized for issuance.

In connection with the Merger, the Company effected a 1-for-30 reverse stock split of its common stock. This reverse stock split became effective on June 13, 2017 and, unless otherwise indicated, all share amounts, per share data, share prices, exercise prices and conversion rates set forth in these notes and the accompanying unaudited condensed consolidated financial statements have, where applicable, been adjusted retroactively to reflect this reverse stock split. Additionally, as a result of the Merger, the Company has recapitalized its stock. All historical preferred stock, common stock, restricted units, warrants and additional paid-in capital, including share and per share amounts, have been retroactively adjusted to reflect the equity structure of the combined company, including the effect of the Merger exchange ratio. Pursuant to the Merger Agreement, each outstanding share of capital stock of Precipio Diagnostics was exchanged for 10.2502 pre-reverse stock split shares of the Company's common stock.

As of December 31, 2016, there were 449,175 share of common stock outstanding.

During 2017, restricted stock of 59,563 shares were granted during the three and six months ended June 30, 2017, none of which vested prior to the merger, upon closing of the merger, all shares fully vested. During 2017, 64,593 shares were released to common stock. We recorded stock compensation expense of approximately $28,000 related to restricted stock that vested during the six months ended June 30, 2017.

On the Closing Date, Precipio Diagnostics received 4,317,152 shares of Precipio common stock from the conversion of preferred stock, senior and junior debt, bridge notes and warrants. Also, certain advisors of Precipio Diagnostics received 321,821 shares of Precipio common stock related to services performed in connection with the Merger. The fair value of these advisory shares was $2.2 million at the date of the Merger and is included as a merger advisory fee expense in the accompanying financial statements.

As part of the Merger, Precipio Diagnostics also received 200,081 shares of Precipio common stock that have not been issued yet. 135,000 of these shares are being held for future issuance to advisors pending completion of certain performance obligations. If these performance obligations are not met, the shares will remain with Precipio Diagnostics as part of the unissued pool. For any shares that remain unissued, it is the intent of the Company to allocate these to Precipio Diagnostics shareholders on a pro rata basis.

Also, upon completion of the Merger, Transgenomic legacy stockholders had 1,255,119 shares of Precipio common stock outstanding.

As of June 30, 2017, there were 6,407,860 shares of Precipio common stock outstanding.

Common Stock Warrants.

Prior to the merger, in connection with the line of credit with Connecticut Innovations, the Company issued warrants to purchase 8,542 Series A Preferred shares of the Company, which were classified as an equity warrant, at an exercise price of $2.93 per unit, subject to adjustments as defined in the warrant agreement. The warrants were valued at $6,000 at the date of the grant utilizing the Black-Sholes model (volatility 40%, expected life 7 years, and risk free rate .36%). The value of the warrants were treated as a debt discount. At the Merger date, the warrants were exercised and then converted into shares of Precipio common stock.

In connection with the Webster Bank agreement, the Company issued 7 years warrants to purchase 20,000 Series B Preferred shares of the Company. At the Merger date, Webster Bank declined to exercise their warrants and, per the terms of the warrant agreement, the warrants were retired.

In March 2016, the Company entered into a redemption and exchange agreement with certain member's relating to their 275,237 Preferred A Units and 208,087 Preferred B Units. Under the terms of the agreement, the unit holders would exchange their units in the Company for the issuance of debt. The aggregate purchase price per the agreement was the member's initial investment of $750,000 for Preferred A Units and $965,000 for Preferred B Units, along with a preferred return of 8%, recorded as a dividend in the amount of $432,716. In addition to the debt issued as consideration for the member's preferred units, the Company also issued common warrant units, which allows the holders to collectively purchase common units of the Company, representing approximately 60% of the Company at the time of exercise. At the time of issuance, this represented approximately 1,958,204 common units. The common warrant units had a $0.00 exercise price with a ten year expiration date. The common warrant units were classified as equity awards and the fair value upon issuance was calculated utilizing a discounted cash flow analysis to value the Company's equity and an option pricing method to allocate the value of the equity. The fair value of the warrants was determined directly utilizing the option pricing method as the exercise price was $0.00. The aggregate value of the common warrant units was $1,421,738, which was considered a deemed dividend. At the time of the Merger, these warrants were converted into 1,958,204 shares of Precipio common stock.

Warrants Assumed in Merger

At the time of the Merger, Transgenomic had a number of outstanding warrants related to various financing transactions that occurred between 2013-2016. Details related to year issued, expiration date, amount of underlying common shares and exercise price are included in the table below.

2017 New Bridge Warrants

During the six months ended June 30, 2017, prior to the Merger, Transgenomic completed the sale of the 2017 Bridge Notes in the amount of $1.2 million and the issuance of the 2017 Bridge Warrants to acquire 40,000 shares of the Company's common stock at an exercise price of $15.00 per share, subject to anti-dilution protection. Aegis Capital Corp. acted as placement agent for the bridge financing and received Aegis Warrants to acquire 5,600 shares of Transgenomic common stock at an exercise price of $15.00 per share. The Aegis Warrants are identical to the 2017 Bridge Warrants except that the Aegis Warrants do not have anti-dilution protection. (See Note 5 - Convertible Bridge Notes).

In connection with the Merger, the holders of the 2017 Bridge Notes, the 2017 Bridge Warrants and the Aegis Warrants agreed to exchange the 2017 Bridge Notes, the 2017 Bridge Warrants and the Aegis Warrants for 2017 New Bridge Notes and the 2017 New Bridge Warrants to acquire 45,600 shares of our common stock. (See Note 5 - Convertible Bridge Notes). The initial exercise price of the 2017 New Bridge Warrants is $7.50 (subject to adjustments). If the Company completes a Qualified Offering (as defined in the 2017 New Bridge Warrants), the exercise price of the 2017 New Bridge Warrants will become the lower of (i) $7.50 or (ii) 110% of the per share offering price in the Qualified Offering, but in no event lower than $1.50 per share.

At issuance, the 2017 New Bridge Warrants had a fair value of $211,000 and were recorded as a debt discount to the related 2017 New Bridge Notes I, with the corresponding entry to additional paid in capital as the warrants were

considered classified as equity in accordance with GAAP.

Side Warrants

In connection with the bridge financing and the assumption of certain obligations by an entity controlled by Mark Rimer (a director of the Company), the Company issued to that entity Side Warrants to purchase an aggregate of 91,429 shares of the Company's common stock at an exercise price of $7.00 per share (subject to adjustment), with a fair value of $487,000 at the date

of issuance. The Side Warrants have a term of 5 years and are exercisable as to 22,857 shares of the Company's common stock upon grant and as to 68,572 shares of the Company's common stock upon the entity's performance of the assumed obligations. The Company has recorded merger advisory expense of $414,000 related to the Side Warrants during the three and six months ended June 30, 2017. The remaining fair value of $73,000 will be recorded as expense at the time the performance obligations are met.

The following represents a summary of the warrants outstanding as of June 30, 2017:

	Issue Year	Expiration	Underlying Shares	Exercise Price
Warrants Assumed in Merger				
(1)	2013	January 2018	23,055	$270.00
(2)	2014	April 2020	12,487	$120.00
(3)	2015	February 2020	23,826	$67.20
(4)	2015	December 2020	4,081	$49.80
(5)	2015	January 2021	38,733	$36.30
(6)	2016	January 2021	29,168	$36.30
Warrants				
(7)	2017	June 2022	45,600	$7.50
(8)	2017	June 2022	91,429	$7.00
			268,379	

(1) These warrants were issued in connection with an offering which was completed in January 2013.
(2) These warrants were issued in connection with a private placement which was completed in October 2014.
(3) These warrants were issued in connection with an offering which was completed in February 2015.
(4) These warrants were issued in connection with an offering which was completed in July 2015.
(5) These warrants were originally issued in connection with an offering in July 2015, and were amended in connection with an offering which was completed in January 2016.
(6) These warrants were issued in connection with an offering which was completed in January 2016.
(7) These are the 2017 New Bridge Warrants which were issued in connection with the Merger. See discussion above for additional information.
(8) These are the Side Warrants which were issued in connection with the Merger. See discussion above for additional information

Series A and Series B Preferred Stock.

The Company had outstanding preferred units of 367,299 for Series A and 412,806 for Series B as of December 31, 2016. These shares have been recapitalized and are included in preferred stock. On the Closing Date, the outstanding preferred units for Series A and Series B, along with the related accumulated dividends, were converted into common shares of the Company.

Preferred Stock.

The Company's Board of Directors is authorized to issue up to 15,000,000 shares of preferred stock in one or more series, from time to time, with such designations, powers, preferences and rights and such qualifications, limitations and restrictions as may be provided in a resolution or resolutions adopted by the Board of Directors. The authority of the Board of Directors includes, but is not limited to, the determination or fixing of the following with respect to shares of such class or any series thereof: (i) the number of shares; (ii) the dividend rate, whether dividends shall be cumulative and, if so, from which date; (iii) whether shares

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are to be redeemable and, if so, the terms and amount of any sinking fund providing for the purchase or redemption of such shares; (iv) whether shares shall be convertible and, if so, the terms and provisions thereof; (v) what restrictions are to apply, if any, on the issue or reissue of any additional preferred stock; and (vi) whether shares have voting rights. The preferred stock may be issued with a preference over the common stock as to the payment of dividends. We have no current plans to issue any additional preferred stock. Classes of stock such as the preferred stock may be used, in certain circumstances, to create voting impediments on extraordinary corporate transactions or to frustrate persons seeking to effect a merger or otherwise to gain control of the Company. For the foregoing reasons, any additional preferred stock issued by the Company could have an adverse effect on the rights of the holders of the common stock.

Series A Senior Preferred Stock.

In connection with the Merger, the Company filed a Certificate of Designation with the Secretary of State of the State of Delaware on June 29, 2017, designating 4,100,000 shares of the Company’s Preferred Stock, par value $0.01 per share, as Series A Senior Convertible Preferred Stock ("Series A Senior") and establishing the rights, preferences and privileges of the new preferred stock. Generally, the holders of the Series A Senior stock are entitled to vote as a single voting group with the holders of the Company's common stock, and the holders of the Series A Senior stock are generally entitled to that number of votes as is equal to the number of whole shares of the Company's common stock into which the Series A Senior stock may be converted as of the record date of such vote or consent.

So long as the shares of Series A Senior stock are outstanding certain actions will require the separate approval of at least two-thirds of the Series A Senior stock, including: changes to the terms (requires three-fourths approval) of the Series A Senior stock, changes to the number of authorized shares of Series A Senior stock, issuing a series of preferred stock that is senior to the Series A Senior stock, changing the size of the board of directors, certain changes to the capital stock of the Company, bankruptcy proceedings and granting security interests in the Company’s assets.

The Series A Senior stock will be convertible into the Company's common stock at any time at the then applicable conversion price. The initial conversion price for the Series A Senior stock issued in connection with the Merger and the other transactions described herein is $3.736329, but will be subject to anti-dilution protections including adjustments for stock splits, stock dividends, other distributions, recapitalizations and the like. Additionally, each holder of the Series A Senior stock will have a right to convert such holder's Series A Senior stock into securities issued in any future private offering of the Company's securities at a 15% discount to the proposed price in such private offering.

The Series A Senior stock will be entitled to an annual 8% cumulative payment in lieu of interest or dividends, payable in-kind for the first two years and in cash or in-kind thereafter, at the option of the Company. The Series A Senior stock also will be entitled to share in any dividends paid on the Company's common stock.

As discussed in Note 3 - Reverse Merger, in connection with the Merger, the Company issued 1) to holders of certain Transgenomic secured indebtedness, 802,925 shares of Series A Senior stock in an amount equal to $3 million, 2) to holders of certain Precipio Diagnostic indebtedness, 802,920 shares of Series A Senior stock in an amount equal to $3 million and 3) to certain investors, 107,056 shares of Series A Senior stock in exchange for $400,000 in a private placement. The Company had outstanding Series A Senior shares of 1,712,901 as of June 30, 2017.

We determined that there was a beneficial conversion feature in connection with the issuances of the Series A Senior stock since the conversion price of $3.736329 was at a discount to the fair market value of the Company's common stock at issuance date. The Series A Senior stock is non-redeemable and as a result, the Company recognized the full beneficial conversion feature in the amount of $5.2 million as a deemed dividend at the time of issuance.

10. FAIR VALUE

FASB guidance on fair value measurements, which defines fair value, establishes a framework for measuring fair value and expands disclosures about fair value measurements for our financial assets and liabilities, as well as for other assets and liabilities that are carried at fair value on a recurring basis in our condensed consolidated financial statements.

FASB guidance establishes a three-level fair value hierarchy based upon the assumptions (inputs) used to price assets or liabilities. The three levels of inputs used to measure fair value are as follows:

Level 1—Unadjusted quoted prices in active markets for identical assets or liabilities;
Level 2—Observable inputs other than those included in Level 1, such as quoted prices for similar assets and liabilities in active markets or quoted prices for identical assets or liabilities in inactive markets; and
Level 3—Unobservable inputs reflecting our own assumptions and best estimate of what inputs market participants would use in pricing the asset or liability.

Common Stock Warrant Liabilities.

Certain of our issued and outstanding warrants to purchase shares of common stock do not qualify to be treated as equity and, accordingly, are recorded as a liability.

2016 Warrant Liability
The Company assumed the 2016 Warrant Liability in the merger and it represents the fair value of Transgenomic warrants issued in January 2016, of which, 25,584 warrants remain outstanding as of June 30, 2017. We are required to record these instruments at fair value at each reporting date and changes are recorded as a non-cash adjustment to earnings. The gains or losses included in earnings are reported in other income (expense) in our condensed consolidated Statement of Operations.
The 2016 Warrant Liability is considered a Level 3 financial instrument and is valued using a binomial lattice simulation model. This method is well suited to valuing options with non-standard features. Assumptions and inputs used in the valuation of the common stock warrants include: our equity value, which was estimated using our stock price of $9.00 as of June 30, 2017; volatility of 121%; and a risk-free interest rate of 1.64%.
During the three months ended June 30, 2017, the changes in the fair value of the liability measured using significant unobservable inputs (Level 3) were comprised of the following:
Dollars in Thousands

	For the Three Months Ended June 30, 2017
Beginning balance at April 1	$ —
Additions - liability assumed in the Merger	615
Total (gains) or losses:	
Recognized in earnings	3
Balance at June 30	$ 618

11. STOCK OPTIONS

Stock Options.

The Company's 2006 Equity Incentive Plan (the "2006 Plan") was terminated as to future awards on July 12, 2016. The Company's 2017 Stock Option and Incentive Plan (the "2017 Plan") was adopted by the Company's stockholders on June 5, 2017 and will expire on June 5, 2027. The following table summarizes stock option activity under our plans during the six months ended June 30, 2017:

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PRECIPIO, INC. AND SUBSIDIARY
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)
Three and Six Months Ended June 30, 2017 and 2016

	Number of Options	Weighted-Average Exercise Price
Outstanding at January 1, 2017	24,600	$ 107.83
Granted	—	—
Forfeited	(2,460)	75.76
Outstanding at June 30, 2017	22,140	$ 111.39
Exercisable at June 30, 2017	19,908	$ 119.13

As of June 30, 2017, there were 21,713 options that were vested or expected to vest with an aggregate intrinsic value of zero with a remaining weighted average contractual life of 6.9 years.

Stock Appreciation Rights (“SARs”)

As of June 30, 2017, 2,777 outstanding and exercisable SARs shares were vested or expected to vest. All outstanding SARs were issued solely to a former chief executive officer. The weighted-average exercise price of these SARs was $129.60 per share and the aggregate intrinsic value was zero with a remaining weighted average contractual life of 6.25 years. During the six months ended June 30, 2017, the SARs liability decreased approximately $5,000 and at June 30, 2017, a liability of approximately $7,000 was recorded in accrued expenses.

12. SUBSEQUENT EVENTS

On August 1, 2017, the Company announced that it was planning a public offering of common stock and warrants in an underwritten public offering. There can be no assurances as to whether the offering will be completed, or as to the size or terms of the offering. Even if the offering is completed, the Company will need to raise additional funding.

Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations

Forward-Looking Information
This Quarterly Report on Form 10-Q, including this Management’s Discussion and Analysis, contains forward-looking statements. These statements are based on management’s current views, assumptions or beliefs of future events and financial performance and are subject to uncertainty and changes in circumstances. Readers of this report should understand that these statements are not guarantees of performance or results. Many factors could affect our actual financial results and cause them to vary materially from the expectations contained in the forward-looking statements. These factors include, among other things: our expected revenue, income (loss), receivables, operating expenses, supplier pricing, availability and prices of raw materials, insurance reimbursements, product pricing, sources of funding operations and acquisitions, our ability to raise funds, sufficiency of available liquidity, future interest costs, future economic circumstances, business strategy, industry conditions, our ability to execute our operating plans, the success of our cost savings initiatives, competitive environment and related market conditions, expected financial and other benefits from our organizational restructuring activities, actions of governments and regulatory factors affecting our business, retaining key employees and other risks as described in our reports filed with the Securities and Exchange Commission. In some cases these statements are identifiable through the use of words such as “anticipate,” “believe,” “estimate,” “expect,” “intend,” “plan,” “project,” “target,” “can,” “could,” “may,” “should,” “will,” “would” or the n

these terms and other similar expressions.

You are cautioned not to place undue reliance on these forward-looking statements. The forward-looking statements we make are not guarantees of future performance and are subject to various assumptions, risks and other factors that could cause actual results to differ materially from those suggested by these forward-looking statements. Actual results may differ materially from those suggested by the forward-looking statements that we make for a number of reasons, including those described in Part II, Item 1A, “Risk Factors,” of this Quarterly Report on Form 10-Q.

We expressly disclaim any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

The following discussion should be read together with our financial statements and related notes contained in this Quarterly Report on Form 10-Q and with the audited financial statements and notes thereto of Precipio Diagnostics for the year ended

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December 31, 2016 contained in our current report on Form 8-K/A, filed with the Securities and Exchange Commission (the "SEC") on July 31, 2017. Results for the three and six months ended June 30, 2017 are not necessarily indicative of results that may be attained in the future.

Merger

On June 29, 2017, or the Closing Date, the Company (then known as Transgenomic, Inc., or Transgenomic), completed a reverse merger, or the Merger with Precipio Diagnostics, LLC, a privately held Delaware limited liability company, or Precipio Diagnostics, in accordance with the terms of the Agreement and Plan of Merger, or the Merger Agreement, dated October 12, 2016, as amended on February 2, 2017 and June 29, 2017, by and among Transgenomic, Precipio Diagnostics and New Haven Labs Inc., or Merger Sub, a wholly-owned subsidiary of Transgenomic. Pursuant to the Merger Agreement, Merger Sub merged with and into Precipio Diagnostics, with Precipio Diagnostics surviving the Merger as a wholly-owned subsidiary of the merged 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. Upon the consummation of the Merger, the historical financial statements of Precipio Diagnostics become the Company's historical financial statements. Accordingly, the historical financial statements of Precipio Diagnostics are included in the comparative prior periods.

Overview

Precipio, Inc., and Subsidiary, ("we", "us", "our", the "Company" or "Precipio") is 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 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.

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- 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 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.

The following discussion should be read together with our financial statements and related notes contained in this Quarterly Report. Results for the three and six months ended June 30, 2017 are not necessarily indicative of results that may be attained in the future.

Second Quarter 2017 Overview and Recent Highlights

During the second quarter of 2017, both Precipio Diagnostics and Transgenomic worked to prepare for the Merger. From an operation perspective, since each company had a certified CLIA lab, management determined that consolidation would both streamline company operations and reduce the regulatory burden, while significantly decreasing operating costs on a going forward basis. Both companies continued to work to integrate their various teams and related operations; the finance teams of both companies worked together to prepare for the combination of both companies financial, billing, AP and accounting systems to ensure a smooth transition upon completion of the Merger. Customer service and logistics functions also were combined to ensure that the proper efficiencies were achieved once the Merger was completed.

From a corporate governance perspective, the Company enhanced its board of directors and will further supplement its board of directors with experienced industry individuals. In addition, the Company also formulated its scientific

advisory board, to create a strong scientific backbone to support the management team, and ensure that the Company continues product development. We continue to build on our long standing relationships with Yale Medicine, Harvard, and Dana Farber. Collaboration with academia and biopharma remains an integral component of our strategy to access advanced genetic technology and diagnostic testing in the cancer marketplace for future growth. In April 2017, we signed a contract renewal with Yale for diagnostic pathology services and medical director leadership. During the three months ending June 30, 2017, we expanded the diagnostic sales force and focused on product branding. These efforts will continue through 2017 and beyond. In addition, significant resource was directed on communicating the broad technical synergies and product development capabilities created through the Merger. We signed our first multi-national distribution agreement with Clearbridge Health, a Singaporean-based healthcare company that will be providing Precipio's services in numerous countries throughout Asia.

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Uncertainties

We have historically operated at a loss and have not consistently generated sufficient cash from operating activities to cover our operating and other cash expenses. We have been able to historically finance our operating losses through borrowings or from the issuance of additional equity. At June 30, 2017, we had cash and cash equivalents of approximately $1.0 million. Our ability to continue as a going concern is dependent upon a combination of generating additional revenue and raising necessary financing to meet our obligations and pay our liabilities arising from normal business operations when they come due. The outcome of these matters cannot be predicted with any certainty at this time and raises substantial doubt that we will be able to continue as a going concern.

Results of Operations for the Three Months Ended June 30, 2017 and 2016

Net Sales. Net sales were as follows:

	Dollars in Thousands			
	Three Months Ended June 30,		Change	
	2017	2016	$	%
Total Net Sales	$260	$504	$(244)	(48)%

Net sales decreased by $0.2 million, or 48%, during the three months ended June 30, 2017 as compared to the same period in 2016. The decrease is entirely due to the decrease in cases processed during the three months ended June 30, 2017 as compared to the same period in 2016. We processed 230 cases during the three months ended June 30, 2017 as compared to 338 cases during the same period in 2016, or a 32% decrease in cases. The decrease in volume is the result of turnover of key sales personnel.

Cost of Diagnostic Services. Cost of diagnostic services includes material and supply costs for the patient tests performed and other direct costs (primarily personnel costs and rent) associated with the operations of our laboratory. Cost of diagnostic services increased by less than $0.1 million, or 19%, for the three months ended June 30, 2017 as compared to the same period in 2016. The increase is due to increased professional fees involved with the processing of patient tests in the three months ended June 30, 2017.

Gross Profit. Gross profit and gross margins were as follows:

	Dollars in Thousands			
	Three Months Ended June 30,		Margin %	
	2017	2016	2017	2016
Gross (Loss) Profit	$(24)	$263	(10)%	52%

Gross loss was a negative (10)% of total net sales, during the second quarter of 2017, compared 52% of total net sales, during the same quarter of 2016. The gross profit decreased by $0.3 million during the three months ended June 30, 2017 as compared to the same period of 2016 due to the decreased revenues discussed above and associated fixed costs to operate the laboratory.

Operating Expenses. Operating expenses primarily consist of personnel costs, professional fees, travel costs, facility costs and depreciation. Our operating expenses increased by $0.2 million to $0.8 million during the three months ended June 30, 2017 as compared to the same period in 2016. The increase in operating expenses reflects the increase in professional fees attributed to legal expenses related to the Merger.

Other Income (Expense). Other expense for both the three months ended June 30, 2017 and 2016 includes interest expense of approximately $0.2 million for interest related to our debt. Also included in other expense for the three months ended June 30, 2017 was $2.6 million of advisory fees related to the Merger.

Results of Operations for the Six Months Ended June 30, 2017 and 2016

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Net Sales. Net sales were as follows:

	Dollars in Thousands			
	Six Months Ended June 30,		Change	
	2017	2016	$	%
Total Net Sales	$508	$1,042	$(534)	(51)%

Net sales decreased by $0.5 million, or 51%, for the six months ended June 30, 2017 as compared to the same period in 2016. The decrease is entirely due to the decrease in cases processed during the six months ended June 30, 2017 as compared to the same period in 2016. We processed 429 cases during the six months ended June 30, 2017 as compared to 727 cases during the same period in 2016, or a 41% decrease in cases. The decrease in volume is the result of turnover of key sales personnel.

Cost of Diagnostic Services. Cost of diagnostic services includes material and supply costs for the patient tests performed and other direct costs (primarily personnel costs and rent) associated with the operations of our laboratory. Cost of diagnostic services remained flat for the six months ended June 30, 2017 as compared to the same period in 2016.

Gross Profit. Gross profit and gross margins were as follows:

	Dollars in Thousands Six Months Ended June 30,		Margin %	
	2017	2016	2017	2016
Gross (Loss) Profit	$42	$563	8%	54%

Gross profit was 8% of total net sales, for the six months ended June 30, 2017, compared to 54% of total net sales, for the same period of 2016. The gross profit decreased by $0.5 million during the six months ended June 30, 2017 as compared to the same period in 2016 and was due to the decreased revenues discussed above.

Operating Expenses. Operating expenses primarily consist of personnel costs, professional fees, travel costs, facility costs and depreciation. Our operating expenses increased by $0.3 million to $1.4 million for the six months ended June 30, 2017 as compared to the same period in 2016. The increase in operating expenses reflects the increase fees attributed to legal and professional expenses related to the Merger.

Other Income (Expense). Other expense for the six months ended June 30, 2017 and 2016 includes interest expense of approximately $0.3 million and $0.2 million, respectively, for interest related to our debt. The increase in the current year is due to increased interest bearing instruments outstanding during the six months ended June 30, 2017 as compared to the same period in 2016. Also included in other expense for the six months ended June 30, 2017 was $2.6 million of advisory fees related to the Merger.

Liquidity and Capital Resources

The condensed consolidated financial statements have been prepared using accounting principles generally accepted in the United States of America (“GAAP”) applicable for a going concern, which assume that the Company will realize its assets and discharge its liabilities in the ordinary course of business. The Company has incurred substantial operating losses and has used cash in its operating activities for the past several years. As of June 30, 2017, the Company had a net loss of $4.4 million and negative working capital of $14.5 million. The Company’s ability to continue as a going concern is dependent upon a combination of achieving its business plan, including generating additional revenue, and raising additional financing to meet its debt obligations and paying liabilities arising from normal business operations when they come due.

Precipio is currently in discussions with certain investors to raise additional capital. There can be no assurance such capital is available at terms favorable or agreeable to management, if at all, or that the Company will successfully complete the proposed capital raise. Since the outcome of these matters cannot be predicted with any certainty at this time, there is substantial doubt that the Company will be able to continue as a going concern.

Notwithstanding the aforementioned circumstances, there remains substantial doubt about the Company's ability to continue as a going concern. There can be no assurance that the Company will be able to successfully achieve its initiatives summarized above in order to continue as a going concern. The accompanying financial statements have been prepared assuming the Company will continue as a going concern and do not include any adjustments that might result should the Company be unable to continue as a going concern as a result of the outcome of this uncertainty.

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Our working capital positions at June 30, 2017 and December 31, 2016 were as follows:

	Dollars in Thousands		
	June 30, 2017	December 31, 2016	Change
Current assets (including cash and cash equivalents of $967 and $51, respectively)	$1,798	$ 552	$1,246
Current liabilities	16,314	3,012	13,302
Working capital	$(14,516)	$ (2,460)	$(12,056)

We completed the Merger on June 29, 2017 and in connection with the Merger we raised approximately $1.2 million in gross proceeds. At June 30, 2017, we had cash on hand of $1.0 million. To execute our strategic plan, management is currently planning to raise additional investment capital. On August 1, 2017, we announced that we were planning a public offering of common stock and warrants in an underwritten public offering. There can be no assurances as to whether the offering will be completed, or as to the size or terms of the offering. Even if the offering is completed, we will need to raise additional funding. We cannot be certain that additional financing will be available on acceptable terms, or at all, and our failure to raise capital could limit our ability to continue our operations. The accompanying financial statements have been prepared assuming we will continue as a going concern and do not include any adjustments that might result should we be unable to continue as a going concern as a result of the outcome of this uncertainty.

Analysis of Cash Flows - Six Months Ended June 30, 2017 and 2016

Net Change in Cash and Cash Equivalents. Cash and cash equivalents increased by $0.9 million during the six months ended June 30, 2017, compared to a decrease of less than $0.1 million during the six months ended June 30, 2016.

Cash Flows Used in Operating Activities. The cash flows used in operating activities of $0.9 million during the six months ended June 30, 2017 included a net loss of $4.4 million and an increase in accounts receivable of $0.1 million. These were partially offset by an increase in accounts payable, accrued expenses and other liabilities of $0.8 million and non-cash adjustments of $3.0 million. The cash flows used in operating activities in the first six months of 2016 included the net loss of $0.8 million and an increase in accounts receivable of $0.3 million. These were partially offset by an increase in accounts payable, accrued expenses and other liabilities of $0.3 million and non-cash adjustments of $0.4 million.

Cash Flows Provided by Investing Activities. Cash flows provided by investing activities were $0.1 million and zero for the six months ended June 30, 2017 and 2016, respectively. The $0.1 million for the six months ended June 30, 2017 was cash acquired as part of the merger transaction.

Cash Flows Provided by Financing Activities. Cash flows provided by financing activities totaled $1.7 million for the six months ended June 30, 2017, which included proceeds of $0.3 million from the issuance of senior notes, $1.4 million from the issuance of convertible notes, and $0.4 million from the issuance of preferred stock. These proceeds were partially offset by payments on our debt, capital lease obligations and for deferred financing costs of $0.4 million. Cash flows provided by financing activities during the six months ended June 30, 2016 included proceeds of $0.5 million from the issuance of convertible notes partially offset by $0.1 million of payments on our debt, capital lease obligations and for deferred financing costs.

Off-Balance Sheet Arrangements

At each of June 30, 2017 and December 31, 2016, we did not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

Contractual Obligations and Commitments

We have entered into certain operating leases and purchase commitments as part of our normal course of business. See the accompanying unaudited condensed consolidated financial statements and Note 7 - “Contingencies” in the Notes to unaudited condensed consolidated financial statements for additional information regarding our contractual obligations and commitments

Critical Accounting Policies and Estimates

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Accounting policies used in the preparation of our financial statements may involve the use of management judgments and estimates. Certain of our accounting policies are considered critical as they are both important to the portrayal of our financial statements and require significant or complex judgments on the part of management. Our judgments and estimates are based on experience and assumptions that we believe are reasonable under the circumstances. Further, we evaluate our judgments and estimates from time to time as circumstances change. Actual financial results based on judgments or estimates may vary under different assumptions or circumstances. For additional information regarding our critical accounting policies and estimates, see the accompanying unaudited condensed consolidated financial statements and Note 2 - “Summary of Significant Accounting Policies” in the Notes to unaudited condensed consolidated Financial Statements and Note 1 of the audited financial statements and notes thereto of Precipio Diagnostics for the year ended December 31, 2016 contained in our current report on Form 8-K/A, filed with the Securities and Exchange Commission (the “SEC”) on July 31, 2017.

Recently Issued Accounting Pronouncements
See the accompanying unaudited condensed consolidated financial statements and Note 2 - “Summary of Significant Accounting Policies” in the Notes to unaudited condensed financial statements for additional information regarding recently issued accounting pronouncements.

Impact of Inflation
We do not believe that price inflation or deflation had a material adverse effect on our financial condition or results of operations during the periods presented.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are a smaller reporting company, as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, and are not required to provide the information required under this item.

Item 4. Controls and Procedures.
Evaluation of Disclosure Controls and Procedures

Our management has concluded that our disclosure controls and procedures nor our internal controls over financial reporting will prevent all fraud and material error. Our disclosure controls and procedures are designed to provide reasonable assurance of achieving our objectives and our President and Chief Financial Officer concluded that our disclosure controls and procedures are not effective at a reasonable assurance level. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, control may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate
A material weakness is a significant deficiency, or combination of deficiencies, in internal control over financial reporting that results in more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected.

Based on the evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that, as of June 30, 2017, the following deficiencies are believed to be material weaknesses:

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The Company’s inability to account for the complex technical accounting treatment of complex debt and equity instruments.

- The Company’s controls as related to revenue recognition resulting from the fact the Company does not have contracts with certain payors and does not have proper controls over the estimates for doubtful accounts and contractual allowances.

Accounting for technical accounting and valuation of complex debt and equity instruments:

A material weakness exists pertaining to a lack of expertise in the technical accounting and valuation of complex debt and equity instruments that are required to be reported in accordance with accounting principles generally accepted in the United States of

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America and the valuation of fair values. To address the material weaknesses the Company continues to seek assistance with various third parties with expertise in such instruments and matters of fair value, in order to ensure that the Company's financial statements were prepared in accordance with U.S. GAAP on a timely basis.

Controls related to revenue recognition:

A material weakness exists due to the fact the Company does not have contracts with certain payors and does not have proper controls over the estimates for doubtful accounts and contractual allowances. The Company’s net patient service revenue is reported at the estimated net realizable amounts from patients, third-party payors and others for services rendered. Revenue estimates are also subject to retroactive adjustments under reimbursement agreements. Healthcare reimbursement laws and regulations governing Medicare and Medicaid programs that represent a portion of the Company’s net patient service revenues are extremely complex and subject to interpretation. As a result, there is at least a reasonable possibility that recorded estimates could change by a material amount in the near future. To address the material weakness the Company has added an additional review and reconciliation step to the revenue recognition process to ensure that all reported revenue recognizes appropriate third party contractual allowances and allowance for doubtful accounts. In addition, the additional review process will include current collection trends of payments and their impact on realizable revenues.

Changes in Internal Control over Financial Reporting
On June 29, 2017, the reverse merger of Precipio Diagnostics, Inc. and Transgenomic Inc. was completed. The reporting period for the six months ended June 30, 2017, reflects the financial statements and operating activity of Precipio Diagnostic, the controlling entity of the merger transaction.

Prior to the merger, Precipio Diagnostics was a privately operated company. Effective with the merger, Transgenomic changed its name to Precipio, Inc. and Mr. Ilan Danieli, Chief Executive Officer of Precipio Diagnostics and Carl Iberger, Chief Financial Officer of Precipio Diagnostics were appointed CEO and CFO respectively of Precipio, Inc., replacing Mr. Paul Kinnon, CEO and acting CFO of Transgenomic Inc.

We have evaluated the changes in our internal control over the financial reporting that occurred during the six months ended June 30, 2017. Management has identified a lack of sufficient personnel in the accounting function due to our limited resources with appropriate skills, training and experience to perform the review processes to ensure the complete and proper application of generally accepted accounting principles. Management is addressing this material weakness with the addition of accounting and financial resource with proper skills, training and experience. As of the merger date, June 29, 2017, Management has added experienced accounting staff consisting of a Director of Accounting, Director of Financial Reporting and a staff accountant and additional administrative staff.

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PART II. OTHER INFORMATION

Item 1. Legal Proceedings

See the accompanying unaudited condensed consolidated financial statements and Note 7 - “Contingencies” in the Notes to unaudited condensed consolidated financial statements for additional information regarding legal proceedings.

Item 1A. Risk Factors

There are a number of risks and uncertainties that may have a material effect on the operating results of our business and our financial condition. The following information updates, and should be read in conjunction with, the factors discussed in Part I, Item 1A, “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2016, which could materially affect our business, financial condition or future results. The risks described in our Annual Report on Form 10-K, as updated in our Quarterly Report for the quarter ended March 31, 2017 and this Quarterly Report, are not the only risks we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition or operating results.

Risks Related to our Business and Strategy

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 June 30, 2017 and December 31, 2016, we have an accumulated total deficit of approximately $12.7 million and $10.8 million, respectively. For the six months ended June 30, 2017 and the fiscal year ended December 31, 2016, we had a net loss and comprehensive loss attributable to common stockholders of approximately $1.8 million and $4.1 million, respectively. 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 common stock. An investor in our common stock 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.

As of June 30, 2017, our cash balance was $1.0 million and our working capital was approximately negative $16.3 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. 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 our operations or obtain funds by entering into agreements on unattractive terms.

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.

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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. In each of our potential product areas, we face significant competition from large biotechnology, medical diagnostic and other companies. 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.

Since our diagnostic technology is under development, we cannot predict the relative competitive position of any product based upon our diagnostic technology. However, we expect that the following factors will determine our ability to compete effectively: safety and efficacy; product price; turnaround time; ease of administration; performance; reimbursement; and marketing and sales capability.

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.

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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 depend upon our officers, 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. 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.

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

We are a small company with 30 full-time employees as of July 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:.

- manage our clinical studies effectively;
- 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.

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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 will 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 Precipio Diagnostics.

In June 2017, we completed our merger with Precipio Diagnostics, LLC, or Precipio Diagnostics. 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 Precipio Diagnostics 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.

Reimbursement and Regulatory Risks Relating to Our Business

If commercial third-party payors or government payors fail to provide coverage or adequate reimbursement, or if there is a decrease in the amount of reimbursement for our existing products or any future products we develop, our ability to successfully commercialize our technology, and our revenue and prospects for profitability, would be harmed.

Sales of our existing and any future products we develop will depend, in large part, upon the availability of reimbursement from third-party payors. These third-party payors include government healthcare programs such as Medicare and Medicaid, managed care providers, accountable care organizations, private health insurers, and other organizations. In particular, we believe that obtaining a positive local coverage determination or national coverage determination, and a favorable reimbursement rate from the Centers for Medicare & Medicaid Services, or CMS, or the applicable Medicare Administrative Contractor, or MAC, for each of our existing products, and any future products we develop, across substantially all medically indicated cancers will be a necessary element in achieving material commercial success. Physicians and patients may not order our products unless commercial third-party payors and government payors authorize such ordering and pay for all, or a substantial portion, of the list price, and certain

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commercial third-party payors may not agree to reimburse our existing products or future products if CMS or the MACs assigned to the jurisdictions in which our operational laboratory facilities are located do not issue positive coverage decisions for such products.

Commercial third-party payors and government payors are increasingly attempting to contain healthcare costs by demanding price discounts, by limiting coverage on which diagnostic products they will pay for and the amounts that they will pay for new molecular diagnostic products, and by creating conditions to reimbursement, such as coverage eligibility requirements based upon clinical evidence development involving research studies and the collection of physician decision impact and patient outcomes data. Because of these cost-containment trends, commercial third-party payors and government payors that currently provide or in the future may provide reimbursement for one or more of our products may reduce, suspend, revoke, or discontinue payments or coverage at any time, including those payors that designate one or more of our existing products and/or clinically indicated tumor types as experimental and investigational. Payors may also create conditions to coverage or contract with third-party vendors to manage laboratory benefit coverage, in both cases creating burdens for ordering physicians and patients that may make our products more difficult to sell. The percentage of submitted claims that are ultimately paid, the length of time to receive payment on claims, and the average reimbursement of those paid claims, is likely to vary from period to period.

As a result, there is significant uncertainty surrounding whether the use of products that incorporate new technology, such as our products, will be eligible for coverage by commercial third-party payors and government payors or, if eligible for coverage, what the reimbursement rates will be for these products. The fact that a diagnostic product has been approved for reimbursement in the past, or has received U.S. Food and Drug Administration, or FDA, approval, for any particular indication or in any particular jurisdiction, does not guarantee that such diagnostic product will remain approved for reimbursement or that similar or additional diagnostic products and/or clinically indicated tumor types will be approved in the future. Reimbursement of our existing and future products by commercial third-party payors and government payors may depend on a number of factors, including a payor’s determination that our existing and future products are:

- not experimental or investigational;
- medically reasonable and necessary;
- appropriate for the specific patient;
- cost effective;
- supported by peer-reviewed publications;
- included in clinical practice guidelines and pathways; and
- supported by clinical utility and health economic studies demonstrating improved outcomes and cost effectiveness.

Market acceptance, sales of products based upon our diagnostic technology, and our profitability may depend on reimbursement policies and health care reform measures. Several entities conduct technology assessments of medical tests and devices and provide the results of their assessments for informational purposes to other parties. These assessments may be used by third-party payors and health care providers as grounds to deny coverage for a test or procedure. The levels at which government authorities and third-party payors, such as private health insurers and health maintenance organizations, may reimburse the price patients pay for such products could affect whether we are able to commercialize our products. Our product candidates may receive negative assessments that may impact our ability to receive reimbursement of the test. Since each payor makes its own decision as to whether to establish a policy to reimburse our test, seeking these approvals may be a time-consuming and costly process. We cannot be sure that reimbursement in the United States or elsewhere will be available for any of our products in the future. If reimbursement is not available or is limited, we may not be able to commercialize our products.

The United States and foreign governments continue to propose and pass legislation designed to reduce the cost of healthcare. We expect that there will continue to be federal and state proposals to implement governmental controls or impose healthcare requirements. In addition, the Medicare program and increasing emphasis on managed or accountable care in the United States will continue to put pressure on product utilization and pricing. Utilization and cost control initiatives could decrease the volume of orders and payment that we would receive for any products in the future, which would limit our revenue and profitability. If we are unable to obtain reimbursement approval from commercial third-party payors and Medicare and Medicaid programs for our product candidates, or if the amount reimbursed is inadequate, our ability to generate revenues could be limited.

Changes in the way that the FDA regulates laboratory tests developed, manufactured, validated, and performed by laboratories like ours could result in additional expense in offering our current and any future products or even possibly delay or suspend development, manufacture, or commercialization of such products.

The FDA does not currently regulate most laboratory developed tests, or LDTs. The FDA historically took the position that, although such LDTs are medical devices, it would exercise enforcement discretion by not requiring compliance with the Federal Food, Drug, and Cosmetic Act, or the FDCA, or its regulations. However, in June 2010, the FDA announced that it intended to

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no longer exercise enforcement discretion for LDTs and in October 2014, the FDA published two draft guidance documents that, if finalized, would implement a regulatory approach for most LDTs. In the draft guidance documents, the FDA stated that it had serious concerns regarding the lack of independent review of the evidence of clinical validity of LDTs and asserted that the requirements under Clinical Laboratory Improvement Amendments, or CLIA, do not address the clinical validity of any LDT. The draft guidance documents proposed to impose a risk-based, phased-in approach for LDTs similar to the existing framework forin vitrodiagnostic devices. In November 2016, the FDA announced that it would not finalize the draft guidance documents for LDTs prior to the end of the Obama administration.

In January 2017, the FDA released a discussion paper synthesizing public comments on the 2014 draft guidance documents and outlining a possible approach to regulation of LDTs. The discussion paper has no legal status and does not represent a final version of the LDT draft guidance documents. In the discussion paper, the FDA states that there is “a growing consensus that additional oversight of LDTs is necessary.” Similar to the FDA’s 2014 draft guidance, the FDA’s discussion paper proposes a risk-based framework that would require most LDTs to comply with most of the FDA’s regulatory requirements for medical devices. Unlike the draft guidance, however, the discussion paper proposes to exempt currently marketed LDTs from premarket review, requiring only new or modified tests to be approved or cleared by the agency. In addition, the FDA proposed requiring LDTs to comply with only a subset of the medical device quality system regulations, or QSRs, and proposed other changes from the 2014 draft guidance. We cannot predict whether the FDA will take action to regulate LDTs under the new administration or what approach the FDA will seek to take.

Legislative proposals have been introduced in Congress or publicly circulated, each of which would implement differing approaches to the regulation of LDTs. We cannot predict whether any of these legislative proposals will be enacted into law or the impact such new legal requirements would have on our business.

In addition, in November 2013, the FDA finalized guidance regarding the sale and use of products labeled for research or investigational use only. Among other things, the guidance states that the FDA continues to be concerned about distribution of research- or investigational-use only products intended for clinical diagnostic use. The guidance states that the FDA will assess whether a manufacturer of such research- or investigational-use only products intends its products be used for clinical diagnostic purposes by examining the totality of circumstances, including advertising, instructions for clinical interpretation, presentations that describe clinical use, and specialized technical support such as assistance performing clinical validation, surrounding the distribution of the product in question. The FDA has advised that if evidence demonstrates that a product is inappropriately labeled for research- or investigational-use only, the device could be deemed misbranded and adulterated within the meaning of the FDCA. If the FDA were to undertake enforcement actions, some of our suppliers may cease selling research-use only products to us, and any failure to obtain an acceptable substitute could significantly and adversely affect our business, financial condition and results of operations.

For tests that are subject to FDA regulation, we may not be able to obtain timely approvals for our tests or otherwise comply with FDA regulatory requirements, which could delay or prevent us from commercializing our tests or subject us to enforcement action and harm our business.

If the FDA takes action to finalize and implement a regulatory system for LDTs, or if legislation is enacted that subjects LDTs to FDA regulation, we would need to comply with FDA regulatory requirements for our LDTs or any future LDTs intended for clinical use. For products that are subject to FDA requirements, including requirements for premarket clearance or approval, we may not be able to obtain such clearance or approvals on a timely basis, or at all. Our business could be negatively impacted if we are required to stop selling molecular information products pending their clearance or approval, or the launch of any new products that we develop could be delayed. The cost of conducting clinical trials and otherwise developing data and information to support premarket applications may be

significant. In order to conduct a clinical investigation involving human subjects for the purpose of demonstrating the safety and effectiveness of a device, a sponsor of an investigation must, among other things, apply for and obtain institutional review board, or IRB, approval of the proposed investigation. In addition, if the clinical study involves a "significant risk" (as defined by the FDA) to human health, the sponsor of the investigation must also submit and obtain FDA approval of an investigational device exemption, or IDE, application. We or the applicable study sponsor, as applicable, may not be able to obtain FDA and/or IRB approval to undertake clinical trials in the United States for any new devices we intend to market in the United States.

If a product is classified as a Class III medical device, that product would likely be required to be approved by the FDA under a premarket approval, or PMA, which must be supported by valid scientific evidence to demonstrate a reasonable assurance of safety and effectiveness of the subject product, typically including the results of human clinical trials that demonstrate the clinical utility of that product. During the review of our PMAs, the FDA may indicate areas in which the FDA believes additional data or information is necessary to reach a decision on the application. We may need to expend significant time and resources in responding to such FDA requests, which could include performing additional testing or developing new data to support the PMA. Depending

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on the nature of the requests, we may not be able to provide the data or information that the FDA believes necessary to resolve the deficiencies.

For devices not subject to a PMA, we may be required to submit either a de novo reclassification request or, if classified as a Class II medical device, a premarket notification or 510(k). Under the 510(k) process, we must demonstrate that our products are substantially equivalent in technological characteristics and intended use to legally-marketed predicate devices. If we are unable to identify an appropriate predicate that is substantially equivalent to our device, we would be required to submit a PMA or a de novo reclassification request. The FDA's 510(k) clearance process usually takes from four to twelve months, but it can take longer. Under the de novo process, we may request that the FDA classify a low or moderate risk device that lacks an appropriate predicate as a Class I or Class II device. The de novo process typically requires the development of clinical data and usually takes between six to twelve months from the time of submission of the de novo application, but can take longer.

In addition, as part of its review of a PMA, the FDA may conduct preapproval inspections pursuant to the FDA's Bioresearch Monitoring (BIMO) program. During such inspections, FDA investigators may review the data and information supporting our PMA applications or may review the procedures and systems used to design or manufacture the device that is under review. The FDA may indicate areas where additional data or information is necessary, or areas where corrective or preventive actions should be implemented. We may need to expend significant time and resources in responding to such FDA requests, and depending on the nature of the requests, we may not be able to provide the data or information or implement the actions that the FDA believes are necessary.

After approval, products subject to FDA regulation are required to comply with post-market requirements. Among the requirements, we and our suppliers must comply with the FDA's QSR, which sets forth requirements for manufacturers of devices, including the methods and documentation for the design, control testing, quality assurance, labeling, packaging, storage, and shipping of our devices. Further, if there are any modifications made to our PMA-approved marketed products, a PMA supplement may be required to be submitted to, and approved by, the FDA before the modified device may be marketed. Other post-market requirements include facility registration, product listing, adverse event reporting, recalls, corrections and removals, and restrictions on advertising and promotion. These requirements could subject our business to further regulatory risks and costs. The FDA enforces the requirements of the FDCA through announced and unannounced inspections. Failure to comply with the FDA's view of our satisfaction of applicable regulatory requirements could require us to expend time and resources to respond to the FDA's observations and to implement corrective and preventive actions, as appropriate. If we cannot resolve such issues to the satisfaction of the FDA, we may be subject to enforcement actions, including untitled or warning letters, fines, injunctions, or civil or criminal penalties. In addition, we could be subject to a recall or seizure of current or future products, operating restrictions, a partial suspension, or a total shutdown of production. Any such enforcement action would have a material adverse effect on our business, financial condition, and operations.

We are subject to the data privacy, security and breach notification requirements of HIPAA, HITECH and other data privacy and security laws, and the failure to comply with these rules, or allegations that we have failed to do so, could result in civil or criminal sanctions.

Numerous federal and state laws and regulations, including the Health Insurance Portability and Accountability Act of 1996, or HIPAA, and the Health Information Technology for Economic and Clinical Health Act, as amended, or HITECH, govern the collection, dissemination, security, use and confidentiality of patient-identifiable health information. As required by HIPAA, the United States Department of Health and Human Services, or HHS, has adopted standards to protect the privacy and security of this health-related information. The HIPAA privacy regulations contain detailed requirements concerning the use and disclosure of individually identifiable health information and the grant of certain rights to patients with respect to such information by "covered entities." Because of our CLIA laboratory we are a covered entity under HIPAA. We have taken actions to comply with the HIPAA privacy

regulations including the creation and implementation of policies and procedures, staff training, execution of HIPAA-compliant contractual arrangements with certain service providers and various other measures. Although we believe we are in substantial compliance, ongoing implementation and oversight of these measures involves significant time, effort and expense.

In addition to the privacy requirements, HIPAA covered entities must implement certain administrative, physical, and technical security standards to protect the integrity, confidentiality and availability of certain electronic health-related information received, maintained, or transmitted by covered entities or their business associates. Although we have taken actions in an effort to be in compliance with these security regulations, a security incident that bypasses our information security systems causing an information security breach, loss of protected health information, or PHI, or other data subject to privacy laws or a material disruption of our operational systems could have a material adverse effect on our business, along with fines. Furthermore, ongoing implementation and oversight of these security measures involves significant time, effort and expense.

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Further, HITECH, as implemented in part by an omnibus final rule published in the Federal Register on January 25, 2013, further requires that patients be notified of any impermissible acquisition, access, use, or disclosure of their unsecured PHI that compromises the privacy or security of such information. HHS has established the presumption that all impermissible uses or disclosures of unsecured PHI constitute breaches unless the covered entity or business associate establishes affirmatively through a risk analysis that there is a low probability the information has been compromised. HITECH and implementing regulations specify that such notifications must be made without unreasonable delay and in no case later than 60 calendar days after discovery of the breach. Breaches affecting 500 patients or more must be reported immediately to HHS, which will post the name of the breaching entity on its public website. Furthermore, breaches affecting 500 patients or more in the same state or jurisdiction must also be reported to the local media. If a breach involves fewer than 500 people, the covered entity must record it in a log and notify HHS of such breaches at least annually. These breach notification requirements apply not only to impermissible disclosures of unsecured PHI to outside third parties but also to impermissible internal access to or use of such PHI. All breaches also require written notice to be sent to affected individuals.

The scope of the privacy and security requirements under HIPAA was substantially expanded by HITECH, which also increased penalties for violations. Currently, violations of the HIPAA privacy, security and breach notification standards may result in civil penalties ranging from $100 to $50,000 per violation, subject to a cap of $1,500,000 in the aggregate for violations of the same standard in a single calendar year. The amount of penalty that may be assessed depends, in part, upon the culpability of the applicable covered entity or business associate in committing the violation. HITECH also authorized state attorneys general to file suit on behalf of residents of their states. Applicable courts may be able to award damages, costs and attorneys' fees related to violations of HIPAA in such cases. HITECH also mandates that the Secretary of HHS conduct periodic compliance audits of a cross-section of HIPAA covered entities and business associates. Every covered entity and business associate is subject to being audited, regardless of the entity's compliance record.

State laws may impose more protective privacy restrictions related to health information and may afford individuals a private right of action with respect to the violation of such laws. Both state and federal laws are subject to modification or enhancement of privacy protection at any time. We are subject to any federal or state privacy-related laws that are more restrictive than the privacy regulations issued under HIPAA. These statutes vary and could impose additional requirements on us and more severe penalties for disclosures of health information. If we fail to comply with HIPAA, similar state laws or any new laws, including laws addressing data confidentiality, security or breach notification, we could incur substantial monetary penalties and substantial damage to our reputation.

States may also impose restrictions related to the confidentiality of personal information that is not considered PHI under HIPAA, including certain identifying information and financial information of our patients. These state laws may impose additional notification requirements in the event of a breach of such personal information. Failure to comply with such data confidentiality, security and breach notification laws may result in substantial monetary penalties.

HIPAA and HITECH also include standards for common healthcare electronic transactions and code sets, such as claims information, plan eligibility and payment information. Covered entities such as us (with our CLIA laboratory) are required to conform to such transaction set standards.

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 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

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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.

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Healthcare policy changes, including legislation reforming the U.S. healthcare system, may have a material adverse effect on our financial condition, results of operations, and cash flows.

In March 2010, legislation collectively referred to as the Affordable Care Act, or ACA, was enacted in the United States. The ACA, as subsequently amended, made a number of substantial changes in the way healthcare is financed by both governmental and private insurers. Among other things, the ACA:

- requires each medical device manufacturer and importer to pay an excise tax equal to 2.3% of the sale price for its taxable medical devices. In 2015, Congress imposed a 2-year moratorium on this medical device tax, so that medical device sales during the period between January 1, 2016 and December 31, 2017 are exempt from the tax. Absent further legislative action, the tax will be automatically reinstated for medical device sales starting on January 1, 2018. If the tax is reinstated and if our products become regulated as medical devices, we could be required to begin paying this tax on the sales of our products for which we submit a marketing application, such as a 510(k) or PMA, to the FDA; and
- mandates a reduction in payments for clinical laboratory services paid under the Medicare Clinical Laboratory Fee Schedule, or CLFS, of 1.75% for the years 2011 through 2015. In addition, a productivity adjustment is made to the fee schedule payment amount.

On April 1, 2013, cuts to the federal budget were implemented, known as sequestration, resulting in a 2% annual cut in Medicare payments for all services, including clinical laboratory testing. Congress has since extended this 2% Medicare sequester through fiscal year 2025. At this time, it remains uncertain how long the cuts will be continued.

Many CPT procedure codes for molecular pathology tests that we use to bill our products were revised by the American Medical Association, or AMA, effective January 1, 2013. These new CPT codes were developed and implemented for individual genes, or the components of a multi-gene panel. In a final rule for calendar year 2013, CMS announced that it decided to keep the new molecular codes on the CLFS rather than move them to the Physician Fee Schedule. CMS then announced that for 2013, it would price the new codes using a “gap filling” process. Under this approach, CMS referred the CPT codes to the MACs to allow them to determine an appropriate price. CMS then calculated the median of the pricing provided by the MACs to establish and publish a National Limitation Amount, or NLA, by CPT code for 2014.

In 2014, the AMA approved and implemented new CPT codes for genomic sequencing-based panel tests in cancer, effective January 1, 2015. In 2015, CMS used a “gap filling” process to price some of these new codes, which involved referring the new codes to the MACs to allow them to determine and submit to CMS an appropriate price if they deemed a code to be a covered service. CMS then established and published for 2016 an NLA for some of these codes, including the code associated with testing for 5-50 genes as calculated by determining the median price as provided by the MACs for the applicable code. If CMS reduces reimbursement for the new CPT codes for individual genes or fails to price new multi-gene panel codes which cover our products, or if commercial payors who often base pricing on Medicare fee schedules reduce non-contracted payment rates below the new NLA amount for CPT codes corresponding to individual genes, mandate use of the new sequencing-based panel CPT codes, or decide to stop payment on specific CPT codes altogether, our revenue could be adversely affected.

Additionally, in April 2014 the Protecting Access to Medicare Act of 2014, or PAMA, was enacted into law. Section 216 of PAMA reforms the Medicare payment system for clinical laboratory tests paid through the CLFS. PAMA establishes a market-based payment system for Medicare payment for clinical diagnostic laboratory tests. Under this new methodology, CMS will establish Medicare payment for each test based on the weighted median of the payment rates for private payors for the test. PAMA also creates a new class of test called the Advanced Diagnostic Laboratory Test, or ADLT, defined as a test offered and furnished by a single laboratory that is not sold for use by a laboratory other than the original developing laboratory and is either a (1) multi-biomarker test of DNA,

RNA or proteins with a unique algorithm yielding a single, patient-specific result, (2) test that is cleared or approved by the FDA, or (3) test meeting other similar criteria established by the Secretary of Health and Human Services.

PAMA requires certain clinical laboratories meeting a threshold of Medicare revenues to report private payor payment rates and corresponding test volumes. PAMA also directed CMS to establish parameters to implement PAMA by June 30, 2015 and requires the market-based payment system to start on January 1, 2017. In June 2016, CMS issued the Medicare Clinical Diagnostic Laboratory Tests Payment System Final Rule, or the Final Rule, to implement the laboratory test payment provisions of PAMA. Because the issuance of the Final Rule was delayed, CMS delayed the market-based payment rates until January 1, 2018. The agency has issued sub-regulatory guidance on data collection and reporting and on additional topics, including a list of specific billing codes for which laboratories must report data. CMS is expected to publish additional sub-regulatory guidance describing how PAMA will be implemented, including an application process for ADLTs. At this time, the full impact of the implementation of PAMA on new and existing tests is uncertain. Our average commercial payor reimbursement starting in 2018 could be adversely affected depending upon if and how commercial payors adopt this new Medicare pricing methodology and the payment rates.

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The Center for Medicare and Medicaid Innovation announced in June 2016 the launch of the Oncology Care Model, or OCM, beginning on July 1, 2016. The OCM is a five-year voluntary program that includes 190 physician practices in 31 states, as well as 16 private payors. Under the OCM, participating practices receive performance based payments on the basis of how their prices for 6-month "episodes" of cancer care triggered by receipt of chemotherapy compare to "benchmark" prices for similar episodes. These benchmarks are based on the historical data for the period of January 2012 through June 2015. The model may impact the utilization of our tests among those practices participating in OCM.

Finally, the recent presidential and congressional elections in the U.S. could result in significant changes in, and uncertainty with respect to, legislation, regulation and government policy that could significantly impact our business and the healthcare industry. While it is not possible to predict whether and when any such changes will occur, specific proposals discussed during and after the election that could have a material impact on us include, but are not limited to, the repeal of the ACA, modifications and elimination of programs and reductions in staffing at the FDA and CMS, and initiatives to contain or reduce governmental spending in the healthcare area, including Medicare and Medicaid reimbursement. We cannot predict what future healthcare initiatives will be introduced or implemented at the federal or state level, or how any future legislation or regulation may affect us. Any taxes imposed by federal legislation and the expansion of the government's role in the U.S. healthcare industry generally, as well as changes to the reimbursement amounts paid by payors for our existing and future products, may reduce our profits and have a material adverse effect on our business, financial condition, results of operations, and cash flows.

If we fail to comply with the complex federal, state, local and foreign laws and regulations that apply to our business, we could suffer severe consequences that could materially and adversely affect our operating results and financial condition.

We are subject to 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, participation in proficiency testing, patient test management, quality control, quality assurance, and inspections. Our laboratory facilities located in the United States each have a current certificate of accreditation under CLIA to conduct our analyses through our accreditation by CAP. To renew these certificates, we are subject to survey and inspection every two years. Moreover, CLIA inspectors may make unannounced inspections of our clinical reference laboratories at any time.

Any sanction imposed under CLIA, its implementing regulations, or state or foreign laws or regulations governing licensure, or our failure to renew a CLIA certificate, a state or foreign license, or accreditation, could have a material adverse effect on our business. Most CLIA deficiencies are not classified as "condition-level" deficiencies, and there are no adverse effects upon the laboratory operations as long as the deficiencies are corrected. Remediation of these deficiencies are routine matters, with corrections occurring within several hours or weeks. More serious CLIA deficiencies could rise to the level of "condition-level" deficiencies, and CMS has the authority to impose a wide range of sanctions, including revocation of the CLIA certification along with a bar on the ownership or operation of a CLIA certified laboratory by any owners or operators of the deficient laboratory. There is an administrative hearing procedure that can be pursued by the laboratory in the event of imposition of such sanctions, during which the sanctions are stayed, but the process can take a number of years to complete. If we were to lose our CLIA certification or CAP accreditation, we would not be able to operate our clinical laboratories and perform our molecular tests, which would result in material harm to our business and results of operations.

In addition to CLIA and HIPAA, our operations are subject to other extensive federal, state, local, and foreign laws and regulations, all of which are subject to change. These laws and regulations currently include, among others:

- HIPAA, under which the Department of Health and Human Services 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; certain of our services, are subject to these standards and requirements;
- amendments to HIPAA under the Health Information Technology for Economic and Clinical Health Act, or the HITECH Act, and related regulatory amendments, which strengthen and expand HIPAA privacy and security standards, increase penalties for violators, extend enforcement authority to state attorneys general, and impose requirements for breach notification;
- 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, which prohibits a physician from making a referral for certain designated health services covered by a federal healthcare 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;

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- 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;
- the federal Civil Monetary Penalties Law, which prohibits, among other things, the offering or transfer of remuneration to a Medicare or other federal 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 other federal or state healthcare program, unless an exception applies;
- other federal and state fraud and abuse laws, such as anti-kickback 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 clinical laboratory claims, which, subject to certain exceptions, precludes the reassignment of such Medicare claims to any other party;
- the rules regarding billing for diagnostic tests reimbursable by the Medicare program, which in certain circumstances prohibit laboratories from charging the Medicare program directly for services provided to hospital inpatients and outpatients, and also prohibit a physician or other supplier from marking up the price of the technical component or professional component of certain diagnostic tests 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;
- state laws that prohibit other specified practices, such as billing physicians for testing that they order; waiving coinsurance, copayments, deductibles, and other amounts owed by patients; billing a state Medicaid program at a price that is higher than what is charged to one or more other payors;
- federal and state laws regulating lobbying activities, including the disclosure of payments made in connection with such activities; and
- similar foreign laws and regulations that apply to us in the countries in which we operate.

Our failure to comply could lead to civil or criminal penalties, exclusion from participation in government healthcare programs, or prohibitions or restrictions on our ability to conduct commercial activities. We believe that we are in material compliance with all statutory and regulatory requirements, but there is a risk that one or more government agencies could take a contrary position. These laws and regulations are complex and are subject to interpretation by the courts and by government agencies. If one or more such agencies allege that we may be in violation of any of these requirements, regardless of the outcome, it could damage our reputation and adversely affect important business relationships with third parties, including managed care organizations and other commercial third-party payors.

Intellectual Property Risks Related to Our Business

If we are unable to protect our intellectual property effectively, we may be unable to prevent third parties from using our technologies, which would impair our competitive advantage.

We rely on patent protection as well as a combination of trademark, copyright and trade secret protection, and other contractual restrictions to protect our proprietary technologies, all of which provide limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. If we fail to protect our intellectual property, we will be unable to prevent third parties from using our technologies and they will be able to compete more effectively against us.

Our future patent applications may not result in issued patents and any patents issued to us may be challenged, invalidated or held unenforceable. We may not be successful in defending challenges made in connection with our patents and patent applications.

In addition to our patents, we rely on contractual restrictions to protect our proprietary technology. We require our employees and third parties to sign confidentiality agreements and employees to also sign agreements assigning to us

all intellectual property arising from their work for us. Nevertheless, these measures may not be effective in protecting our intellectual property rights.

We depend on certain technologies that are licensed to us. We do not control these technologies and any loss of our rights to them could prevent us from selling some of our products.

We have entered into several license agreements with third parties for certain licensed technologies that are, or may become, relevant to the products we market, or plan to market, including our license agreement with Dana-Farber Cancer Institute, Inc., pursuant to which we license our ICE-COLD-PCR technology. In addition, we may in the future elect to license third party intellectual property to further our business objectives and/or as needed for freedom to operate for our products. We do not and will not own the patents, patent applications or other intellectual property rights that are a subject of these licenses. Our rights to use these technologies and employ the inventions claimed in the licensed patents, patent applications and other intellectual property rights are or will be subject to the continuation of and compliance with the terms of those licenses.

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We might not be able to obtain licenses to technology or other intellectual property rights that we require. Even if such licenses are obtainable, they may not be available at a reasonable cost or multiple licenses may be needed for the same product (e.g., stacked royalties). We could therefore incur substantial costs related to royalty payments for licenses obtained from third parties, which could negatively affect our gross margins. Further, we could encounter delays in product introductions, or interruptions in product sales, as we develop alternative methods or products.

In some cases, we do not or may not control the prosecution, maintenance, or filing of the patents or patent applications to which we hold licenses, or the enforcement of these patents against third parties. As a result, we cannot be certain that drafting or prosecution of the licensed patents and patent applications by the licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights.

The patents issued to us may not be broad enough to provide any meaningful protection one or more of our competitors may develop more effective technologies, designs or methods without infringing our intellectual property rights and one or more of our competitors may design around our proprietary technologies.

If we are not able to protect our proprietary technology, trade secrets and know-how, our competitors may use our inventions to develop competing products. We own certain patents relating to our diagnostic technology. However, these patents may not protect us against our competitors, and patent litigation is very expensive. We may not have sufficient cash available to pursue any patent litigation to its conclusion because other than revenue from licensing, milestone and royalty income we currently generate only minimal revenue from our diagnostic services.

We cannot rely solely on our current patents to be successful. The standards that the U.S. Patent and Trademark Office and foreign patent office’s use to grant patents, and the standards that U.S. and foreign courts use to interpret patents, are not the same and are not always applied predictably or uniformly and can change, particularly as new technologies develop. As such, the degree of patent protection obtained in the U.S. may differ substantially from that obtained in various foreign countries. In some instances, patents have been issued in the U.S. while substantially less or no protection has been obtained in Europe or other countries.

We cannot be certain of the level of protection, if any, which will be provided by our patents if we attempt to enforce them and they are challenged in court where our competitors may raise defenses such as invalidity, unenforceability or possession of a valid license. In addition, the type and extent of any patent claims that may be issued to us in the future are uncertain. Any patents which are issued may not contain claims that will permit us to stop competitors from using similar technology.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights and we may be unable to protect our rights to, or use, our diagnostic technology.

Third parties may challenge the validity of our patents and other intellectual property rights, resulting in costly litigation or other time-consuming and expensive proceedings, which could deprive us of valuable rights. If we become involved in any intellectual property litigation, interference or other judicial or administrative proceedings, we will incur substantial expenses and the diversion of financial resources and technical and management personnel. An adverse determination may subject us to significant liabilities or require us to seek licenses that may not be available from third parties on commercially favorable terms, if at all. Further, if such claims are proven valid, through litigation or otherwise, we may be required to pay substantial financial damages, which can be tripled if the infringement is deemed willful, or be required to discontinue or significantly delay development, marketing, selling and licensing of the affected products and intellectual property rights.

Our competitors may have filed, and may in the future file, patent applications covering technology similar to ours. Any such patent application may have priority over our patent applications and could further require us to obtain rights to issued patents covering such technologies. There may be third-party patents, patent applications and other intellectual property relevant to our potential products that may block or compete with our products or processes. If another party has filed a United States patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the United States Patent and Trademark Office to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful, resulting in a loss of our United States patent position with respect to such inventions. In addition, we may not prevail in any of these suits or that the damages or other remedies if any, awarded against us could be substantial. Claims of intellectual property infringement may require us to enter into royalty or license agreements with third parties that may not be available on acceptable terms, if at all. We may also become subject to injunctions against the further development and use of our technology, which would have a material adverse effect on our business, financial condition and results of operations.

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Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

Third parties may assert ownership or commercial rights to inventions we develop.

Third parties may in the future make claims challenging the inventorship or ownership of our intellectual property. For example, third parties that have been introduced to or have benefited from our inventions may attempt to replicate or reverse engineer our products and circumvent ownership of our inventions. We have written agreements with collaborators that provide for the ownership of intellectual property arising from our collaborations. In some instances, there may not be adequate written provisions to address clearly the resolution of intellectual property rights that may arise from a collaboration. If we cannot successfully negotiate sufficient ownership and commercial rights to the inventions that result from our use of a third-party collaborator's materials where required, or if disputes otherwise arise with respect to the intellectual property developed with the use of a collaborator's samples, we may be limited in our ability to capitalize on the market potential of these inventions. In addition, we may face claims that our agreements with employees, contractors, or consultants obligating them to assign intellectual property to us are ineffective, or in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes regarding intellectual property we have developed or will develop and interfere with our ability to capture the commercial value of such inventions. Litigation may be necessary to resolve an ownership dispute, and if we are not successful, we may be precluded from using certain intellectual property, or may lose our exclusive rights in that intellectual property. Either outcome could have an adverse impact on our business.

Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets.

We employ individuals who were previously employed at other diagnostic or biopharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

The testing, manufacturing and marketing of medical diagnostic devices entails an inherent risk of product liability and personal injury claims.

To date, we have experienced no product liability or personal injury claims, but any such claims arising in the future could have a material adverse effect on our business, financial condition and results of operations. Potential product liability or personal injury claims may exceed the amount of our insurance coverage or may be excluded from coverage under the terms of our policy or limited by other claims under our umbrella insurance policy. Additionally, our existing insurance may not be renewed by us at a cost and level of coverage comparable to that presently in effect, if at all. In the event that we are held liable for a claim against which we are not insured or for damages exceeding the limits of our insurance coverage, such claim could have a material adverse effect on our cash flow and thus potentially a materially adverse effect on our business, financial condition and results of operations.

All of our diagnostic technology development and our clinical services are performed at two laboratories, and in the event either or both of these facilities were to be affected by a termination of the lease or a man-made or natural disaster, our operations could be severely impaired.

We are performing all of our diagnostic services in our CLIA laboratory located in New Haven, Connecticut and our research and development operations are based in our facility in Omaha, Nebraska. Despite precautions taken by us, any future natural or man-made disaster at these laboratories, such as a fire, earthquake or terrorist activity, could cause substantial delays in our operations, damage or destroy our equipment and testing samples or cause us to incur additional expenses.

In addition, we are leasing the facilities where our laboratories operate. We are currently in compliance with all and any lease obligations, but should the leases terminate for any reason, or if at any time either of the laboratories is moved due to conditions outside our control, it could cause substantial delay in our diagnostics operations, damage or destroy our equipment and biological samples or cause us to incur additional expenses. In the event of an extended shutdown of either laboratory, we may be unable to perform our services in a timely manner or at all and therefore would be unable to operate in a commercially competitive manner. This could harm our operating results and financial condition.

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Further, if we have to use a substitute laboratory while our facilities were shut down, we could only use another facility with established state licensure and accreditation under CLIA. We may not be able to find another CLIA-certified facility and comply with applicable procedures, or find any such laboratory that would be willing to perform the tests for us on commercially reasonable terms. Additionally, any new laboratory opened by us would be subject to certification under CLIA and licensure by various states, which would take a significant amount of time and result in delays in our ability to continue our operations.

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

None other than the sales previously disclosed in our Current reports on Form 8-K filed on April 17,2017, June 27, 2017 and June 20, 2017.

Item 6. Exhibits

(a) Exhibits

2.1	Second Amendment to the Merger Agreement (incorporated by reference to Exhibit 2.1 of the Company's Form 8-K filed on June 30, 2017)
3.1	Third Amended and Restated Certificate of Incorporation, as amended (incorporated by reference to Exhibit 3.1 of the Company's Form 8-K filed on June 30, 2017)
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 of the Company's Form 8-K filed on June 30, 2017)
3.3	Certificate of Elimination (incorporated by reference to Exhibit 3.3 of the Company's Form 8-K filed on June 30, 2017)
10.1	Securities Purchase Agreement, dated as of April 13, 2017, between the Company and the investors parties thereto (incorporated by reference to Exhibit 10.1 of the Company's Form 8-K filed on April 17, 2017)
10.2	Form of Bridge Notes (incorporated by reference to Exhibit 10.2 of the Company's Form 8-K filed on April 17, 2017)
10.3	Form of Bridge Warrant (incorporated by reference to Exhibit 10.3 of the Company's Form 8-K filed on April 17, 2017)
10.4	Precipio Note (incorporated by reference to Exhibit 10.4 of the Company's Form 8-K filed on April 17, 2017)
10.5	Subordination Agreement (incorporated by reference to Exhibit 10.5 of the Company's Form 8-K filed on April 17, 2017)
10.6	Side Letter to extend Maturity Date of Unsecured Convertible Promissory Note by and between the Company and MAZ Partners LP, dated as of June 21, 2017 (incorporated by reference to Exhibit 10.1 of the Company's Form 8-K filed on June 27, 2017)
10.7	2017 Stock Option and Incentive Plan (incorporated by reference to Exhibit 10.1 of the Company's Form 8-K filed on June 28, 2017)
10.8	Form of Non-Qualified Stock Option Agreement for Non-Employee Directors (incorporated by reference to Exhibit 10.2 of the Company's Form 8-K filed on June 28, 2017)
10.9	Form of Non-Qualified Stock Option Agreement for Company Employees (incorporated by reference to Exhibit 10.3 of the Company's Form 8-K filed on June 28, 2017)
10.1	Form of Incentive Stock Option Agreement (incorporated by reference to Exhibit 10.4 of the Company's Form 8-K filed on June 28, 2017)
10.11	Securities Purchase Agreement with the Private Placement Purchasers (incorporated by reference to Exhibit 10.1 of the Company's Form 8-K filed on June 30, 2017)
10.12	Investors' Rights Agreement (incorporated by reference to Exhibit 10.2 of the Company's Form 8-K filed on June 30, 2017)
10.13	Exchange Agreement (incorporated by reference to Exhibit 10.3 of the Company's Form 8-K filed on June 30, 2017)
10.14	New Bridge Securities Purchase Agreement (incorporated by reference to Exhibit 10.4 of the Company's Form 8-K filed on June 30, 2017)
10.15	Form of New Bridge Promissory Note (incorporated by reference to Exhibit 10.5 of the Company's Form 8-K filed on June 30, 2017)
10.16	Form of New Bridge Warrant (incorporated by reference to Exhibit 10.6 of the Company's Form 8-K filed on June 30, 2017)
10.17	Form of Side Warrant (incorporated by reference to Exhibit 10.7 of the Company's Form 8-K filed on June 30, 2017)

10.18	Amended and Restated Pathology Services Agreement, dated March 21, 2017, by and between the Company and Yale University (incorporated by reference to Exhibit 10.1 of the Company's Form 8-K/A filed on July 31, 2017)
10.19	Lease, dated July 11, 2017, by and between the Company and Science Park Development Corporation (incorporated by reference to Exhibit 10.2 of the Company's Form 8-K/A filed on July 31, 2017)
31.1	Certification of Ilan Danieli, Chief Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, as amended.

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31.2	Certification of Carl Iberger, Chief Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, as amended.
32.1	Certification of Ilan Danieli, Chief Executive Officer, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, as amended.
32.2	Certification of Carl Iberger, Chief Financial Officer, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, as amended.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

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SIGNATURES

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

PRECIPIO, INC.

Date: August 21, 2017 By: /S/ ILAN DANIELI
Ilan Danieli
Chief Executive Officer (Principal Executive Officer)

Date: August 21, 2017 By: /S/ CARL IBERGER
Carl Iberger
Chief Financial Officer (Principal Financial Officer)