
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM 10-Q**

(Mark One)

- QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended September 30, 2021

OR

- TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from ____ to ____

Commission File Number: 001-36439

PRECIPIO, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

91-1789357
(I.R.S. Employer
Identification No.)

4 Science Park, New Haven, CT
(Address of principal executive offices)

06511
(Zip Code)

(203) 787-7888

(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.01 par value per share	PRPO	The Nasdaq Stock Market LLC

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

Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 such files).

Yes No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer
Emerging growth company

Smaller reporting company

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

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

As of November 10, 2021, the number of shares of common stock outstanding was 22,708,342.

[Table of Contents](#)

PRECIPIO, INC. AND SUBSIDIARIES

INDEX

	<u>Page No.</u>
<u>PART I. Financial Information</u>	3
<u>Item 1. Condensed Consolidated Financial Statements</u>	3
<u>Condensed Consolidated Balance Sheets at September 30, 2021 (unaudited) and December 31, 2020</u>	3
<u>Condensed Consolidated Statements of Operations for the Three and Nine Months Ended September 30, 2021 and 2020 (unaudited)</u>	4
<u>Condensed Consolidated Statements of Stockholders' Equity for the Three and Nine Months Ended September 30, 2021 and 2020 (unaudited)</u>	5
<u>Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2021 and 2020 (unaudited)</u>	7
<u>Notes to the Unaudited Condensed Consolidated Financial Statements</u>	9
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	32
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	38
<u>Item 4. Controls and Procedures</u>	38
<u>PART II. Other Information</u>	40
<u>Item 1. Legal Proceedings</u>	40
<u>Item 1A. Risk Factors</u>	40
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	42

Item 3.	Defaults Upon Senior Securities	42
Item 4.	Mine Safety Disclosures	42
Item 5.	Other Information	42
Item 6.	Exhibits	42
Signatures		43

[Table of Contents](#)

PART 1. FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements

PRECIPIO, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(Dollars in thousands, except share data)

	September 30, 2021	December 31, 2020
	(unaudited)	
ASSETS		
CURRENT ASSETS:		
Cash	\$ 13,223	\$ 2,656
Accounts receivable, net	570	874
Inventories	680	350
Other current assets	617	324
Total current assets	<u>15,090</u>	<u>4,204</u>
PROPERTY AND EQUIPMENT, NET	813	277
OTHER ASSETS:		
Finance lease right-of-use assets, net	487	204
Operating lease right-of-use assets, net	144	306
Intangibles, net	14,955	15,667
Other assets	116	55
Total assets	<u>\$ 31,605</u>	<u>\$ 20,713</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Current maturities of long-term debt, less debt issuance costs	\$ 26	\$ 648
Current maturities of finance lease liabilities	244	48
Current maturities of operating lease liabilities	93	225
Accounts payable	1,572	1,693
Accrued expenses	1,565	2,036
Deferred revenue	<u>148</u>	<u>6</u>

Total current liabilities	3,648	4,656
LONG TERM LIABILITIES:		
Long-term debt, less current maturities and debt issuance costs	167	362
Finance lease liabilities, less current maturities	187	116
Operating lease liabilities, less current maturities	57	92
Common stock warrant liabilities	1,629	1,325
Total liabilities	5,688	6,551
COMMITMENTS AND CONTINGENCIES (Note 6)		
STOCKHOLDERS' EQUITY:		
Preferred stock - \$0.01 par value, 15,000,000 shares authorized at September 30, 2021 and December 31, 2020, 47 shares issued and outstanding at September 30, 2021 and December 31, 2020, liquidation preference of \$331 at September 30, 2021	—	—
Common stock, \$0.01 par value, 150,000,000 shares authorized at September 30, 2021 and December 31, 2020, 22,708,292 and 17,576,916 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	227	176
Additional paid-in capital	103,542	85,523
Accumulated deficit	(77,889)	(71,564)
Total Precipio, Inc. stockholders' equity	25,880	14,135
Noncontrolling interest in joint venture	37	27
Total stockholders' equity	25,917	14,162
Total liabilities and stockholders' equity	\$ 31,605	\$ 20,713

See notes to unaudited condensed consolidated financial statements.

[Table of Contents](#)

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

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2021</u>	<u>2020</u>	<u>2021</u>	<u>2020</u>
SALES:				
Service revenue, net	\$ 1,998	\$ 1,998	\$ 5,980	\$ 5,072
Other revenue	141	51	514	104
Revenue, net of contractual allowances and adjustments	2,139	2,049	6,494	5,176
Adjustment for allowance for doubtful accounts	107	(422)	(80)	(1,025)
Net sales	2,246	1,627	6,414	4,151
COST OF SALES:				
Cost of service revenue	1,450	1,244	4,121	3,472
Cost of other revenue	268	6	546	6
Total cost of sales	1,718	1,250	4,667	3,478
Gross profit	528	377	1,747	673

OPERATING EXPENSES:

Operating expenses	2,967	2,809	8,455	7,567
OPERATING LOSS	(2,439)	(2,432)	(6,708)	(6,894)
OTHER INCOME (EXPENSE):				
Interest expense, net	(6)	(3)	(14)	(470)
Warrant revaluation	578	(857)	(434)	(293)
Gain on settlement of liability	13	—	47	—
Gain on forgiveness of Paycheck Protection Program loan	—	—	794	—
Loss on extinguishment of convertible notes	—	—	—	(1,225)
Other income	—	—	—	153
Total other income (expense)	585	(860)	393	(1,835)
LOSS BEFORE INCOME TAXES	(1,854)	(3,292)	(6,315)	(8,729)
INCOME TAX EXPENSE	—	—	—	—
NET LOSS	(1,854)	(3,292)	(6,315)	(8,729)

Less: Net income attributable to noncontrolling interest in joint venture	(6)	(10)	(10)	(27)
Deemed dividends related to beneficial conversion feature of preferred stock and fair value of warrant down round features	—	—	—	(3,344)
NET LOSS ATTRIBUTABLE TO PRECIPPIO, INC. COMMON STOCKHOLDERS	<u>\$ (1,860)</u>	<u>\$ (3,302)</u>	<u>\$ (6,325)</u>	<u>\$ (12,100)</u>
BASIC AND DILUTED LOSS PER COMMON SHARE	<u>\$ (0.08)</u>	<u>\$ (0.21)</u>	<u>\$ (0.31)</u>	<u>\$ (1.01)</u>
BASIC AND DILUTED WEIGHTED-AVERAGE SHARES OF COMMON STOCK OUTSTANDING	<u>22,708,034</u>	<u>16,007,025</u>	<u>20,555,588</u>	<u>11,925,642</u>

See notes to unaudited condensed consolidated financial statements.

[Table of Contents](#)

PRECIPPIO, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(Dollars in thousands)
(unaudited)

	For the Three Months Ended September 30, 2021								
	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Precippio, Inc.	Noncontrolling Interest in	
	Outstanding Shares	Par Value	Outstanding Shares	Par Value				Joint Venture	Total
Balance, July 1, 2021	47	\$ —	22,707,063	\$ 227	\$ 103,029	\$ (76,029)	\$ 27,227	\$ 31	\$ 27,258
Net (loss) income	—	—	—	—	—	(1,860)	(1,860)	6	(1,854)
Proceeds upon issuance of common stock	—	—	1,229	—	3	—	3	—	3

from exercise of stock options					510		510		510
Stock-based compensation	—	—	—	—	510	—	510	—	510
Balance, September 30, 2021	<u>47</u>	<u>\$ —</u>	<u>22,708,292</u>	<u>\$ 227</u>	<u>\$ 103,542</u>	<u>\$ (77,889)</u>	<u>\$ 25,880</u>	<u>\$ 37</u>	<u>\$25,917</u>

	For the Nine Months Ended September 30, 2021								
	Preferred Stock		Common Stock		Additional		Noncontrolling		
	Outstanding	Par	Outstanding	Par	Paid-in	Accumulated	Total	Interest in	
	Shares	Value	Shares	Value	Capital	Deficit	Precipio, Inc.	Joint Venture	Total
Balance, January 1, 2021	47	\$ —	17,576,916	\$ 176	\$ 85,523	\$ (71,564)	\$ 14,135	\$ 27	\$14,162
Net (loss) income	—	—	—	—	—	(6,325)	(6,325)	10	(6,315)
Issuance of common stock in connection with purchase agreements	—	—	500,000	5	1,255	—	1,260	—	1,260
Issuance of common stock in connection with at the market offering, net of issuance costs	—	—	4,501,000	45	14,902	—	14,947	—	14,947
Proceeds upon issuance of common stock from exercise of warrants	—	—	74,000	1	399	—	400	—	400
Proceeds upon issuance of common stock from exercise of stock options	—	—	1,229	—	3	—	3	—	3
Issuance of common stock for consulting services	—	—	55,147	—	150	—	150	—	150
Stock-based compensation	—	—	—	—	1,310	—	1,310	—	1,310
Balance, September 30, 2021	<u>47</u>	<u>\$ —</u>	<u>22,708,292</u>	<u>\$ 227</u>	<u>\$ 103,542</u>	<u>\$ (77,889)</u>	<u>\$ 25,880</u>	<u>\$ 37</u>	<u>\$25,917</u>

See notes to unaudited condensed consolidated financial statements

PRECIPIO, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY - CONTINUED
(Dollars in thousands)
(unaudited)

	For the Three Months Ended September 30, 2020								
	Preferred Stock		Common Stock		Additional		Total	Noncontrolling	
	Outstanding	Par	Outstanding	Par	Paid-in	Accumulated		Precipio, Inc.	Interest in
	Shares	Value	Shares	Value	Capital	Deficit			
Balance, July 1, 2020	47	\$ —	14,616,916	\$ 146	\$ 78,857	\$ (66,393)	\$ 12,610	\$ 17	\$12,627
Net loss	—	—	—	—	—	(3,302)	(3,302)	10	(3,292)
Issuance of common stock in connection with purchase agreements	—	—	2,060,000	21	4,293	—	4,314	—	4,314
Stock-based compensation	—	—	—	—	212	—	212	—	212
Balance, September 30, 2020	<u>47</u>	<u>\$ —</u>	<u>16,676,916</u>	<u>\$ 167</u>	<u>\$ 83,362</u>	<u>\$ (69,695)</u>	<u>\$ 13,834</u>	<u>\$ 27</u>	<u>\$13,861</u>

	For the Nine Months Ended September 30, 2020								
	Preferred Stock		Common Stock		Additional		Total	Noncontrolling	
	Outstanding	Par	Outstanding	Par	Paid-in	Accumulated		Precipio, Inc.	Interest in
	Shares	Value	Shares	Value	Capital	Deficit			
Balance, January 1, 2020	47	\$ —	7,898,117	\$ 79	\$ 74,065	\$ (60,939)	\$ 13,205	\$ —	\$13,205
Net loss	—	—	—	—	—	(8,756)	(8,756)	27	(8,729)
Conversion of convertible notes into common stock	—	—	3,908,145	39	2,137	—	2,176	—	2,176
Issuance of common stock in connection with purchase agreements	—	—	4,870,654	49	6,872	—	6,921	—	6,921
Write-off beneficial conversion feature in conjunction with convertible note extinguishment	—	—	—	—	(523)	—	(523)	—	(523)
Write-off debt premiums (net of debt discounts) in conjunction with convertible note conversions	—	—	—	—	270	—	270	—	270
Stock-based compensation	—	—	—	—	541	—	541	—	541
Balance, September 30, 2020	<u>47</u>	<u>\$ —</u>	<u>16,676,916</u>	<u>\$ 167</u>	<u>\$ 83,362</u>	<u>\$ (69,695)</u>	<u>\$ 13,834</u>	<u>\$ 27</u>	<u>\$13,861</u>

See notes to unaudited condensed consolidated financial statements

[Table of Contents](#)

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

	Nine Months Ended September 30,	
	2021	2020
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (6,315)	\$ (8,729)
Adjustments to reconcile net loss to net cash flows used in operating activities:		
Depreciation and amortization	835	829
Amortization of operating lease right-of-use asset	162	161
Amortization of finance lease right-of-use asset	44	38
Amortization of deferred financing costs, debt discounts and debt premiums	2	319
Gain on forgiveness of debt	(794)	—
Gain on settlement of liability	(47)	—
Loss on extinguishment of convertible notes	—	1,225
Stock-based compensation	1,310	541
Value of stock issued in payment of services	150	—
Provision for losses on doubtful accounts	82	1,025
Warrant revaluation	434	293
Derecognition of finance lease right-of-use asset	60	—
Gain from sale of fixed asset	—	(55)
Changes in operating assets and liabilities:		
Accounts receivable	222	(1,537)
Inventories	(330)	(96)
Finance lease right-of-use assets	(41)	—
Other assets	(354)	(151)
Accounts payable	(156)	(107)
Operating lease liabilities	(167)	(157)
Accrued expenses and other liabilities	(274)	418
Net cash used in operating activities	(5,177)	(5,983)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(624)	(121)
Proceeds from sale of fixed asset	—	55
Net cash used in investing activities	(624)	(66)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Principal payments on finance lease obligations	(79)	(47)
Issuance of common stock, net of issuance costs	16,207	6,921
Proceeds from exercise of warrants	400	—
Proceeds from exercise of stock options	3	—
Proceeds from PPP Loan	—	787
Principal payments on long-term debt	(33)	(302)
Payments on common stock warrant liabilities	(130)	—
Net cash flows provided by financing activities	16,368	7,359
NET CHANGE IN CASH	10,567	1,310
CASH AT BEGINNING OF PERIOD	2,656	848
CASH AT END OF PERIOD	\$ 13,223	\$ 2,158

See notes to unaudited condensed consolidated financial statements.

[Table of Contents](#)

PRECIPIO, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS- CONTINUED
(Dollars in thousands)
(unaudited)

	<u>Nine Months Ended September 30,</u>	
	<u>2021</u>	<u>2020</u>
SUPPLEMENTAL CASH FLOW INFORMATION		
Cash paid during the period for interest	\$ 22	\$ 25
SUPPLEMENTAL DISCLOSURE OF CONSULTING SERVICES OR ANY OTHER NON-CASH COMMON STOCK RELATED ACTIVITY		
Purchases of equipment financed through accounts payable	35	—
Equipment financed through finance lease obligations	—	21
Conversion of convertible debt, plus interest, into common stock	—	2,176
Prepaid insurance financed with loan	—	23
Write-off of beneficial conversion feature in conjunction with convertible note extinguishment	—	523
Finance lease right-of-use assets obtained in exchange for finance lease obligations	346	—
Write-off of (debt premiums) debt discounts, net, in conjunction with convertible note conversions	—	(270)

See notes to unaudited condensed consolidated financial statements.

[Table of Contents](#)

PRECIPIO, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
For the Three and Nine Months Ended September 30, 2021 and 2020

1. BUSINESS DESCRIPTION*Business Description.*

Precipio, Inc., and its subsidiaries, (collectively, “we”, “us”, “our”, the “Company” or “Precipio”) is a cancer diagnostics and reagent technology company providing diagnostic products, reagents 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 technologies developed in collaboration with academic institutions, and to deliver quality diagnostic information to physicians and their patients worldwide.

We operate a cancer diagnostic laboratory located in New Haven, Connecticut and have partnered with various academic institutions to capture the expertise, experience and technologies developed within academia to provide a better standard of cancer diagnostics and aim to solve the growing problem of cancer misdiagnosis.

In support of our platform, we also operate a research and development facility in Omaha, Nebraska which focuses on the development of various technologies, among them our internally developed proprietary products IV-Cell and HemeScreen. To expand and accelerate our product offering capabilities to commercial laboratories, the Omaha facility was recently CLIA and CAP certified. Functioning side-by-side as a CLIA operating laboratory, the Omaha facility is designed to expand our proficiencies and knowledge in transitioning R&D lab generated technology into a commercial laboratory environment.

Capitalizing on this strategy, during the end of the third quarter 2020, we transitioned our HemeScreen technology from the R&D facility to the commercial laboratory setting launching the HemeScreen Reagent Rental (HSRR) program. HSRR offers oncology practices and hospitals diagnostic reagent sets of the patent-pending HemeScreen technology at significantly lower costs, while reducing the test reporting time from seven (7) to ten (10) days down to one (1) day and improving patient care. HemeScreen tests various molecular markers required for the diagnosis of certain hematologic malignancies, such as acute myeloid leukemia (AML) and myeloproliferative neoplasm (MPN). The HSRR program provides a turn-key test offering together with an option to lease-to-own diagnostic testing equipment from the Company. In most practice settings, such hematologic cancer tests are referenced out as both the cost of equipment and the cost of the diagnostic reagents are prohibitive. By utilizing our HSRR program, the customer can generate in-house testing revenues through reagent purchase contracts and economical lease-to-own rates instead of sending out the same tests to large commercial reference laboratories. The HSRR customer also benefits from obtaining faster results, thus ultimately providing better patient care. During the first half of 2021, the Company began to recognize recurring revenues from its first few HSRR accounts.

During the second quarter of 2021, the Company expanded access to its COVID-19 rapid antibody test by listing on Amazon.com's healthcare website platform. The antibody test is manufactured in the U.S. by Nirmidas Biotech, of California. Precipio holds the exclusive rights to distribute this product on Amazon's platform. The Company's COVID-19 rapid antibody test may currently be purchased by any medical practitioner having a National Provider Identifier ("NPI"), hospitals, medical centers and other qualified medical POC providers

The Company also holds an exclusive license to patented ICE-COLD-PCR ("ICP") technology from Dana-Farber Cancer Institute, Inc., or Dana-Farber, at Harvard University. We believe that such technology will provide additional services and products directed at improving diagnostic outcomes and providing physicians with options for targeted therapies.

Joint Venture.

In April 2020, the Company formed a joint venture with Poplar Healthcare PLLC ("Poplar"), which we refer to as the "Joint Venture". The Joint Venture was formed by the Limited Liability Company Agreement of Precipio

[Table of Contents](#)

Oncometrix LLC, a Delaware limited liability company ("POC"), which was entered into as of April 11, 2020 (the "Effective Date"), by and among POC, Poplar, and Precipio SPV Inc. ("Precipio SPV"), a newly formed subsidiary of the Company, together with such other persons who from time to time become party to the Limited Liability Company Agreement by executing a counterpart signature page in accordance with the terms hereof. POC was formed as a limited liability company on April 2, 2020 in accordance with the statutes and laws of the State of Delaware relating to limited liability companies. Precipio SPV was incorporated in the State of Delaware on March 10, 2020 for the sole purpose of being a party to the Joint Venture.

Under the terms of the Joint Venture, Precipio SPV has a 49% ownership interest in the Joint Venture, with Poplar having a 51 % ownership. Pursuant to the Limited Liability Company Agreement, Poplar, at any time, has the

right to require Precipio SPV to purchase all, but not less than all, of Poplar's shares in the Joint Venture (the "Poplar Put Right"). The purchase price for Poplar's shares shall be \$1.00 per share, or fifty-one dollars, and Precipio SPV would, therefore, become the sole 100% owner of the Joint Venture at the time the Poplar Put Right became effective. The Company has determined that it holds a variable interest in the Joint Venture and is the primary beneficiary of the variable interest entity ("VIE"). See Note 2 - Summary of Significant Accounting Policies for further discussion regarding consolidation of variable interest entities.

The business purpose of the Joint Venture is to facilitate and capitalize on the combined capabilities, resources and healthcare industry relationships of its members by partnering, promoting and providing oncology services to office based physicians, hospitals and medical centers. Operational services of the Joint Venture are performed entirely by its members and employees of its members. Precipio SPV's responsibilities include product and account management services, selling & marketing, laboratory diagnostic services and general & administrative services. Precipio SPV is entitled to a management fee for the services it provides. This management fee is established through service agreements which were executed in conjunction with the formation of the Joint Venture. Poplar receives a similar fee for the billing services that it provides.

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 September 30, 2021, the Company had a net loss of \$6.3 million, working capital of \$11.4 million and net cash used in operating activities of \$5.2 million. The Company's ability to continue as a going concern over the next twelve months from the date of issuance of these condensed consolidated financial statements in this Quarterly Report on Form 10-Q is dependent upon a combination of achieving its business plan, including generating additional revenue and avoiding potential business disruption due to the novel coronavirus ("COVID-19") pandemic, and raising additional financing to meet its debt obligations and paying liabilities arising from normal business operations when they come due.

To meet its current and future obligations the Company has taken the following steps to capitalize the business and successfully achieve its business plan:

- On April 2, 2021, the Company entered into a sales agreement with A.G.P./Alliance Global Partners ("AGP"), pursuant to which the Company may offer and sell its common stock, par value \$0.01 per share (the "Common Stock") (the "Shares"), having aggregate sales proceeds of up to \$22.0 million, to or through AGP, as sales agent (the "AGP Sales Agreement"), from time to time, in an "at the market offering" (as defined in Rule 415(a)(4) under the Securities Act of 1933, as amended) of the Shares (the "ATM Offering"). The Company is limited in the number of shares it can sell in the ATM Offering due to the offering limitations currently applicable to the Company under General Instruction I.B.6. of Form S-3 and the Company's public float as of the applicable date of such sales, as well as the number of authorized and unissued shares available for issuance, in accordance with the terms of the AGP Sales Agreement. The offer and sales of our shares of Common Stock to or through AGP, will be made pursuant to the registration statement (the "Registration Statement") on Form S-3 (File No. 333-237445), which was declared effective by the Securities and Exchange Commission (the "SEC") on April 13,

[Table of Contents](#)

2020, for an aggregate offering price of up to \$50.0 million. From April 2, 2021 through the date the condensed consolidated financial statements were issued, we have already received

approximately \$15.4 million in gross proceeds through the AGP Sales Agreement from the sale of 4,501,000 shares of common stock, leaving the Company an additional \$6.6 million available for future sales pursuant to the AGP Sales Agreement.

Notwithstanding the aforementioned circumstances, there remains substantial doubt about the Company's ability to continue as a going concern for the next twelve months from the date these condensed consolidated financial statements were issued. 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 over the next twelve months from the date of issuance of this Quarterly Report Form 10-Q. The accompanying condensed consolidated 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 and, as of September 30, 2021 and for the three and nine months ended September 30, 2021 and 2020, are unaudited and reflect all adjustments (consisting of only normal recurring adjustments) that are 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 for the year ended December 31, 2020 contained in our Annual Report on Form 10-K, filed with the Securities and Exchange Commission (the "SEC") on March 29, 2021. The results of operations for the interim periods presented are not necessarily indicative of the results for fiscal year 2021.

The condensed consolidated financial statements include the accounts of Precipio and its wholly owned subsidiaries, and the Joint Venture which is a VIE in which we are the primary beneficiary. Refer to the section titled "Consolidation of Variable Interest Entities" for further information related to our accounting for the Joint Venture. All intercompany balances have been eliminated in consolidation.

Reclassifications.

Certain prior period amounts of property and equipment, net and operating lease right-of-use ("ROU") assets have been reclassified to finance lease right-of-use assets to conform to the current period presentation. These reclassifications had no effect on previously reported net earnings or total assets. As of December 31, 2020, the amounts reclassified to finance lease right-of-use assets were \$0.2 million of property and equipment, net and less than \$0.1 million of operating lease right-of-use assets.

Recently Adopted Accounting Pronouncements.

In December 2019, the FASB issued ASU 2019-12 "Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes", which is intended to improve consistent application and simplify the accounting for income taxes. This ASU removes certain exceptions to the general principles in Topic 740 and clarifies and amends existing guidance. The Company adopted this guidance on January 1, 2021. The adoption of this standard was not material to our condensed consolidated financial statements.

Recent Accounting Pronouncements Not Yet Adopted.

In July 2021, the FASB issued ASU 2021-05, Lease (Topic 842), "Lessors - Certain Leases with Variable Lease Payments". This guidance amends the lease classification accounting for lessors for certain leases with variable lease payments that do not depend on a reference index or a rate and would have resulted in the recognition of a loss at lease commencement if classified as a sales-type or direct financing lease. Under the new guidance, these leases will be classified

[Table of Contents](#)

as an operating lease. The amendments are effective for fiscal years beginning after December 15, 2021, with early adoption permitted. The Company is currently evaluating the impact that this ASU will have on its condensed consolidated financial statements and related disclosures.

In May 2021, the FASB issued ASU 2021-04, “*Issuer’s Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options*” which clarifies the accounting for a modification or an exchange of a freestanding equity-classified written call option that remains equity classified after a modification or exchange and the related EPS effects of such transaction if recognized as an adjustment to equity. This ASU becomes effective for all entities for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years, and should be applied prospectively to modifications or exchanges occurring on or after the effective date. The Company is currently evaluating the impact that this ASU will have on its condensed consolidated financial statements and related disclosures.

In August 2020, the FASB issued ASU 2020-06 “*Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity’s Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity’s Own Equity*.” This ASU amends the guidance on convertible instruments and the derivatives scope exception for contracts in an entity’s own equity and improves and amends the related EPS guidance for both Subtopics. The ASU will be effective for annual reporting periods after December 15, 2023 and interim periods within those annual periods and early adoption is permitted in annual reporting periods ending after December 15, 2020. The Company is currently assessing the potential impact that the adoption of this ASU will have on its condensed consolidated financial statements.

In June 2016, the FASB issued ASU 2016-13 “*Measurement of Credit Losses on Financial Instruments*” and subsequent amendments to the initial guidance: ASU 2018-19, ASU 2019-04 and ASU 2019-05 (collectively, “Topic 326”), which replaces current methods for evaluating impairment of financial instruments not measured at fair value, including trade accounts receivable and certain debt securities, with a current expected credit loss model. Topic 326, as amended, is effective for the Company for reporting periods beginning after December 15, 2022. The Company is currently assessing the potential impact that the adoption of this ASU will have on its condensed consolidated financial statements.

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 3,596,917 and 1,832,514 shares of our common stock have been excluded from the computation of diluted loss per share at September 30, 2021 and 2020, respectively, because the effect is anti-dilutive due to the net loss.

The following table summarizes the outstanding securities not included in the computation of diluted net loss per share:

	<u>September 30,</u>	
	<u>2021</u>	<u>2020</u>
Stock options	2,647,516	808,245
Warrants	831,901	906,769
Preferred stock	117,500	117,500

Total	<u>3,596,917</u>	<u>1,832,514</u>
-------	------------------	------------------

Consolidation of Variable Interest Entities.

We evaluate any entity in which we are involved to determine if the entity is a VIE and if so, whether we hold a variable interest and are the primary beneficiary. We consolidate VIEs that are subject to assessment when we are deemed to be the primary beneficiary of the VIE. The process for determining whether we are the primary beneficiary of the VIE is to conclude whether we are a party to the VIE holding a variable interest that meets both of the following criteria: (1)

12

[Table of Contents](#)

has the power to make decisions that most significantly affect the economic performance of the VIE, and (2) has the obligation to absorb losses or the right to receive benefits that in either case could potentially be significant to the VIE.

We have determined that we hold a variable interest in the Joint Venture, have the power to make significant operational decisions on behalf of the VIE and also have the obligation to absorb the majority of the losses from the VIE. As such we have also determined that we are the primary beneficiary of the VIE. The following table presents information about the carrying value of the assets and liabilities of the Joint Venture which we consolidate and which are included on our condensed consolidated balance sheets. Intercompany balances are eliminated in consolidation and not reflected in the following table.

(dollars in thousands)	<u>September 30, 2021</u>	<u>December 31, 2020</u>
Assets:		
Accounts receivable, net	\$ 205	\$ 538
Total assets	<u>\$ 205</u>	<u>\$ 538</u>
Liabilities:		
Accrued expenses	\$ 19	\$ 27
Total liabilities	<u>\$ 19</u>	<u>\$ 27</u>
Noncontrolling interest in Joint Venture	<u>\$ 37</u>	<u>\$ 27</u>
Total stockholders' equity	<u>\$ 72</u>	<u>\$ 53</u>

3. LONG-TERM DEBT

Long-term debt consists of the following:

	<u>Dollars in Thousands</u>	
	<u>September 30, 2021</u>	<u>December 31, 2020</u>
Department of Economic and Community Development (DECD)	\$ 212	\$ 233
DECD debt issuance costs	(19)	(22)
Financed insurance loan	—	12
Paycheck Protection Program	—	787
Total long-term debt	<u>193</u>	<u>1,010</u>
Current portion of long-term debt	(26)	(648)
Long-term debt, net of current maturities	<u>\$ 167</u>	<u>\$ 362</u>

Department of Economic and Community Development.

On January 8, 2018, the Company received gross proceeds of \$400,000 when it entered into an agreement with the Connecticut Department of Economic and Community Development (“DECD”) by which the Company received a grant of \$100,000 and a loan of \$300,000 secured by substantially all of the Company’s assets (the “DECD 2018 Loan”). The DECD 2018 Loan is a ten-year loan due on December 31, 2027 and includes interest paid monthly at 3.25%.

Due to the economic impact of COVID-19, DECD offered financial relief to all businesses with certain loans, including the Company’s DECD 2018 Loan. The relief includes the option to defer all payments from April 1, 2020 to August 1, 2020 and the deferred payments will be added to the end of the loan. The Company chose to defer its payments and the maturity date of the DECD 2018 Loan was extended to May 31, 2028. The payment deferral modification did not have a material impact on the Company’s cash flows.

Debt issuance costs associated with the DECD 2018 Loan were approximately \$31,000. Amortization of the debt issuance costs were less than \$1,000 for the three months ended September 30, 2021 and 2020, respectively and approximately \$3,000 and \$2,000 for the nine months ended September 30, 2021 and 2020, respectively. Net debt issuance costs were approximately \$19,000 and \$22,000 at September 30, 2021 and December 31, 2020, respectively, and are presented as a reduction of the related debt in the accompanying condensed consolidated balance sheets. Amortization for each of the next five years is expected to be approximately \$3,000.

[Table of Contents](#)

Paycheck Protection Program.

On April 23, 2020, the Company entered into a promissory note (the “Promissory Note”) evidencing an unsecured \$787,200 loan under the Paycheck Protection Program (the “PPP Loan”). The Paycheck Protection Program (or “PPP”) was established under the recently congressionally-approved Coronavirus Aid, Relief, and Economic Security Act (the “CARES Act”) and is administered by the U.S. Small Business Administration. The PPP Loan to the Company was made through Webster Bank, N.A.

Under the terms of the CARES Act, PPP Loan recipients can apply for and be granted forgiveness for all or a portion of loans granted under the PPP. Such forgiveness will be determined, subject to limitations, based on the use of loan proceeds for payroll costs and mortgage interest, rent or utility costs and the maintenance of employee and compensation levels.

As of December 31, 2020, using the eight-week forgiveness period, the Company had incurred approximately \$0.8 million in payroll, payroll related costs and other anticipated qualifying expenses with \$0.6 million the PPP Loan’s outstanding balance included in current maturities of long-term debt and \$0.2 million included in long-term debt in the Company’s condensed consolidated balance sheet.

On February 11, 2021, the Company filed its application for loan forgiveness with Webster Bank and was subsequently notified by Webster Bank that effective March 24, 2021 the PPP Loan, plus accrued interest, was considered fully forgiven. As a result, the Company recorded a gain on forgiveness of debt of \$0.8 million in the condensed consolidated statements of operations during the nine months ended September 30, 2021.

4. CONVERTIBLE NOTES

Convertible Bridge Notes.

On April 20, 2018, the Company entered into a securities purchase agreement (the “2018 Note Agreement”) with certain investors, as amended on November 29, 2018 (the “Amendment Agreement”) and amended on April 16, 2019 (“Amendment No.2 Agreement”). The Company also entered into a securities purchase agreement on May 14, 2019. In connection with these securities purchase agreements, the Company issued Senior Secured Convertible Promissory Notes (the “Bridge Notes”) along with warrants during 2018 and 2019.

On March 26, 2020, the Company entered into an amendment agreement (the “March 2020 Amendment”) amending the terms of that certain Amendment No. 2 Agreement dated April 16, 2019 and the securities purchase agreement dated May 14, 2019. As a result of the March 2020 Amendment, (i) the maturity date of the Bridge Notes issued in April 2019 (the “April 2019 Bridge Notes”) and the Bridge Notes issued in May 2019 (the “May 2019 Bridge Notes”) was extended three months from April 16, 2020 to July 16, 2020, (ii) the floor price at which conversions may occur under the April 2019 Bridge Notes and the May 2019 Bridge Notes was amended from \$2.25 to \$0.40, and (iii) guaranteed interest on the April 2019 Bridge Notes and the May 2019 Bridge Notes was amended from twelve months to eighteen months.

The Company reviewed the modifications and concluded that the March 2020 Amendment would be treated as an extinguishment of the related April 2019 Bridge Notes and May 2019 Bridge Notes. As a result, the Company recorded a debt premium on the post-modification debt of \$0.8 million and a loss on extinguishment of convertible notes of \$1.2 million in the condensed consolidated statements of operations during the nine months ended September 30, 2020.

During the three and nine months ended September 30, 2020, zero and \$2.2 million, respectively, of bridge notes, plus interest, were converted into zero and 3,908,145 shares of common stock of the Company, respectively.

During the three months ended September 30, 2020, there was no Bridge Note activity. During the nine months ended September 30, 2020, the change in Bridge Note debt discounts and debt premiums was as follows:

(Dollars in thousands)

For the Nine Months Ended September 30,

14

[Table of Contents](#)

	2020	
	Debt Discounts	Debt Premiums
Beginning balance at January 1	\$ (1,796)	\$ —
Additions:	—	793
Deductions:		
Amortization (accretion) (1)	703	(385)
Write-off related to note conversions (2)	138	(408)
Write-off related to note extinguishment (3)	955	—
Balance at September 30	<u>\$ —</u>	<u>\$ —</u>

- (1) Amortization/accretion is recognized as interest expense/income within the condensed consolidated statements of operations based on the effective interest method.
- (2) Write-offs associated with note conversions are recognized as an offset to additional paid-in capital at the time of the conversion.
- (3) Write-offs associated with note extinguishment are recognized as a loss and included in loss on extinguishment of convertible notes in the condensed consolidated statements of operations.

There were zero convertible notes outstanding at September 30, 2021 and December 31, 2020, respectively.

5. ACCRUED EXPENSES OTHER CURRENT LIABILITIES.

Accrued expenses at September 30, 2021 and December 31, 2020 are as follows:

(dollars in thousands)	2021	2020
Accrued expenses	\$ 739	\$ 906
Accrued compensation	417	685
Accrued franchise, property and sales and use taxes	390	426
Accrued interest	19	19
	<u>\$ 1,565</u>	<u>\$ 2,036</u>

The Company recorded certain settled reductions in accrued expenses and accounts payable as gains which are included in gain on settlement of liability, net in the condensed consolidated statements of operations. During the three and nine months ended September 30, 2021 less than \$0.1 million, respectively, was recorded as a gain. There were no gains on settlement of liability recorded during the three and nine months ended September 30, 2020.

6. COMMITMENTS AND CONTINGENCIES

The Company is involved in legal proceedings related to matters, which are incidental to its business. Also, the Company is delinquent on the payment of outstanding accounts payable for certain vendors and suppliers who have taken or have threatened to take legal action to collect such outstanding amounts. See below for a discussion on these matters.

LITIGATIONS

CPA Global provides us with certain patent management services. On February 6, 2017, CPA Global claimed that we owed 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 less than \$0.1 million has been recorded and is reflected in accounts payable within the accompanying condensed consolidated balance sheets at September 30, 2021 and December 31, 2020.

[Table of Contents](#)

LEGAL AND REGULATORY ENVIRONMENT

The healthcare industry is subject to numerous laws and regulations of federal, state and local governments. These laws and regulations include, but are not 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.

7. LEASES

The Company leases administrative facilities and laboratory equipment through operating lease agreements. In addition we rent various equipment used in our diagnostic lab and in our administrative offices through finance lease arrangements. Our operating leases include both lease (e.g., fixed payments including rent) and non-lease components (e.g., common area or other maintenance costs). The facility leases include one or more options to renew, from 1 to 5 years or more. The exercise of lease renewal options is typically at our sole discretion, therefore, the renewals to extend the lease terms are not included in our ROU assets and lease liabilities as they are not reasonably certain of exercise. We regularly evaluate the renewal options and, when they are reasonably certain of exercise, we include the renewal period in our lease term. As our leases do not provide an implicit rate, we use our collateralized incremental borrowing rate based on the information available at the lease commencement date in determining the present value of the lease payments.

Operating leases result in the recognition of ROU assets and operating lease liabilities on the balance sheet. ROU assets represent our right to use the leased asset for the lease term and lease liabilities represent our obligation to make lease payments. Operating lease ROU assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. Lease expense is recognized on a straight-line basis over the lease term. Leases with an initial term of 12 months or less are not recorded on the balance sheet. The primary leases we enter into with initial terms of 12 months or less are for equipment.

The Company also recognizes ROU assets from finance leases in connection with its HSRR program. For certain customers in the HSRR program, the Company leases diagnostic testing equipment and then subleases the equipment to the customer. Finance lease ROU assets and finance lease liabilities are recognized at the lease commencement date, and at the sublease commencement date the finance lease ROU asset is derecognized and is recorded as cost of sales in the condensed consolidated statements of operations. Derecognized finance lease ROU assets for the three and nine months ended September 30, 2021 were less than \$0.1 million, respectively. There were no finance lease ROU asset transactions during the three and nine months ended September 30, 2020. Where Precipio is the lessor, customers lease diagnostic testing equipment from the Company with the transfer of ownership to the customer at the end of the lease term at no additional cost. For these contracts, the Company accounts for the arrangements as sales-type leases. The lease asset for sales-type leases is the net investment in leased asset, which is included in other current assets and other assets in our condensed consolidated balance sheets. The net investment in leased assets was \$0.1 million and less than \$0.1 million as of September 30, 2021 and December 31, 2020, respectively.

[Table of Contents](#)

The balance sheet presentation of our operating and finance leases is as follows:

(dollars in thousands)

Classification on the Consolidated Balance Sheet	September 30, 2021	December 31, 2020 (1)
Assets:		
Operating lease right-of-use assets, net	\$ 144	\$ 306
Finance lease right-of-use assets, net (2)	487	204

Total lease assets \$ 631 \$ 510

Liabilities:

Current:

Current maturities of operating lease liabilities	\$ 93	\$ 225
Current maturities of finance lease liabilities	244	48

Noncurrent:

Operating lease liabilities, less current maturities	57	92
Finance lease liabilities, less current maturities	187	116

Total lease liabilities \$ 581 \$ 481

- (1) As of December 31, 2020, \$175 of property and equipment, net and \$29 of operating lease right-of-use assets were reclassified to finance lease right-of-use assets to conform to the current period presentation.
- (2) As of September 30, 2021 and December 31, 2020, finance lease right-of-use assets included \$155 and \$29, respectively, of assets related to finance leases associated with the HSRR program.

As of September 30, 2021 and December 31, 2020, the estimated future minimum lease payments, excluding non-lease components, are as follows:

(dollars in thousands)

	Operating Leases		Finance Leases		Total	
	September 30, 2021	December 31, 2020	September 30, 2021	December 31, 2020	September 30, 2021	December 31, 2020
		\$	\$	\$	\$	\$
2021	60	241	60	61	120	302
2022	48	48	176	49	224	97
2023	35	35	100	38	135	73
2024	17	17	80	28	97	45
2025	—	—	65	13	65	13
Thereafter	—	—	26	—	26	—
Total lease obligations	160	341	507	189	667	530
Less: Amount representing interest	(10)	(24)	(76)	(25)	(86)	(49)
Present value of net minimum lease obligations	150	317	431	164	581	481
Less, current portion	(93)	(225)	(244)	(48)	(337)	(273)
Long term portion	<u>57</u>	<u>92</u>	<u>187</u>	<u>116</u>	<u>244</u>	<u>208</u>

[Table of Contents](#)

Other information as of September 30, 2021 and December 31, 2020:

	September 30, 2021	December 31, 2020
Weighted-average remaining lease term (years):		
Operating leases	1.7	1.9

Finance leases	3.2	3.6
Weighted-average discount rate:		
Operating leases	8.00%	8.00%
Finance leases	18.84%	8.28%

During the nine months ended September 30, 2021 and 2020, operating cash flows from operating leases was \$0.2 million, respectively, and operating lease ROU assets obtained in exchange for operating lease liabilities was zero, respectively.

Operating Lease Costs

Operating lease costs were approximately \$0.1 million during the three months ended September 30, 2021 and 2020, respectively, and \$0.3 million and \$0.2 million during the nine months ended September 30, 2021 and 2020, respectively. These costs are primarily related to long-term operating leases for the Company's facilities and laboratory equipment. Short-term and variable lease costs were \$0.1 million for the three and nine months ended September 30, 2021 and 2020, respectively.

Finance Lease Costs

Finance lease amortization and interest expenses are included in the condensed consolidated statements of operations for the three and nine months ended September 30, 2021 and 2020. The balances within these accounts are less than \$0.1 million, respectively.

8. STOCKHOLDERS' EQUITY

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. On December 20, 2018, the Company's shareholders approved the proposal to authorize the Company's Board of Directors to, in its discretion, amend the Company's Third Amended and Restated Certificate of Incorporation to increase the total number of authorized shares of common stock from 150,000,000 shares to 250,000,000 shares. The Company has not yet effected this increase.

During the three and nine months ended September 30, 2021, the Company issued zero and 74,000 shares of its common stock, respectively, in connection with the exercise of 74,000 warrants. The warrant exercises resulted in net cash proceeds to the Company of zero and \$0.4 million during the three and nine months ended September 30, 2021, respectively.

During the three and nine months ended September 30, 2021, the Company issued zero and 55,147 shares of its common stock, respectively, in connection with consulting services of zero and approximately \$0.2 million, respectively.

During the three and nine months ended September 30, 2021, the Company issued 1,229 shares of its common stock, respectively, in connection with the exercise of 1,229 stock options. The stock option exercises resulted in net cash proceeds to the Company of \$3,000 for the three and nine months ended September 30, 2021, respectively.

During the three and nine months ended September 30, 2020, the Company issued zero and 3,908,145 shares of its common stock, respectively, in connection with the conversion of convertible notes, plus interest, totaling zero and \$2.2

million, respectively. There were no shares issued in connection with the conversion of convertible notes during the three and nine months ended September 30, 2021. See Note 4 – Convertible Notes.

LP Purchase Agreement

On September 7, 2018, the Company entered into a purchase agreement (the “LP Purchase Agreement”) with Lincoln Park, pursuant to which Lincoln Park has agreed to purchase from the Company up to an aggregate of \$10,000,000 of common stock of the Company (subject to certain limitations) from time to time over the term of the LP Purchase Agreement.

During the three and nine months ended September 30, 2020, we received zero and \$1.4 million, respectively, from the sale of zero and 1,040,654 shares of common stock to Lincoln Park under the LP Purchase Agreement, respectively. The LP Purchase Agreement terminated during our second fiscal quarter of 2020.

LP 2020 Purchase Agreement

On March 26, 2020, the Company entered into a purchase agreement (the “LP 2020 Purchase Agreement”) and a registration rights agreement (the “LP 2020 Registration Rights Agreement”) with Lincoln Park pursuant to which Lincoln Park has agreed to purchase from us, from time to time, up to \$10,000,000 of our common stock, subject to certain limitations, during the 24 month term of the LP 2020 Purchase Agreement. Pursuant to the terms of the LP 2020 Purchase Agreement, on the agreement date, the Company issued 250,000 shares of its common stock to Lincoln Park as consideration for its commitment to purchase shares of common stock of the Company under the LP Purchase Agreement (the “LP 2020 Commitment Shares”). Pursuant to the terms of the LP 2020 Registration Rights Agreement, on March 27, 2020, as amended on April 8, 2020, the Company filed with the SEC a registration statement on Form S-1 to register for resale under the Securities Act of 1933, as amended, or the Securities Act, 1,770,000 shares of common stock, which includes the LP 2020 Commitment Shares, that have been or may be issued to Lincoln Park under the LP 2020 Purchase Agreement. The Form S-1 was declared effective by the SEC on April 13, 2020. As of June 22, 2020, all shares registered under this S-1 had been sold and/or issued to Lincoln Park. On June 26, 2020, the Company filed with the SEC a registration statement on Form S-1 to register for resale under the Securities Act of 1933, as amended, or the Securities Act, an additional 4,500,000 shares of common stock that have been or may be issued to Lincoln Park under the LP Purchase Agreement. The Form S-1 was amended on July 7, 2020 and declared effective by the SEC on July 7, 2020. For the three and nine months ended September 30, 2020, 2,060,000 shares, respectively, registered under this S-1 had been sold and/or issued to Lincoln Park. As of September 30, 2021, 3,460,000 shares registered under this S-1 had been sold and/or issued to Lincoln Park.

As of the date of this Quarterly Report on Form 10-Q, we have received an aggregate of \$8.8 million from the sale of common stock to Lincoln Park under the LP 2020 Purchase Agreement, including zero and \$1.3 million from the sale of zero and 500,000 shares of common stock, respectively, during the three and nine months ended September 30, 2021. The Company terminated the LP 2020 Purchase Agreement effective June 14, 2021.

At The Market Offering Agreement

On April 2, 2021, the Company entered into a sales agreement with A.G.P./Alliance Global Partners (“AGP”), pursuant to which the Company may offer and sell its common stock, par value \$0.01 per share (the “Common Stock”) (the “Shares”), having aggregate sales proceeds of up to \$22.0 million. Shares can be sold either directly to or through AGP as a sales agent (the “AGP Sales Agreement”), from time to time, in an “at the market offering” (as defined in Rule 415(a)(4) under the Securities Act of 1933, as amended) of the Shares (the “ATM Offering”). The Company is limited in the number of shares it can sell in the ATM Offering due to the offering limitations currently applicable to the Company under General Instruction I.B.6. of Form S-3 and the Company’s public float as of the applicable date of such sales, as well as the number of authorized and unissued shares available for issuance, in accordance with the terms of the AGP Sales Agreement.

[Table of Contents](#)

The sale of our shares of Common Stock to or through AGP, will be made pursuant to the registration statement (the “Registration Statement”) on Form S-3 (File No. 333-237445), which was declared effective by the Securities and Exchange Commission (the “SEC”) on April 13, 2020, for an aggregate offering price of up to \$50.0 million.

Under the AGP Sales Agreement, Shares may be sold by any method permitted by law deemed to be an “at the market offering.” AGP will also be able to sell shares of Common Stock by any other method permitted by law, including in negotiated transactions with the Company’s prior written consent. Upon delivery of a placement notice and subject to the terms and conditions of the AGP Sales Agreement, AGP is required to use its commercially reasonable efforts consistent with its normal trading and sales practices, applicable state and federal law, rules and regulations, and the rules of The Nasdaq Capital Market to sell the Shares from time to time based upon the Company’s instructions, including any price, time or size limits specified by the Company. AGP is not under any obligation to purchase any of the Shares on a principal basis pursuant to the AGP Sales Agreement, except as otherwise agreed by AGP and the Company in writing and expressly set forth in a placement notice. AGP’s obligations to sell the Shares under the AGP Sales Agreement are subject to satisfaction of certain conditions, including customary closing conditions. The Company is not obligated to make any sales of Shares under the AGP Sales Agreement and any determination by the Company to do so will be dependent, among other things, on market conditions and the Company’s capital raising needs.

The Company has agreed to pay AGP a cash fee of 3.0% of the aggregate gross proceeds from the sale of the Shares on the Company’s behalf pursuant to the AGP Sales Agreement. The AGP Sales Agreement contains representations, warranties and covenants that are customary for transactions of this type. In addition, the Company has provided AGP with customary indemnification and contribution rights. The Company has also agreed to reimburse AGP for certain specified expenses, including the expenses of counsel to AGP. The offering of the Shares pursuant to the AGP Sales Agreement will terminate upon the termination of the AGP Sales Agreement by AGP or the Company, as permitted therein.

During the three and nine months ended September 30, 2021, we received net proceeds of zero and approximately \$14.9 million, respectively, from the sale of zero and 4,501,000 shares of common stock through AGP, respectively. There were no sales of common stock through AGP from October 1, 2021 through the date of this Quarterly Report on Form 10-Q.

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.

Series B Preferred Stock.

The Company filed a Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock (“Series B Preferred Stock”) with the State of Delaware, which designates 6,900 shares of our preferred stock as Series B Preferred Stock. The Series B Preferred Stock has a stated value of \$1,000 per share and a par value of \$0.01 per share. The Series B Preferred Stock includes a beneficial ownership blocker but has no dividend rights (except to the extent dividends are also paid on the common stock). On August 28, 2017, the Company completed an underwritten public offering (the “August 2017 Offering”) consisting of the Company’s Series B Preferred Stock and warrants.

The conversion price of the Series B Preferred Stock contains a down round feature. The Company will recognize the effect of the down round feature when it is triggered. At that time, the effect would be treated as a

deemed dividend and as a reduction of income available to common shareholders in our basic earnings per share calculation.

The March 2020 Amendment, see Note 4 – Convertible Notes, triggered the down round feature of the Series B Preferred Stock and, as a result, the conversion price of the Company’s Series B Convertible Preferred Stock was automatically adjusted from \$2.25 per share to \$0.40 per share. In connection with the down round adjustment, the

[Table of Contents](#)

Company calculated an incremental beneficial conversion feature of approximately \$3.3 million which was recognized as a deemed dividend at time of the down round adjustment (“Deemed Dividend A”).

There were no conversions of Series B Preferred Stock during the three and nine months ended September 30, 2021 and 2020, respectively. At September 30, 2021 and December 31, 2020, the Company had 6,900 shares of Series B Preferred Stock designated and issued and 47 shares of Series B Preferred Stock outstanding. Based on the stated value of \$1,000 per share and a conversion price of \$0.40 per share, the outstanding shares of Series B Preferred Stock at September 30, 2021 were convertible into 117,500 shares of common stock.

Common Stock Warrants.

The following represents a summary of the warrants outstanding as of September 30, 2021:

	<u>Issue Year</u>	<u>Expiration</u>	<u>Underlying Shares</u>	<u>Exercise Price</u>
<i>Warrants</i>				
(1)	2017	June 2022	2,540	\$ 41.25
(1)	2017	June 2022	500	\$ 7.50
(2)	2017	June 2022	6,095	\$ 105.00
(3)	2017	August 2022	25,201	\$ 0.40
(4)	2017	August 2022	4,000	\$ 46.88
(5)	2017	August 2022	47,995	\$ 150.00
(5)	2017	August 2022	9,101	\$ 7.50
(6)	2017	August 2022	16,664	\$ 0.40
(6)	2017	August 2022	7,335	\$ 0.40
(7)	2017	October 2022	666	\$ 0.40
(8)	2018	October 2022	7,207	\$ 112.50
(9)	2018	April 2023	69,964	\$ 5.40
(9)	2018	April 2023	78,414	\$ 5.40
(10)	2018	October 2022	15,466	\$ 11.25
(11)	2018	July 2023	14,671	\$ 5.40
(11)	2018	July 2023	14,672	\$ 5.40
(11)	2018	August 2023	20,903	\$ 5.40
(11)	2018	August 2023	20,903	\$ 5.40
(11)	2018	September 2023	19,816	\$ 5.40
(11)	2018	September 2023	20,903	\$ 5.40
(12)	2018	November 2023	75,788	\$ 5.40
(12)	2018	December 2023	51,282	\$ 5.40
(13)	2019	April 2024	147,472	\$ 5.40

(14)	2019	May 2024	154,343	\$	9.56
			831,901		

- (1) These warrants were issued in connection with a June 2017 merger transaction (the “Merger”).
- (2) These warrants were issued in connection with the Merger.
- (3) These warrants were issued in connection with an underwritten public offering completed on August 28, 2017 (the “August 2017 Offering”) and are the August 2017 Offering Warrants discussed below.
- (4) These warrants were issued in connection with the August 2017 Offering.
- (5) These warrants were issued in connection with the conversion of our Series A Senior stock, at the time of the closing of the August 2017 Offering.
- (6) These warrants were issued in connection with the conversion of convertible bridge notes, at the time of the closing of the August 2017 Offering, and are the Note Conversion Warrants discussed below.
- (7) These warrants were issued in connection with the waiver of default the Company received in the fourth quarter of 2017 in connection with the Convertible Promissory Notes and are the Convertible Promissory Note Warrants discussed below.

[Table of Contents](#)

- (8) These warrants were issued in connection with the Debt Obligation settlement agreements and are the Creditor Warrants discussed below.
- (9) These warrants were issued in connection with the 2018 Note Agreement and are the April 2018 Warrants discussed below.
- (10) These warrants were issued in connection with the 2018 Note Agreement and are the Advisor Warrants discussed below.
- (11) These warrants were issued in connection with the 2018 Note Agreement and are the Q3 2018 Warrants discussed below.
- (12) These warrants were issued in connection with the 2018 Note Agreement and subsequent Amendment Agreement and are the Q4 2018 Warrants discussed below.
- (13) These warrants were issued in connection with the 2018 Note Agreement and subsequent Amendment No. 2 Agreement and are the April 2019 Warrants discussed below.
- (14) These warrants were issued in connection with the May 2019 Bridge Notes and are the May 2019 Warrants discussed below.

During the three months ended September 30, 2021 and 2020, zero warrants expired, respectively. During the nine months ended September 30, 2021 and 2020, 239 and 2,420 warrants expired, respectively. These warrants had been issued in connection with transactions which were completed between October 2014 and January 2016.

During the nine months ended September 30, 2021, 357 warrants were settled for cash of approximately \$0.1 million. For further discussion, see the 2016 Warrant Liability in Note 9 – Fair Value.

August 2017 Offering Warrants

In connection with the August 2017 Offering, the Company issued 178,666 warrants at an exercise price of \$45.00 per share, which contain a down round provision (the “August 2017 Offering Warrants”). The August 2017 Offering Warrants were exercisable immediately and expire 5 years from date of issuance.

As a result of the March 2020 Amendment, the exercise price of the August 2017 Offering Warrants was adjusted from \$2.25 per share to \$0.40 per share. At the time the exercise price was adjusted, the Company calculated the fair value of the down round provision on the warrants to be approximately \$6,000 and recorded this as a deemed dividend (“Deemed Dividend B”).

Note Conversion Warrants

Upon the closing of the August 2017 Offering, the Company issued 23,999 warrants to purchase the Company's common stock (the "Note Conversion Warrants"). The Note Conversion Warrants have an exercise price of \$45.00 per share and contain a down round provision.

As a result of the March 2020 Amendment, the exercise price of the Note Conversion Warrants was adjusted from \$2.25 per share to \$0.40 per share. At the time the exercise price was adjusted, the Company calculated the fair value of the down round provision on the warrants to be approximately \$5,000 and recorded this as a deemed dividend ("Deemed Dividend C").

Convertible Promissory Note Warrants

The Convertible Promissory Note Warrants had an original exercise price of \$45.00 per share and contain a down round provision.

As a result of the March 2020 Amendment, the exercise price of the Convertible Promissory Note Warrants was adjusted from \$2.25 per share to \$0.40 per share. At the time the exercise price was adjusted, the Company calculated the fair value of the down round provision on the warrants to be less than \$1,000 and recorded this as a deemed dividend ("Deemed Dividend D").

[Table of Contents](#)

Creditor Warrants

In the fourth quarter of 2017, the Company entered into Settlement Agreements with the Creditors pursuant to which the Company agreed to issue, to certain of its Creditors, 7,207 Creditor Warrants (the "Creditor Warrants") to purchase 7,207 shares of the Company's common stock at an exercise price of \$112.50 per share. The Creditor Warrants were issued in February 2018.

April 2018 Warrants

In connection with the issuance of Bridge Notes in April 2018, the Company issued 243,224 warrants at an exercise price of \$11.25 per share at time of issuance. At issuance, half of these April 2018 Warrants had a five-year term and half had a one-year term. In April 2019, as a result of the Amendment No.2 Agreement, the exercise price of the April 2018 Warrants was adjusted to \$5.40 per share and all April 2018 Warrants that had a one-year term were amended to have a five-year term.

There were 43,138 April 2018 Warrants exercised during the nine months ended September 30, 2021 for proceeds to the Company of approximately \$0.2 million. During the nine months ended September 30, 2021, the intrinsic value of the April 2018 Warrants exercised was less than \$0.1 million.

Advisor Warrants

At the time of the 2018 Note Agreement, the Company issued 15,466 warrants with an exercise price of \$11.25 per share to a financial advisor.

Q3 2018 Warrants

In connection with the issuance of Bridge Notes during the third quarter of 2018, the Company issued 196,340 warrants with an exercise price of \$11.25 per share at time of issuance (the “Q3 2018 Warrants”). At the time of issuance, half of these Q3 2018 Warrants had a five-year term and half had a one-year term. In September 2018, the exercise price was modified to \$7.50 per share. In April 2019, as a result of the Amendment No.2 Agreement, the exercise price of the Q3 2018 Warrants was adjusted to \$5.40 per share and all Q3 2018 Warrants that had a one-year term were amended to have a five-year term.

There were 30,862 Q3 2018 Warrants exercised during the nine months ended September 30, 2021 for proceeds to the Company of approximately \$0.2 million. During the nine months ended September 30, 2021, the intrinsic value of the Q3 2018 Warrants exercised was less than \$0.1 million.

Q4 2018 Warrants

In connection with the issuance Bridge Notes during the fourth quarter of 2018, the Company issued 300,115 warrants with an exercise price of \$5.40 per share at time of issuance and a five-year term (the “Q4 2018 Warrants”).

April 2019 Warrants

In connection with the issuance of the April 2019 Bridge Notes, the Company issued 147,472 warrants with an exercise price of \$5.40 per share and a five-year term.

May 2019 Warrants

In connection with the issuance of the May 2019 Bridge Notes, the Company issued 154,343 warrants with an exercise price of \$5.40 per share and a five-year term.

[Table of Contents](#)

Deemed Dividends

As discussed above, certain of our preferred stock and warrant issuances contain down round provisions which require us 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 earnings per share.

There were no deemed dividends during the three and nine months ended September 30, 2021 or the three months ended September 30, 2020. The following represents a summary of the dividends recorded for the nine months ended September 30, 2020:

Deemed Dividends	Amount Recorded (in thousands)
<i>Dividends resulting from the March 2020 Amendment</i>	
Deemed Dividend A	\$ 3,333
Deemed Dividend B	6
Deemed Dividend C	5
Deemed Dividend D	*
For the nine months ended September 30, 2020	\$ 3,344

* Represents less than one thousand dollars

9. 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. 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 statements of operations.

2016 Warrant Liability

The Company has a warrant liability related to warrants issued in January 2016 (the “2016 Warrant Liability”) and it represents the fair value of such warrants, of which, 357 warrants were settled for cash of approximately \$0.1 million in January 2021. The balance of the 2016 Warrant Liability was zero as of September 30, 2021.

[Table of Contents](#)

The 2016 Warrant Liability is considered a Level 3 financial instrument and was valued using the Black Scholes model. As of December 31, 2020, assumptions and inputs used in the valuation of the 2016 Warrant Liability include: remaining life to maturity of less than one month; annual volatility of 135%; and a risk-free interest rate of 0.08%.

Bridge Note Warrant Liabilities

During 2018 and 2019, the Company issued warrants in connection with the issuance of Bridge Notes. All of these warrants issuances were classified as warrant liabilities (the “Bridge Note Warrant Liabilities”). See Note 4 - Convertible Notes for further discussion.

The Bridge Note Warrant Liabilities are considered Level 3 financial instruments and were valued using the Black Scholes model. As of September 30, 2021, assumptions used in the valuation of the Bridge Note Warrant Liabilities include: remaining life to maturity of 0.6 to 2.6 years; volatility rate of 169% to 206%; and risk free rate of 0.05% to 0.41%. As of December 31, 2020, assumptions used in the valuation of the Bridge Note Warrant Liabilities include: remaining life to maturity of 1.3 to 3.4 years; volatility rate of 162% to 201%; and risk free rate of 0.10% to 0.17%.

During the three and nine months ended September 30, 2021 and 2020, the change in the fair value of the warrant liabilities measured using significant unobservable inputs (Level 3) were comprised of the following:

Dollars in Thousands

	Three Months Ended September 30, 2021		
	2016 Warrant Liability	Bridge Note Warrant Liabilities	Total Warrant Liabilities
Beginning balance at July 1	\$ –	\$ 2,207	\$ 2,207
Total gains:			
Revaluation recognized in earnings	–	(578)	(578)
Balance at September 30	<u>\$ –</u>	<u>\$ 1,629</u>	<u>\$ 1,629</u>

	Three Months Ended September 30, 2020		
	2016 Warrant Liability	Bridge Note Warrant Liabilities	Total Warrant Liabilities
Beginning balance at July 1	\$ 39	\$ 735	\$ 774
Total losses:			
Revaluation recognized in earnings	63	794	857
Balance at September 30	<u>\$ 102</u>	<u>\$ 1,529</u>	<u>\$ 1,631</u>

Dollars in Thousands

	Nine Months Ended September 30, 2021		
	2016 Warrant Liability	Bridge Note Warrant Liabilities	Total Warrant Liabilities
Beginning balance at January 1	\$ 130	\$ 1,195	\$ 1,325
Total losses:			
Revaluation recognized in earnings	–	434	434
Deductions – warrant exercises	(130)	–	(130)
Balance at September 30	<u>\$ –</u>	<u>\$ 1,629</u>	<u>\$ 1,629</u>

	Nine Months Ended September 30, 2020		
	2016 Warrant Liability	Bridge Note Warrant Liabilities	Total Warrant Liabilities
Beginning balance at January 1	\$ 70	\$ 1,268	\$ 1,338
Total losses:			
Revaluation recognized in earnings	32	261	293
Balance at September 30	<u>\$ 102</u>	<u>\$ 1,529</u>	<u>\$ 1,631</u>

[Table of Contents](#)

10. EQUITY INCENTIVE PLAN

The Company currently issues stock awards under its 2017 Stock Option and Incentive Plan, as amended (the "2017 Plan") which will expire on June 5, 2027. The shares authorized for issuance under the 2017 Plan were 2,717,431 at September 30, 2021, of which 68,767 were available for future grant. The shares authorized under the 2017 Plan were increased by 925,000 shares by stockholder vote on June 18, 2021 and are subject to annual increases on January 1 by 5% of the number of shares of common stock issued and outstanding on the immediately preceding December 31, or such lesser number of shares determined by the Company's Board of Directors or Compensation Committee. During the nine months ended September 30, 2021, the shares authorized for issuance increased by 1,803,845 shares.

Stock Options.

The Company accounts for all stock-based compensation payments to employees and directors, including grants of employee stock options, at fair value at the date of grant and expenses the benefit in operating expense in the condensed consolidated statements of operations over the service period of the awards. The Company records the expense for stock-based compensation awards subject to performance-based milestone vesting over the remaining service period when management determines that achievement of the milestone is probable based on the expected satisfaction of the performance conditions as of the reporting date. The fair value of each stock option granted is estimated on the date of grant using the Black-Scholes option pricing model, which requires various assumptions including estimating stock price volatility, expected life of the stock option, risk free interest rate and estimated forfeiture rate.

During the nine months ended September 30, 2021, the Company granted stock options to purchase up to 1,907,347 shares of common stock at a weighted average exercise price of \$2.89 per share. The following table summarizes stock option activity under our plans during the nine months ended September 30, 2021:

	Number of Options	Weighted-Average Exercise Price
Outstanding at January 1, 2021	822,992	\$ 4.46
Granted	1,907,347	2.89
Exercised	(1,229)	2.04
Forfeited	(81,594)	2.83
Outstanding at September 30, 2021	<u>2,647,516</u>	<u>\$ 3.38</u>
Exercisable at September 30, 2021	<u>633,027</u>	<u>\$ 4.91</u>

As of September 30, 2021, there were 1,972,128 options that were vested or expected to vest with an aggregate intrinsic value of \$0.7 million and a remaining weighted average contractual life of 8.9 years.

During the nine months ended September 30, 2020, there were 393,050 options granted with a weighted average exercise price of \$1.99 per share and 75,135 options forfeited with a weighted average exercise price of \$13.86 per share.

For the three and nine months ended September 30, 2021, we recorded compensation expense for all stock awards of \$0.5 million and \$1.3 million, respectively, within operating expense in the accompanying statements of operations. For the three and nine months ended September 30, 2020, we recorded compensation expense for all stock awards of \$0.2 million and \$0.5 million, respectively. As of September 30, 2021, the unrecognized compensation

expense related to unvested stock awards was \$5.4 million, which is expected to be recognized over a weighted-average period of 3.0 years.

11. SALES SERVICE REVENUE, NET AND ACCOUNTS RECEIVABLE

ASC Topic 606, "Revenue from contracts with customers"

The Company follows the guidance of ASC 606 for the recognition of revenue from contracts with customers to transfer goods and services. The Company performed a comprehensive review of its existing revenue arrangements following the five-step model:

26

[Table of Contents](#)

Step 1: Identification of the contract with the customer. Sub-steps include determining the customer in a contract; Initial contract identification and determine if multiple contracts should be combined and accounted for as a single transaction.

Step 2: Identify the performance obligation in the contract. Sub-steps include identifying the promised goods and services in the contract and identifying which performance obligations within the contract are distinct.

Step 3: Determine the transaction price. Sub-steps include variable consideration, constraining estimates of variable consideration, the existence of a significant financing component in the contract, noncash consideration and consideration payable to a customer.

Step 4: Allocate transaction price. Sub-steps include assessing the amount of consideration to which the Company expects to be entitled in exchange for transferring the promised goods or services to the customer.

Step 5: Satisfaction of performance obligations. Sub-steps include ascertaining the point in time when an asset is transferred to the customer and the customer obtains control of the asset upon which time the Company recognizes revenue.

Nature of Contracts and Customers

The Company's contracts and related performance obligations are similar for its customers and the sales process for all customers starts upon the receipt of requisition forms from the customers for patient diagnostic testing and the execution of contracts for biomarker testing and clinical research. Payment terms for the services provided are 30 days, unless separately negotiated.

Diagnostic testing

Control of the laboratory testing services is transferred to the customer at a point in time. As such, the Company recognizes revenue for laboratory testing services at a point in time based on the delivery method (web-portal access or fax) for the patient's laboratory report, per the contract.

Clinical research grants

Control of the clinical research services are transferred to the customer over time. The Company will recognize revenue utilizing the "effort based" method, measuring its progress toward complete satisfaction of the performance obligation.

Biomarker testing and clinical project services

Control of the biomarker testing and clinical project services are transferred to the customer over time. The Company utilizes an “effort based” method of assessing performance and measures progress towards satisfaction of the performance obligation based upon the delivery of results.

The Company generates revenue from the provision of diagnostic testing provided to patients, biomarker testing provided to bio-pharma customers and clinical research grants funded by both bio-pharma customers and government health programs.

Reagents and other diagnostic products

Control of reagents and other diagnostic products are transferred to the customer at a point in time and, as such, the Company recognizes these revenues at a point in time based on the delivery method. These revenues include revenues from reagent sets for our HSRR program, COVID-19 antibody tests and other product sales and are included in other revenue in our condensed consolidated statements of operations.

27

[Table of Contents](#)

Equipment leasing

The Company accounts for sales-type leases within the scope of ASC 842, Leases, as ASC 606 specifically excludes leases from its guidance. The sales-type leases result in the derecognition of the underlying asset, the recognition of profit or loss on the sale, and the recognition of an investment in leased asset. Revenue from sales-type leases is recognized upfront on the commencement date of the lease, and is included in other revenue in our condensed consolidated statements of operations. For the three and nine months ended September 30, 2021, revenue from sales-type leases was less than \$0.1 million, respectively. There was no revenue from sales-type leases for the three and nine months ended September 30, 2020.

Disaggregation of Revenues by Transaction Type

We operate in one business segment and, therefore, the results of our operations are reported on a consolidated basis for purposes of segment reporting, consistent with internal management reporting. Service revenue, net for the three and nine months ended September 30, 2021 and 2020 was as follows:

(dollars in thousands)	For the Three Months Ended September 30,					
	Diagnostic Testing		Biomarker Testing		Total	
	2021	2020	2021	2020	2021	2020
Medicaid	\$ 4	\$ 15	\$ —	\$ —	\$ 4	\$ 15
Medicare	942	811	—	—	942	811
Self-pay	65	196	—	—	65	196
Third party payers	952	950	—	—	952	950
Contract diagnostics	—	—	35	26	35	26
Service revenue, net	<u>\$ 1,963</u>	<u>\$ 1,972</u>	<u>\$ 35</u>	<u>\$ 26</u>	<u>\$ 1,998</u>	<u>\$ 1,998</u>

(dollars in thousands)	For the Nine Months Ended September 30,					
	Diagnostic Testing		Biomarker Testing		Total	
	2021	2020	2021	2020	2021	2020
Medicaid	\$ 35	\$ 40	\$ —	\$ —	\$ 35	\$ 40
Medicare	2,935	1,979	—	—	2,935	1,979
Self-pay	181	332	—	—	181	332
Third party payers	2,773	2,313	—	—	2,773	2,313
Contract diagnostics	—	—	56	408	56	408
Service revenue, net	<u>\$ 5,924</u>	<u>\$ 4,664</u>	<u>\$ 56</u>	<u>\$ 408</u>	<u>\$ 5,980</u>	<u>\$ 5,072</u>

Revenue from the Medicare and Medicaid programs account for a portion of the Company's patient diagnostic service revenue. Laws and regulations governing those programs are extremely complex and subject to interpretation. As a result, there is at least a reasonable possibility that recorded estimates will change by a material amount in the near term.

Revenue Recognition

Revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To the extent the transaction price includes variable consideration, the Company estimates the amount of variable consideration that should be included in the transaction price using the expected value method based on historical experience. The Company does not typically enter arrangements where multiple contracts can be combined as the terms regarding services are generally found within a single agreement/requisition form. The Company derives its revenues from the following types of transactions: diagnostic testing ("Diagnostic"), revenues from the Company's ICP technology and bio-pharma projects encompassing genetic diagnostics (collectively "Biomarker"), revenues from clinical research grants from state and federal research programs and diagnostic product sales, including revenues from equipment leases and reagent sales associated with our HSRR program.

[Table of Contents](#)

Deferred revenue

Deferred revenue, or unearned revenue, refers to advance payments for products or services that are to be delivered in the future. The Company records such prepayment of unearned revenue as a liability, as revenue that has not yet been earned, but represents products or services that are owed to a customer. As the product or service is delivered over time, the Company recognizes the appropriate amount of revenue from deferred revenue. For the period ended September 30, 2021 and December 31, 2020, the deferred revenue was \$148,000 and \$6,000, respectively.

Contractual Allowances and Adjustments

We are reimbursed by payers for services we provide. Payments for services covered by payers average less than billed charges. We monitor revenue and receivables from payers and record an estimated contractual allowance for certain revenue and receivable balances as of the revenue recognition date to properly account for anticipated differences between amounts estimated in our billing system and amounts ultimately reimbursed by payers. Accordingly, the total revenue and receivables reported in our condensed consolidated financial statements are recorded at the amounts expected to be received from these payers. For service revenue, the contractual allowance is estimated based on several criteria, including unbilled claims, historical trends based on actual claims paid, current contract and reimbursement terms and changes in customer base and payer/product mix. The billing functions for the remaining portion of our revenue are contracted and fixed fees for specific services and are recorded without an

allowance for contractual discounts. The following table presents our revenues initially recognized for each associated payer class during the three and nine months ended September 30, 2021 and 2020.

(dollars in thousands)	For the Three Months Ended September 30,					
	Gross Revenues		Contractual Allowances and adjustments		Revenues, net of Contractual Allowances and adjustments	
	2021	2020	2021	2020	2021	2020
Medicaid	\$ 4	\$ 15	\$ —	\$ —	\$ 4	\$ 15
Medicare	942	811	—	—	942	811
Self-pay	65	196	—	—	65	196
Third party payers	3,313	3,188	(2,361)	(2,238)	952	950
Contract diagnostics	35	26	—	—	35	26
	4,359	4,236	(2,361)	(2,238)	1,998	1,998
Other	141	51	—	—	141	51
	<u>\$ 4,500</u>	<u>\$ 4,287</u>	<u>\$ (2,361)</u>	<u>\$ (2,238)</u>	<u>\$ 2,139</u>	<u>\$ 2,049</u>

(dollars in thousands)	For the Nine Months Ended September 30,					
	Gross Revenues		Contractual Allowances and adjustments		Revenues, net of Contractual Allowances and adjustments	
	2021	2020	2021	2020	2021	2020
Medicaid	\$ 35	\$ 40	\$ —	\$ —	\$ 35	\$ 40
Medicare	2,935	1,979	—	—	2,935	1,979
Self-pay	181	335	—	(3)	181	332
Third party payers	9,670	7,944	(6,897)	(5,631)	2,773	2,313
Contract diagnostics	56	408	—	—	56	408
	12,877	10,706	(6,897)	(5,634)	5,980	5,072
Other	514	104	—	—	514	104
	<u>\$13,391</u>	<u>\$10,810</u>	<u>\$ (6,897)</u>	<u>\$ (5,634)</u>	<u>\$ 6,494</u>	<u>\$ 5,176</u>

[Table of Contents](#)

Allowance for Doubtful Accounts

The Company provides for a general allowance for collectability of services when recording net sales. The Company has adopted the policy of recognizing net sales to the extent it expects to collect that amount. Reference is made to FASB 954-605-45-5 and ASU 2011-07, Health Care Entities: Presentation and Disclosure of Patient Service Revenue, Provision for Bad Debt, and the Allowance for Doubtful Accounts. The change in the allowance for doubtful accounts is directly related to the increase in patient service revenues. The following table presents our reported revenues net of the collection allowance and adjustments for the three and nine months ended September 30, 2021 and 2020.

For the Three Months Ended September 30,

(dollars in thousands)	Revenues, net of					
	Contractual Allowances and adjustments		Allowances for doubtful accounts		Total	
	2021	2020	2021	2020	2021	2020
Medicaid	\$ 4	\$ 15	\$ (3)	\$ (15)	\$ 1	\$ —
Medicare	942	811	(47)	(121)	895	690
Self-pay	65	196	—	—	65	196
Third party payers	952	950	157	(286)	1,109	664
Contract diagnostics	35	26	—	—	35	26
	1,998	1,998	107	(422)	2,105	1,576
Other	141	51	—	—	141	51
	<u>\$ 2,139</u>	<u>\$ 2,049</u>	<u>\$ 107</u>	<u>\$ (422)</u>	<u>\$ 2,246</u>	<u>\$ 1,627</u>

For the Nine Months Ended September 30,

(dollars in thousands)	Revenues, net of					
	Contractual Allowances and adjustments		Allowances for doubtful accounts		Total	
	2021	2020	2021	2020	2021	2020
Medicaid	\$ 35	\$ 40	\$ (2)	\$ (40)	\$ 33	\$ —
Medicare	2,935	1,979	(36)	(296)	2,899	1,683
Self-pay	181	332	—	—	181	332
Third party payers	2,773	2,313	(42)	(689)	2,731	1,624
Contract diagnostics	56	408	—	—	56	408
	5,980	5,072	(80)	(1,025)	5,900	4,047
Other	514	104	—	—	514	104
	<u>\$ 6,494</u>	<u>\$ 5,176</u>	<u>\$ (80)</u>	<u>\$ (1,025)</u>	<u>\$ 6,414</u>	<u>\$ 4,151</u>

Costs to Obtain or Fulfill a Customer Contract

Sales commissions are expensed when incurred because the amortization period would have been one year or less. These costs are recorded in operating expenses in the condensed consolidated statements of operations.

Shipping and handling costs are comprised of inbound and outbound freight and associated labor. The Company accounts for shipping and handling activities related to contracts with customers as fulfillment costs which are included in cost of sales in the condensed consolidated statements of operations.

Accounts Receivable

The Company has provided an allowance for potential credit losses, which has been determined based on management's industry experience. The Company grants credit without collateral to its patients, most of who are insured under third party payer agreements.

The following summarizes the mix of receivables outstanding related to payer categories:

(dollars in thousands)	September 30, 2021	December 31, 2020
Medicaid	\$ 17	\$ 131
Medicare	492	1,054
Self-pay	94	276
Third party payers	1,102	3,373
Contract diagnostic services and other	168	53
	<u>\$ 1,873</u>	<u>\$ 4,887</u>
Less allowance for doubtful accounts	(1,303)	(4,013)
Accounts receivable, net	<u>\$ 570</u>	<u>\$ 874</u>

The following table presents the roll-forward of the allowance for doubtful accounts for the nine months ended September 30, 2021.

(dollars in thousands)		Allowance for Doubtful Accounts
Balance, January 1, 2021		\$ (4,013)
Collection Allowance:		
Medicaid	\$ (2)	
Medicare	(36)	
Third party payers	(42)	
	<u>(80)</u>	
Bad debt expense	\$ (2)	
Total charges		(82)
Write-offs		2,792
Balance, September 30, 2021		<u>\$ (1,303)</u>

Customer Revenue and Accounts Receivable Concentration

Our customers are oncologists, hospitals, reference laboratories, physician-office laboratories, and pharma and biotech companies. Customers that accounted for 10% or greater of our net sales or accounts receivable for the identified periods is as follows:

	Net sales				Accounts receivable, as of	
	Three Months Ended		Nine Months Ended		September 30, 2021	December 31, 2020
	September 30, 2021	2020	September 30, 2021	2020		
Customer A	*	*	*	*	22 %	*

* represents less than 10%

12. SUBSEQUENT EVENTS

The Company has evaluated events and transactions subsequent to September 30, 2021 through the date the condensed consolidated financial statements were issued and there are no other events to report other than what has been disclosed in the condensed consolidated financial statements.

[Table of Contents](#)

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: the expected or potential impact of COVID-19 which is highly uncertain and will depend on future developments, our expected revenue, income (loss), receivables, operating expenses, supplier pricing, availability and prices of raw materials, insurance reimbursements, product pricing, sources of funding operations, 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 negative versions of 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 and our prior filings with the Securities and Exchange Commission.

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 condensed consolidated financial statements and related notes contained in this Quarterly Report on Form 10-Q and with the financial statements, related notes and Management’s Discussion and Analysis included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020, which we filed with the Securities and Exchange Commission on March 29, 2020. Results for the three and nine months ended September 30, 2021 are not necessarily indicative of results that may be attained in the future.

Overview

We are a cancer diagnostics and reagent technology company providing diagnostic products, reagents 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 technologies developed in collaboration with 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 various academic institutions to capture the expertise, experience and technologies developed within academia to provide a better standard of cancer diagnostics and aim to solve the growing problem of cancer misdiagnosis. In support of this platform, we also operate a research and development facility in Omaha, Nebraska which focuses on the development of various technologies, among them our internally developed proprietary products IV-Cell and HemeScreen. To expand our product offering capabilities, the Omaha facility was recently CLIA and CAP certified in order to process a variety of commercial molecular tests previously referenced out and to further expand our capabilities and know-how in transitioning R&D lab generated technology into a commercial laboratory environment.

The Company also holds an exclusive license to patented ICE-COLD-PCR (“ICP”) technology from Dana-Farber Cancer Institute, Inc., or Dana-Farber, at Harvard University. We believe that such technology will provide additional

[Table of Contents](#)

services and products directed at improving diagnostic outcomes and providing physicians with options for targeted therapies.

In April 2020, we formed a Joint Venture with Poplar. Poplar provides specialized laboratory testing services to a nationwide client base of gastroenterologists, dermatologists, oncologists, urologists, gynecologists and their patients. The business purpose of the Joint Venture is to facilitate and capitalize on the combined capabilities, resources and healthcare industry relationships of its members by partnering, promoting and providing oncology services to office based physicians, hospitals and medical centers. Under the terms of the Joint Venture, Precipio SPV has a 49% ownership interest in the Joint Venture, with Poplar having a 51% ownership. We have determined that we hold a variable interest in the Joint Venture and that we are the primary beneficiary of the Joint Venture. Due to this determination, we consolidate the Joint Venture. See Note 2 - Summary of Significant Accounting Policies for further discussion.

Recent Developments

Business Activities – HemeScreen

The HemeScreen Reagent Program (“HSSR”) offers oncology practices and hospitals diagnostic reagent sets of our patent-pending HemeScreen technology at significantly lower costs, while reducing the test reporting time from 7 to 10 days down to 1 day and improving patient care. The HSSR program provides a turn-key test offering together with an option to lease-to-own diagnostic testing equipment from the Company. In most practice settings, such hematologic cancer tests are referenced out as both the cost of equipment and the cost of the diagnostic reagents are prohibitive. By utilizing our HSSR program the customer can generate in-house testing revenues through reagent purchase contracts and economical lease-to-own rates. Customers can generate in-house revenues and profits instead of sending out the same tests to large commercial reference laboratories. The HSSR customer also benefits from obtaining faster results, thus ultimately providing better patient care. During the first half of 2021, the Company began to recognize recurring revenues from its first few HSSR accounts.

Business Activities – COVID Testing

During the second quarter of 2021, the Company expanded access to its COVID-19 rapid antibody test by listing on Amazon.com’s healthcare website platform. The antibody test is manufactured in the USA by Nirmidas Biotech, of California. Precipio holds the exclusive rights to distribute this product on Amazon’s platform. The COVID-19 rapid antibody test may currently be purchased by any medical practitioner having a National Provider Identifier (“NPI”), hospitals, medical centers and other qualified medical POC providers.

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 September 30, 2021, the Company had a net loss of \$6.3 million, working capital of \$11.4 million and net cash used in operating activities of \$5.2 million. The Company’s ability to continue as a going concern over the next twelve months from the

date of issuance of this Quarterly Report on Form 10-Q is dependent upon a combination of achieving its business plan, including generating additional revenue and avoiding potential business disruption due to COVID-19, and raising additional financing to meet its debt obligations and paying liabilities arising from normal business operations when they come due.

To meet its current and future obligations the Company has taken the following steps to capitalize the business and successfully achieve its business plan:

- On April 2, 2021, the Company entered into a sales agreement with A.G.P./Alliance Global Partners (“AGP”), pursuant to which the Company may offer and sell its common stock, par value \$0.01 per share (the “Common Stock”) (the “Shares”), having aggregate sales proceeds of up to \$22.0 million, to or through AGP, as sales agent (the “AGP Sales Agreement”), from time to time, in an “at the market

[Table of Contents](#)

offering” (as defined in Rule 415(a)(4) under the Securities Act of 1933, as amended) of the Shares (the “ATM Offering”). The Company is limited in the number of shares it can sell in the ATM Offering due to the offering limitations currently applicable to the Company under General Instruction I.B.6. of Form S-3 and the Company’s public float as of the applicable date of such sales, as well as the number of authorized and unissued shares available for issuance, in accordance with the terms of the AGP Sales Agreement. The offer and sales of our shares of Common Stock to or through AGP, will be made pursuant to the registration statement (the “Registration Statement”) on Form S-3 (File No. 333-237445), which was declared effective by the Securities and Exchange Commission (the “SEC”) on April 13, 2020, for an aggregate offering price of up to \$50.0 million. From April 2, 2021 through the date the condensed consolidated financial statements were issued, we have already received approximately \$15.4 million in gross proceeds through the AGP Sales Agreement from the sale of 4,501,000 shares of common stock, leaving the Company an additional \$6.6 million available for future sales pursuant to the AGP Sales Agreement.

Notwithstanding the aforementioned circumstances, there remains substantial doubt about the Company’s ability to continue as a going concern over the next twelve months from the date of issuance of this Quarterly Report on Form 10-Q. 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 condensed consolidated 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.

Outlook - COVID-19 related

The COVID-19 outbreak, which spread worldwide in the first quarter of 2020, has caused significant business disruption. The extent of the impact of the ongoing COVID-19 pandemic on the Company’s operational and financial performance will depend on certain developments, including the duration and spread of the outbreak, and impact on the Company’s customers, employees and vendors, all of which are uncertain and cannot be predicted. These uncertainties could have a material adverse effect on our business, financial condition or results of operations. We have been actively monitoring the COVID-19 situation and its impact on the global economy and the Company. As the global pandemic evolves, we will continue to monitor the extent to which COVID-19 impacts our revenues, expenses and liquidity.

Results of Operations for the Three Months Ended September 30, 2021 and 2020

Net Sales. Net sales were as follows:

	Dollars in Thousands			
	Three Months Ended			
	September 30,		Change	
	2021	2020	\$	%
Service revenue, net, less allowance for doubtful accounts	\$ 2,105	\$ 1,576	\$ 529	34 %
Other	141	51	90	176 %
Net Sales	<u>\$ 2,246</u>	<u>\$ 1,627</u>	<u>\$ 619</u>	<u>38 %</u>

Net sales for the three months ended September 30, 2021 were approximately \$2.2 million, an increase of \$0.6 million as compared to the same period in 2020. During the three months ended September 30, 2021, patient diagnostic service revenue increased \$0.5 million as compared to the same period in 2020 due to an increase in cases processed. This increase was the result of a lower allowance for doubtful accounts recorded during the three months ended September 30, 2021 as compared to the prior year period. We processed 1,103 cases during the three months ended September 30, 2021 as compared to 1,135 cases during the same period in 2020, or a 3% decrease in cases. Contract diagnostics revenue of less than \$0.1 million for the three months ended September 30, 2021 was flat as compared to the same period in 2020. Other revenue increased \$0.1 million for the three months ended September 30, 2021 as compared to the same period in 2020, mostly resulting from increased revenue related to our HSRR program.

[Table of Contents](#)

Cost of Sales. Cost of sales includes material and supply costs for the patient tests performed, costs related to HSRR products and other direct costs (primarily personnel costs, pathologist interpretation costs and rent) associated with the operations of our laboratory. Cost of sales increased by \$0.5 million for the three months ended September 30, 2021 as compared to the same period in 2020. The increase included a \$0.2 million increase in patient diagnostic costs and a \$0.3 million increase in costs related to our HSRR program revenue as we increased personnel and other costs to support new customers.

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

	Dollars in Thousands			
	Three Months Ended			
	September 30,		Margin %	
	2021	2020	2021	2020
Gross Profit	<u>\$ 528</u>	<u>\$ 377</u>	<u>24 %</u>	<u>23 %</u>

Gross margin was 24% of total net sales, for the three months ended September 30, 2021, compared to 23% of total net sales for the same period in 2020. Gross profit was approximately \$0.5 million and \$0.4 million during the three months ended September 30, 2021 and 2020, respectively. The gross margin increased during the three months ended September 30, 2021, as compared to the prior year period, as a result of an increase in patient diagnostic case revenue partially offset by the increase in costs associated with our HSRR program as discussed above. We operate a fully staffed CLIA and CAP certified clinical pathology and molecular laboratory. As such, it is necessary to maintain

appropriate staffing levels to provide industry standard laboratory processing and reporting to ordering physicians. An increase in case volume will enable our laboratory to yield economies of scale and to leverage fixed expenses. We anticipate case volume and HSRR revenues to increase during the remainder of 2021 and into 2022 and for our costs per case to improve as additional economies of scale are possible.

Operating Expenses. Operating expenses primarily consist of personnel costs, professional fees, travel costs, facility costs and depreciation and amortization. Our operating expenses increased by \$0.2 million to \$3.0 million for the three months ended September 30, 2021 as compared to the same period in 2020. The increase included increases of \$0.2 million in general and administrative expenses and \$0.3 million in stock based compensation expenses, partially offset by a decrease of \$0.3 million in sales and marketing expenses.

Other (Expense) Income. We recorded net other income of \$0.6 million and net other expense of \$0.9 million for the three months ended September 30, 2021 and 2020, respectively. The current year period other income of \$0.6 is primarily attributable to income recorded on warrant revaluations.

Results of Operations for the Nine Months Ended September 30, 2021 and 2020

Net Sales. Net sales were as follows:

	Dollars in Thousands			
	Nine Months Ended		Change	
	September 30,			
	2021	2020	\$	%
Service revenue, net, less allowance for doubtful accounts	\$ 5,900	\$ 4,047	\$ 1,853	46 %
Other	514	104	410	394 %
Net Sales	<u>\$ 6,414</u>	<u>\$ 4,151</u>	<u>\$ 2,263</u>	<u>55 %</u>

Net sales for the nine months ended September 30, 2021 were approximately \$6.4 million, an increase of \$2.3 million as compared to the same period in 2020. During the nine months ended September 30, 2021, patient diagnostic service revenue increased \$2.2 million as compared to the same period in 2020 due to an increase in cases processed and a lower allowance for doubtful accounts that was recorded. We processed 3,354 cases during the nine months ended September 30, 2021 as compared to 2,575 cases during the same period in 2020, or a 30% increase in cases. The increase in patient diagnostic service revenue was partially offset by a decrease of \$0.4 million in service revenue from contract

[Table of Contents](#)

diagnostics for the nine months ended September 30, 2021 as compared to the same period in 2020. Other revenue increased \$0.4 million for the nine months ended September 30, 2021 as compared to the same period in 2020, mostly resulting from increased revenue related to our HSRR program.

Cost of Sales. Cost of sales includes material and supply costs for the patient tests performed, costs related to HSRR products and other direct costs (primarily personnel costs, pathologist interpretation costs and rent) associated with the operations of our laboratory. Cost of sales increased by \$1.2 million for the nine months ended September 30, 2021 as compared to the same period in 2020. The increase included an increase in patient diagnostic costs and costs related to HSRR revenue partially offset by a decrease in contract diagnostic costs which are in line with the changes in related revenues discussed above.

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

	Dollars in Thousands			
	Nine Months Ended		Margin %	
	September 30,			
	2021	2020	2021	2020
Gross Profit	\$ 1,747	673	27 %	16 %

Gross margin was 27% of total net sales, for the nine months ended September 30, 2021, compared to 16% of total net sales for the same period in 2020. Gross profit was approximately \$1.7 million and \$0.7 million during the nine months ended September 30, 2021 and 2020, respectively. The gross margin increased during the nine months ended September 30, 2021, as compared to the prior year period, as a result of increases in case volume and revenue. We operate a fully staffed CLIA and CAP certified clinical pathology and molecular laboratory. As such, it is necessary to maintain appropriate staffing levels to provide industry standard laboratory processing and reporting to ordering physicians. The increase in case volume enabled our laboratory to yield economies of scale and to leverage fixed expenses. We anticipate case volume to increase during 2021 and for our costs per case to improve as additional economies of scale are possible.

Operating Expenses. Operating expenses primarily consist of personnel costs, professional fees, travel costs, facility costs and depreciation and amortization. Our operating expenses increased by \$0.9 million to \$8.5 million for the nine months ended September 30, 2021 as compared to the same period in 2020. The increase included an increase of \$0.6 million in general and administrative expenses due to an increase in personnel costs and professional fees and an increase of \$0.8 million in stock based compensation expenses. These increases were partially offset by a decrease of \$0.6 million in sales and marketing expenses resulting from a decrease in personnel costs.

Other (Expense) Income. We recorded net other income of \$0.4 million and net other expense of \$1.8 million for the nine months ended September 30, 2021 and 2020, respectively. The current year period other income of \$0.4 million includes \$0.4 million of expense from warrant revaluations partially offset by \$0.8 million of a gain on forgiveness of debt related to the forgiveness of our PPP Loan.

During the nine months ended September 30, 2020, net other expense of \$1.8 million includes \$0.3 million of interest expense from the amortization of debt discounts, net of accretion of debt premiums, related to convertible notes, \$0.2 million of other interest expense, \$1.2 million expense for loss on extinguishment of convertible notes which was recorded in conjunction with the March 2020 Amendment and \$0.3 million of expense recorded on warrant revaluations. The expenses were partially offset by \$0.2 million of other income. Approximately \$0.1 million of the other income is funds we received from the U.S. Department of Health and Human Services (“HHS”). As part of the CARES Act, HHS distributed funds to healthcare providers that received Medicare fee-for-service reimbursements in 2019. The payments from HHS are not loans and will not be required to be repaid.

[Table of Contents](#)

Liquidity and Capital Resources

Our working capital positions were as follows:

	Dollars in Thousands		
	September 30, 2021	December 31, 2020	Change
Current assets (including cash of \$13,223 and \$2,656 respectively)	\$ 15,090	\$ 4,204	\$ 10,886
Current liabilities	3,648	4,656	(1,008)

Working capital	\$	11,442	\$	(452)	\$	11,894
-----------------	----	--------	----	-------	----	--------

During the nine months ended September 30, 2021 we received net proceeds of \$16.2 million from the sale of 5,001,000 shares of our common stock and \$0.4 million from the issuance of 74,000 shares of common stock in connection with the exercise of 74,000 warrants.

Analysis of Cash Flows – Nine Months Ended September 30, 2021 and 2020

Net Change in Cash. Cash increased by \$10.6 million and \$1.3 million during the nine months ended September 30, 2021 and 2020, respectively.

Cash Flows Used in Operating Activities. The cash flows used in operating activities of approximately \$5.2 million during the nine months ended September 30, 2021 included a net loss of \$6.3 million, an increase in inventories of \$0.3 million, an increase in finance lease right of use assets of less than \$0.1 million, an increase in other assets of \$0.3 million, a decrease in accounts payable, accrued expenses and other liabilities of \$0.4 million and a decrease in operating lease liabilities of \$0.2 million. These were partially offset by a decrease in accounts receivable of \$0.2 million and non-cash adjustments of \$2.2 million. The non-cash adjustments included \$0.1 million for the change in provision for losses on doubtful accounts. We routinely provide a reserve for doubtful accounts as a result of having limited in-network payer contracts. Non-cash adjustments also included \$0.8 million for a gain on forgiveness of debt, which resulted from the forgiveness of the PPP Loan. The other non-cash adjustments to net loss of approximately \$2.9 million include, among other things, depreciation and amortization, warrant revaluations and stock based compensation. The cash flows used in operating activities of approximately \$6.0 million during the nine months ended September 30, 2020 included a net loss of \$8.7 million, an increase in accounts receivable of \$1.5 million, an increase in inventories and other assets of \$0.3 million and a decrease in accounts payable and operating lease liabilities of \$0.3 million. These were partially offset by an increase in accrued expenses and other liabilities of \$0.4 million and non-cash adjustments of \$4.4 million.

Cash Flows Used In Investing Activities. Cash flows used in investing activities were \$0.6 million and \$0.1 million for the nine months ended September 30, 2021 and 2020, respectively, resulting from purchases of property and equipment.

Cash Flows Provided by Financing Activities. Cash flows provided by financing activities totaled \$16.4 million for the nine months ended September 30, 2021, which included proceeds of \$16.2 million from the issuance of common stock and \$0.4 million from warrant exercises. These were partially offset by payments on our long-term debt and finance lease obligations of \$0.1 million and payments on common stock warrant liabilities of \$0.1 million. Cash flows provided by financing activities totaled \$7.4 million for the nine months ended September 30, 2020, which included proceeds of \$6.9 million from the issuance of common stock and proceeds of \$0.8 million from the PPP Loan. These proceeds were partially offset by payments on our long-term debt and convertible notes of \$0.3 million.

Off-Balance Sheet Arrangements

At each of September 30, 2021 and December 31, 2020, 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.

No significant changes to contractual obligations and commitments occurred during the nine months ended September 30, 2021, as compared to those disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020, filed with the Securities and Exchange Commission on March 29, 2021.

Critical Accounting Policies and Estimates

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. Our critical accounting policies are discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020, filed with the Securities and Exchange Commission on March 29, 2021.

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 consolidated 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

As of the end of the period covered by this Quarterly Report on Form 10-Q, management performed, with the participation of our Chief Executive Officer and Chief Financial Officer, an evaluation of the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). Our disclosure controls and procedures are designed to provide reasonable assurance that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission (the “SEC”), and that such information is accumulated and communicated to management including our Chief Executive Officer and our Chief Financial Officer, to allow timely decisions regarding required disclosures. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and no evaluation of controls and procedures can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected. Management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at a reasonable assurance level as of September 30, 2021.

[Table of Contents](#)

Changes in Internal Control over Financial Reporting

We have evaluated the changes in our internal control over financial reporting that occurred during the three months ended September 30, 2021 and concluded that there have not been any changes that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

[Table of Contents](#)

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

CPA Global provides us with certain patent management services. On February 6, 2017, CPA Global claimed that we owed 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 less than \$0.1 million has been recorded and is reflected in accounts payable within the accompanying condensed consolidated balance sheets at September 30, 2021 and December 31, 2020.

LEGAL AND REGULATORY ENVIRONMENT

The healthcare industry is subject to numerous laws and regulations of federal, state and local governments. These laws and regulations include, but are not 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.

Item 1A. Risk Factors

As disclosed in “Item 1A. Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2020, 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, 2020, which could materially affect our business, financial condition or future results. The risks described in this Quarterly Report and our Annual Report on Form 10-K 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.

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 September 30, 2021, we had a net loss of \$6.3 million, working capital of \$11.4 million and net cash used in operating activities of \$5.2 million. To date, we have experienced negative cash flow from development of our diagnostic technology, as well as from the costs associated with establishing a laboratory and building a sales force to market our products and services. We expect to incur substantial net losses for the foreseeable future to further develop and commercialize our diagnostic technology. We also expect that our selling, general and administrative expenses will continue to increase due to the additional costs associated with market development activities and expanding our staff to sell and support our products. Our ability to achieve or, if achieved, sustain profitability is based on numerous factors, many of which are beyond our control, including the market acceptance of our products, competitive product development and our market penetration and margins. We may never be able to generate sufficient revenue to achieve or, if achieved, sustain profitability.

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

[Table of Contents](#)

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

As of September 30, 2021, our cash balance was \$13.2 million and our working capital was approximately \$11.4 million. Due to our recurring losses from operations and the expectation that we will continue to incur losses in the future, we may be required to raise additional capital to complete the development and commercialization of our current product candidates and to pay off our obligations. To date, to fund our operations and develop and commercialize our products, we have relied primarily on equity and debt financings. In future periods, when we seek additional capital, we may seek to sell additional equity and/or debt securities or to obtain a credit facility, which we may not be able to do on favorable terms, or at all. Our ability to obtain additional financing will be subject to a number of factors, including market conditions, our operating performance and investor sentiment. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue the development and/or commercialization of one or more of our product candidates, restrict or cease our operations or obtain funds by entering into agreements on unattractive terms.

We face risks related to health pandemics and other widespread outbreaks of contagious disease, including the novel coronavirus, COVID-19, which could significantly disrupt our operations and impact our financial results.

Our business could be disrupted and materially adversely affected by the recent outbreak of COVID-19. In December 2019, an outbreak of respiratory illness caused by a strain of novel coronavirus, COVID-19, began in China. As of September 2021, that outbreak has led to numerous confirmed cases worldwide, including in the United States. The outbreak and government measures taken in response have also had a significant impact, both direct and indirect, on businesses and commerce. Global health concerns, such as coronavirus, could also result in social, economic, and labor instability in the countries in which we or the third parties with whom we engage operate.

The spread of COVID-19 has created a worldwide humanitarian and economic crisis. The events we are living through are in many ways unprecedented, with large-scale quarantines, border closings, school closings, and physical distancing. Governments and communities have been jolted into action to “flatten the curve.” As an organization we have accelerated our actions to protect employees, customers and suppliers.

The progression of the outbreak and its effects on our business and operations are uncertain. While we can only estimate the financial impacts to our business, based on current data, we have experienced business interruptions in certain urban markets that continue to range from 30% to 85%. With the understanding that it is extremely difficult to project the full and ongoing impact of state-by-state quarantine and shelter-in-place orders, we anticipate that such rules and restrictions on businesses will continue through 2021 and quite possibly beyond, in various degrees, as the country re-opens state by state, county by county and city by city. Returning to normalcy is conditioned on many factors surrounding the control and or eradication of COVID-19. As such, we are unable to provide additional insight on the impact to our business at this time.

Going forward, we expect that challenges to our business will continue. We have been and will continue to be prudent in managing through this economic crisis. Digital connectivity is now fundamental to the continuity of our business operations. We continually engage our employees and customers in keeping safe. We monitor adherence to governmental guidelines. We have employed remote work where possible. In this uncharted time, we recognize the need for frequent and transparent communication to all parties. As necessary, we will provide additional information related to this economic condition, including the impact to our future operating results due to downturns in global economies and financial markets.

[Table of Contents](#)

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

None.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

(a) Exhibits

- 31.1 [Certification of Principal Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, as amended.](#)
- 31.2 [Certification of Principal Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, as amended.](#)
- 32.1* [Certification of Principal Executive Officer, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, as amended.](#)
- 32.2* [Certification of Principal Financial Officer, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, as amended.](#)
- 101.INS XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL 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
- 104 Cover Page Interactive Data File - the cover page interactive data file does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.

* This certification is not deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, except to the extent that the Registrant specifically incorporates it by reference

[Table of Contents](#)

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: November 12, 2021

By: /S/ ILAN DANIELI

Ilan Danieli
Chief Executive Officer (Principal Executive Officer)

