

**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, 2020
- TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Commission File Number: 001-39049

EXAGEN INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

1261 Liberty Way
Vista, California
(Address of Principal Executive Offices)

20-0434866
(I.R.S. Employer
Identification No.)

92081
(Zip Code)

(760) 560-1501

(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, par value \$0.001 per share	XGN	The Nasdaq Global Market

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 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 during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a 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 Securities Exchange Act of 1934.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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 Securities Act

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

Total shares of common stock outstanding as of the close of business on November 6, 2020 was 12,652,138.

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Part I. Financial Information
Item 1. Condensed Financial Statements
Exagen Inc.
Condensed Balance Sheets
(in thousands, except share and per share data)

	September 30, 2020 (Unaudited)	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	\$ 61,434	\$ 72,084
Accounts receivable, net	9,297	5,715
Prepaid expenses and other current assets	1,824	3,451
Total current assets	72,555	81,250
Property and equipment, net	1,758	1,380
Goodwill	5,506	5,506
Other assets	174	174
Total assets	\$ 79,993	\$ 88,310
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 2,454	\$ 1,476
Accrued and other current liabilities	5,820	4,419
Total current liabilities	8,274	5,895
Borrowings-non-current portion, net of discounts and debt issuance costs	26,453	25,854
Deferred tax liabilities	147	264
Other non-current liabilities	645	638
Total liabilities	35,519	32,651
Commitments and contingencies (Note 5)		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized, no shares issued or outstanding at September 30, 2020 and December 31, 2019	—	—
Common stock, \$0.001 par value; 200,000,000 shares authorized at September 30, 2020 and December 31, 2019; 12,652,113 and 12,560,990 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	13	13
Additional paid-in capital	222,297	220,248
Accumulated deficit	(177,836)	(164,602)
Total stockholders' equity	44,474	55,659
Total liabilities and stockholders' equity	\$ 79,993	\$ 88,310

The accompanying notes are an integral part of these financial statements

Exagen Inc.
Unaudited Condensed Statements of Operations
(in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenue	\$ 10,775	\$ 10,439	\$ 29,307	\$ 30,173
Operating expenses:				
Costs of revenue	4,341	4,783	12,224	14,217
Selling, general and administrative expenses	9,202	7,306	27,104	20,787
Research and development expenses	1,018	507	2,403	1,610
Total operating expenses	14,561	12,596	41,731	36,614
Loss from operations	(3,786)	(2,157)	(12,424)	(6,441)
Interest expense	(647)	(909)	(1,913)	(2,720)
Change in fair value of financial instruments	—	(200)	—	267
Other income, net	125	125	985	264
Loss before income taxes	(4,308)	(3,141)	(13,352)	(8,630)
Income tax benefit	—	—	118	—
Net loss	(4,308)	(3,141)	(13,234)	(8,630)
Accretion of redeemable convertible preferred stock	—	(338)	—	(4,640)
Deemed dividend recorded in connection with financing transactions	—	(13,601)	—	(13,601)
Net loss attributable to common stockholders (Note 2)	\$ (4,308)	\$ (17,080)	\$ (13,234)	\$ (26,871)
Net loss per share, basic and diluted (Note 2)	\$ (0.34)	\$ (11.29)	\$ (1.05)	\$ (48.70)
Weighted-average number of shares used to compute net loss per share, basic and diluted (Note 2)	12,644,348	1,513,189	12,626,259	551,730

The accompanying notes are an integral part of these financial statements

Exagen Inc.

Unaudited Condensed Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)
(in thousands, except share data)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balances at December 31, 2019	12,560,990	\$ 13	\$ 220,248	\$ (164,602)	\$ 55,659
Exercise of stock options	43,700	—	10	—	10
Stock-based compensation	—	—	431	—	431
Net exercise of common stock warrants	22,366	—	—	—	—
Net loss	—	—	—	(5,563)	(5,563)
Balances at March 31, 2020	12,627,056	13	220,689	(170,165)	50,537
Exercise of stock options	3,599	—	2	—	2
Stock-based compensation	—	—	647	—	647
Exercise of common stock warrants	9,754	—	18	—	18
Net loss	—	—	—	(3,363)	(3,363)
Balances at June 30, 2020	12,640,409	13	221,356	(173,528)	47,841
Exercise of stock options	55	—	—	—	—
Issuance of stock under Employee Stock Purchase Plan	11,649	—	142	—	142
Stock-based compensation	—	—	799	—	799
Net loss	—	—	—	(4,308)	(4,308)
Balances at September 30, 2020	12,652,113	\$ 13	\$ 222,297	\$ (177,836)	\$ 44,474

The accompanying notes are an integral part of these financial statements

Exagen Inc.

Unaudited Condensed Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)
(in thousands, except share and per share data)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount			
Balances at December 31, 2018	532,606,084	\$ 105,232	63,005	\$ —	\$ 40,598	\$ (152,564)	\$ (111,966)
Accretion of redeemable convertible preferred stock	—	2,114	—	—	(2,114)	—	(2,114)
Exercise of stock options	—	—	24	—	—	—	—
Stock-based compensation	—	—	—	—	12	—	12
Issuance of Series G redeemable convertible preferred stock for aggregate proceeds of \$0.078 per share, net of issuance costs of \$96 (Note 7)	97,646,289	7,520	—	—	—	—	—
Net loss	—	—	—	—	—	(2,704)	(2,704)
Balances at March 31, 2019	630,252,373	114,866	63,029	—	38,496	(155,268)	(116,772)
Accretion of redeemable convertible preferred stock	—	2,188	—	—	(2,188)	—	(2,188)
Exercise of stock options	—	—	26	—	—	—	—
Stock-based compensation	—	—	—	—	11	—	11
Issuance of Series G redeemable convertible preferred stock for aggregate proceeds of \$0.078 per share, net of issuance costs of \$28 (Note 7)	51,282,048	3,972	—	—	—	—	—
Net loss	—	—	—	—	—	(2,785)	(2,785)
Balances at June 30, 2019	681,534,421	121,026	63,055	—	36,319	(158,053)	(121,734)
Accretion of redeemable convertible preferred stock	—	338	—	—	(338)	—	(338)
Stock-based compensation	—	—	—	—	62	—	62
Issuance of Series H redeemable convertible preferred stock for aggregate proceeds of \$0.047 per share, net of issuance costs of \$318 (Note 7)	233,446,519	3,941	—	—	6,741	—	6,741
Deemed dividend recognized on beneficial conversion features of Series H redeemable convertible preferred stock (Note 7)	—	6,741	—	—	(6,741)	—	(6,741)
Deemed dividend from conversion of Series G to Series H redeemable convertible preferred stock (Note 7)	97,592,739	6,860	—	—	(6,860)	—	(6,860)
Conversion of preferred stock to common stock in connection with initial public offering (Note 7)	(1,012,573,679)	(138,906)	7,816,643	8	138,898	—	138,906
Issuance of common stock in initial public offering, net of underwriting discount, commissions and issuance costs (Note 8)	—	—	4,140,000	4	50,514	—	50,518
Net exercise of common and preferred stock warrants	—	—	539,794	1	510	—	511
Reclassification of redeemable convertible preferred stock warrant liabilities as equity	—	—	—	—	726	—	726
Net loss	—	—	—	—	—	(3,141)	(3,141)
Balances at September 30, 2019	—	\$ —	12,559,492	\$ 13	\$ 219,831	\$ (161,194)	\$ 58,650

The accompanying notes are an integral part of these financial statements

Exagen Inc.
Unaudited Statements of Cash Flows
(in thousands)

	Nine Months Ended September 30,	
	2020	2019
Cash flows from operating activities:		
Net loss	\$ (13,234)	\$ (8,630)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	392	480
Amortization of debt discount and debt issuance costs	202	575
Non-cash interest expense	397	484
Revaluation of warrant liabilities	—	(267)
Deferred income taxes	(117)	—
Loss on disposal of assets	—	20
Stock-based compensation	1,877	85
Changes in assets and liabilities:		
Accounts receivable, net	(3,582)	(286)
Prepaid expenses and other current assets	1,627	510
Other assets	—	(24)
Accounts payable	781	174
Accrued and other liabilities	1,472	1,095
Net cash used in operating activities	(10,185)	(5,784)
Cash flows from investing activities:		
Purchases of property and equipment	(450)	(377)
Proceeds from sale of property and equipment	—	300
Net cash used in investing activities	(450)	(77)
Cash flows from financing activities:		
Proceeds from exercise of stock options	12	—
Proceeds from common stock issued under Employee Stock Purchase Plan	142	—
Proceeds from exercise of common stock warrants	18	—
Principal payment on capital lease obligations	(187)	(94)
Proceeds from Paycheck Protection Program loan	2,865	—
Repayment of Paycheck Protection Program loan	(2,865)	—
Proceeds from initial public offering, net of issuance costs and offering costs	—	52,195
Proceeds from issuance of Series G redeemable convertible preferred stock, net of issuance costs	—	7,742
Proceeds from issuance of Series H redeemable convertible preferred stock, net of issuance costs	—	10,682
Net cash (used in) provided by financing activities	(15)	70,525
Net change in cash, cash equivalents and restricted cash	(10,650)	64,664
Cash, cash equivalents and restricted cash, beginning of period	72,184	13,264
Cash, cash equivalents and restricted cash, end of period	\$ 61,534	\$ 77,928
Supplemental disclosure of cash flow information:		
Cash paid for interest expense	\$ 1,312	\$ 1,661
Supplemental disclosure of non-cash items:		
Accretion to redemption value of redeemable convertible preferred stock	\$ —	\$ 4,640
Equipment purchased under capital lease obligations	\$ 123	\$ 412
Costs incurred, but not paid, in connection with capital expenditures	\$ 197	\$ 71
Conversion of redeemable convertible preferred stock	\$ —	\$ 138,906
Net exercise of common and preferred stock warrants	\$ —	\$ 511
Issuance costs included in accounts payable and accrued liabilities	\$ —	\$ 1,677
Reclassification of redeemable convertible preferred stock warrant liabilities as equity	\$ —	\$ 726
Deemed dividend recognized for beneficial conversion features of Series H redeemable convertible preferred stock	\$ —	\$ 6,741
Deemed dividend from conversion of Series G to Series H redeemable convertible preferred stock	\$ —	\$ 6,860
Conversion of Series G to Series H redeemable convertible preferred stock	\$ —	\$ 11,875

The accompanying notes are an integral part of these financial statements

Exagen Inc.

Notes to Unaudited Interim Condensed Financial Statements

Note 1. Organization

Description of Business

Exagen Inc. (the Company) was incorporated under the laws of the state of New Mexico in 2002, under the name Exagen Corporation. In 2003, Exagen Corporation changed its state of incorporation from New Mexico to Delaware by merging with and into Exagen Diagnostics, Inc., pursuant to which the Company changed its name to Exagen Diagnostics, Inc. In January 2019, the Company changed its name to Exagen Inc. The Company is dedicated to transforming the care continuum for patients suffering from debilitating and chronic autoimmune diseases by enabling timely differential diagnosis and optimizing therapeutic intervention.

Liquidity

The Company has incurred recurring losses and negative cash flows from operating activities since inception. The Company anticipates that it will continue to incur net losses into the foreseeable future. At September 30, 2020, the Company had cash and cash equivalents of \$61.4 million and had an accumulated deficit of \$177.8 million. Since inception, the Company has financed its operations primarily through private placements of preferred securities, the sale of common stock through its initial public offering (IPO) and debt financing arrangements. Based on the Company's current business plan, management believes that its existing capital resources will be sufficient to fund the Company's obligations for at least twelve months following the issuance of these condensed financial statements.

To execute its business plans, the Company may need additional funding to support its continuing operations and pursue its growth strategy. Until such time as the Company can achieve significant cash flows from operations, if ever, it expects to finance its operations through the sale of its stock, debt financings or other strategic transactions. Although the Company has been successful in raising capital in the past, there is no assurance that it will be successful in obtaining such additional financing on terms acceptable to the Company, if at all. The terms of any financing may adversely affect the holdings or the rights of the Company's stockholders. If the Company is unable to obtain funding, the Company could be forced to delay, reduce or eliminate some or all of its programs, product portfolio expansion plans or commercialization efforts, which could have a material adverse effect on the Company's business, operating results and financial condition and the Company's ability to achieve its intended business objectives.

Note 2. Summary of Significant Accounting Policies

Basis of Presentation and Use of Estimates

The accompanying interim condensed balance sheet as of September 30, 2020, the condensed statements of operations and the condensed statements of redeemable convertible preferred stock and stockholders' equity (deficit) for the three and nine months ended September 30, 2020 and 2019 and cash flows for the nine months ended September 30, 2020 and 2019 and the related footnote disclosure are unaudited and have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission (SEC), and with accounting principles generally accepted in the United States (GAAP) applicable to interim financial statements. In management's opinion, the unaudited interim condensed financial statements have been prepared on the same basis as the audited financial statements and include all normal adjustments, necessary for the fair presentation of the Company's financial position as of September 30, 2020 and its results of operations for the three and nine months ended September 30, 2020 and 2019, statements of redeemable convertible preferred stock and stockholders' equity (deficit) for the three and nine months ended September 30, 2020 and 2019 and cash flows for the nine months ended September 30, 2020 and 2019 in accordance with GAAP. The results for the nine months ended September 30, 2020 are not necessarily indicative of the results expected for the full fiscal year or any other interim period. The year-end condensed balance sheet data was derived from audited financial statements, but does not include all disclosures required by accounting principles generally accepted in the United States of

America. These unaudited condensed financial statements should be read in conjunction with the Company's audited financial statements for the year ended December 31, 2019, included in its Annual Report on Form 10-K filed with the SEC on March 25, 2020.

The preparation of the accompanying condensed financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities as of the date of the condensed financial statements, and the reported amounts of revenue and expenses during the reporting period. Actual results could materially differ from those estimates.

Significant estimates and assumptions made in the accompanying condensed financial statements include, but are not limited to revenue recognition, the fair value of financial instruments measured at fair value, the recoverability of its long-lived assets (including goodwill), net deferred tax assets (and related valuation allowance), and for periods prior to the IPO, the fair value of the Company's common stock and redeemable convertible preferred stock. The Company evaluates its estimates and assumptions on an ongoing basis using historical experience and other factors and adjusts those estimates and assumptions when facts and circumstances dictate. Actual results could materially differ from those estimates.

Concentration of Credit Risk and Other Risk and Uncertainties

Financial instruments that potentially subject the Company to credit risk consist principally of cash, cash equivalents, and accounts receivable. Substantially all the Company's cash and cash equivalents are held at one financial institution that management believes is of high credit quality. Such deposits may, at times, exceed federally insured limits.

Significant payers and customers are those which represent more than 10% of the Company's total revenue or accounts receivable balance at each respective balance sheet date. For each significant payer and customer, revenue as a percentage of total revenue and accounts receivable as a percentage of total accounts receivable are as follows:

	Revenue			
	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Medicare	20 %	25 %	21 %	26 %
Janssen (SIMPONI®)	13 %	*	12 %	*
Blue Shield	12 %	13 %	12 %	13 %
Medicare Advantage	11 %	12 %	11 %	11 %
United Healthcare	*	10 %	*	10 %

	Accounts Receivable	
	September 30, 2020	December 31, 2019
Janssen (SIMPONI®)	37 %	19 %
Anthem Blue Cross Blue Shield	12 %	*
Blue Shield	10 %	15 %
United Healthcare	*	22 %

* Less than 10%.

For the three months ended September 30, 2020 and 2019, approximately 68%, and 83%, respectively, of the Company's revenue was related to the AVISE® CTD test. For the nine months ended September 30, 2020 and 2019, approximately 71% and 83%, respectively, of the Company's revenue was related to the AVISE® CTD test.

The Company is dependent on key suppliers for certain laboratory materials. For the three months ended September 30, 2020 and 2019, approximately 98% and 97%, respectively, of the Company's diagnostic testing supplies were purchased from two suppliers. For the nine months ended September 30, 2020 and 2019, approximately 97% and 96%, respectively, of the Company's diagnostic testing supplies were purchased from two suppliers. An interruption in the supply of these materials would impact the Company's ability to perform testing services.

Disaggregation of Revenue

The following table includes the Company's revenues as disaggregated by payer and customer category (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenue:				
Healthcare insurers	\$ 5,749	\$ 6,188	\$ 15,949	\$ 17,716
Government	2,184	2,665	6,236	7,964
Client	1,260	1,007	3,088	3,200
Other(1)	235	148	636	458
Janssen (SIMPONI®)	1,347	431	3,398	835
Total revenue	\$ 10,775	\$ 10,439	\$ 29,307	\$ 30,173

(1) Includes patient self-pay that is immaterial.

Fair Value Measurements

The carrying value of the Company's cash and cash equivalents, other assets and accrued liabilities approximate fair value due to the short-term nature of these items. Based on the borrowing rates currently available to the Company for debt with similar terms and consideration of default and credit risk, the carrying value of the Company's long-term borrowings approximates its fair value, which is considered a Level 2 input.

Fair value is defined as the exchange price that would be received for an asset or an exit price paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs.

The fair value hierarchy defines a three-level valuation hierarchy for disclosure of fair value measurements as follows:

- Level 1 - Unadjusted quoted prices in active markets for identical assets or liabilities;
- Level 2 - Inputs other than quoted prices included within Level I that are observable, unadjusted quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities; and
- Level 3 - Unobservable inputs that are supported by little or no market activity for the related assets or liabilities.

The categorization of a financial instrument within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement.

Cash, Cash Equivalents and Restricted Cash

The Company considers all highly-liquid investments purchased with a remaining maturity date upon acquisition of three months or less to be cash equivalents and are stated at cost, which approximates fair value.

In 2016, the Company entered into an arrangement with a financial institution with which it has an existing banking relationship whereby in exchange for the issuance of corporate credit cards, the Company agreed to obtain a \$0.1 million certificate of deposit with this financial institution as collateral for the balances borrowed on these credit cards. The Company has classified the value of this certificate of deposit (including all interest earned thereon) within other assets in the accompanying balance sheets. The Company has the right to terminate the credit card program at any time. Upon termination of the credit card program and repayment of all outstanding balances owed, the Company may redeem the certificate of deposit (and all interest earned thereon).

Cash, cash equivalents and restricted cash presented in the accompanying condensed statements of cash flows consist of the following (in thousands):

	September 30, 2020	December 31, 2019
Cash and cash equivalents	\$ 61,434	\$ 72,084
Restricted cash	100	100
	<u>\$ 61,534</u>	<u>\$ 72,184</u>

Revenue Recognition

Substantially all of the Company's revenue has been derived from sales of its testing products and is primarily comprised of a high volume of relatively low-dollar transactions. The Company primarily markets its testing products to rheumatologists and their physician assistants in the United States. The healthcare professionals who order the Company's testing products and to whom test results are reported are generally not responsible for payment for these products. The parties that pay for these services (the Payers) consist of healthcare insurers, government payers (primarily Medicare and Medicaid), client payers (i.e., hospitals, other laboratories, etc.), and patient self-pay. The Company's service is a single performance obligation that is completed upon the delivery of test results to the prescribing physician which triggers revenue recognition.

Payers are billed at the Company's list price. Net revenues recognized consist of amounts billed net of allowances for differences between amounts billed and the estimated consideration the Company expects to receive from such payers. The process for estimating revenues and the ultimate collection of accounts receivable involves significant judgment and estimation. The Company follows a standard process, which considers historical denial and collection experience, insurance reimbursement policies and other factors, to estimate allowances and implicit price concessions, recording adjustments in the current period as changes in estimates occur. Further adjustments to the allowances, based on actual receipts, is recorded upon settlement. The transaction price is estimated using an expected value method on a portfolio basis. The Company's portfolios are grouped per payer (i.e. each individual third-party insurance, Medicare, client payers, patient self-pay, etc.) and per test basis.

Collection of the Company's net revenues from payers is normally a function of providing complete and correct billing information to the healthcare insurers and generally occurs within 30 to 90 days of billing. Contracts do not contain significant financing components based on the typical period of time between performance of services and collection of consideration.

Janssen Promotion Agreement

In December 2018, the Company entered into a co-promotion agreement with Janssen Biotech, Inc. (Janssen) to co-promote SIMPONI® in the United States (the Janssen Agreement). The Company is responsible for the costs associated with its salesforce over the course of such co-promotion. Janssen is responsible for all other aspects of the commercialization of SIMPONI® under the Janssen agreement. In exchange for the Company's sales and co-promotional services, the Company is entitled to a quarterly tiered promotion fee based on the incremental increase in total prescribed units of SIMPONI® for that quarter over a predetermined baseline. For all periods presented, the tiered promotion fee ranged from \$750 to \$1,250 per prescription over a predetermined baseline. Due in part to COVID-19, in June 2020, the Janssen Agreement was amended (Amended Janssen Agreement). In accordance with the Amended Janssen Agreement, the predetermined baseline for prescribed units for each remaining quarter in 2020 was adjusted and is subject to further adjustment, and for each of the third and fourth quarters of 2020, the Company will receive a minimum promotion fee of \$0.3 million and the fee will be capped at 5% above the adjusted predetermined baseline. The predetermined baseline for 2021 will be agreed upon by the Company and Janssen no

later than November 30, 2020. In addition, during the term of the Janssen agreement, the Company is restricted from promoting any other biologic or Janus kinase inhibitor, or JAK inhibitor, used for treatment of indications covered by the agreement without first obtaining Janssen's written consent.

The Amended Janssen Agreement expires on December 31, 2021, unless extended by the Company for an additional 12 months upon 180 days written notice prior to the end of the current term. If the Company elects to extend the term, the predetermined baseline for 2022 will be subject to future agreement by the Company and Janssen. Janssen may terminate the Amended Janssen Agreement at any time for any reason upon 30 days' notice to the Company, and the Company may terminate the Amended Janssen Agreement for any reason at the end of any calendar quarter upon 30 days' notice to Janssen. Either party may terminate the Amended Janssen Agreement in the event of the other party's default of any of its material obligations under the agreement if such default remains uncured for a specified period of time following receipt of written notice of such default.

The Company's obligations relating to sales and co-promotion services for SIMPONI® is a series of single performance obligations since Janssen simultaneously receives and consumes benefits provided by the Company's sales and co-promotional services. The method for measuring progress towards satisfying the performance obligations is based on prescribed units in excess of the contractual baseline at the contractual rate earned per unit since the agreement is cancelable. The Company recognized co-promotional revenue of approximately \$1.3 million and \$0.4 million during the three months ended September 30, 2020 and 2019, respectively. The Company recognized co-promotional revenue of approximately \$3.4 million and \$0.8 million during the nine months ended September 30, 2020 and 2019, respectively. The related expenses for marketing SIMPONI® are included in selling, general and administrative expenses and are expensed as incurred.

Research and Development

Costs associated with research and development activities are expensed as incurred and include, but are not limited to, personnel-related expenses, including stock-based compensation expense, materials, laboratory supplies, consulting costs, costs associated with setting up and conducting clinical studies and allocated overhead including rent and utilities.

Advertising and Marketing Costs

Costs associated with advertising and marketing activities are expensed as incurred. Total advertising and marketing costs were approximately \$0.3 million and \$0.4 million for the three months ended September 30, 2020 and 2019, respectively, and \$0.9 million and \$1.1 million for the nine months ended September 30, 2020 and 2019, respectively, and are included in selling, general and administrative expenses in the accompanying condensed statements of operations.

Shipping and Handling Costs

Costs incurred for shipping and handling are included in costs of revenue in the accompanying condensed statements of operations and totaled approximately \$0.4 million for each of the three months ended September 30, 2020 and 2019, and \$1.1 million for each of the nine months ended September 30, 2020 and 2019.

Stock-Based Compensation

The Company recognizes compensation expense for all stock-based awards to employees and directors based on the grant-date estimated fair values over the requisite service period of the awards (usually the vesting period) on a straight-line basis. The fair value of stock options and purchases under the employee stock purchase plan (ESPP) rights is determined using the Black-Scholes-Merton (BSM) option pricing model, which requires management to make certain assumptions regarding a number of complex and subjective variables. Equity award forfeitures are recorded as they occur.

The BSM option pricing model incorporates various estimates, including the fair value of the Company's common stock, expected volatility, expected term and risk-free interest rates. The weighted-average expected term of options was calculated using the simplified method. This decision was based on the lack of relevant historical data due to the Company's limited historical experience. In addition, due to the Company's limited historical data, the estimated volatility incorporates the historical volatility over the expected term of the award of comparable companies whose share prices are publicly available. The risk-free interest rate for periods within the contractual term of the option is

based on the U.S. Treasury yield in effect at the time of grant. The dividend yield was zero, as the Company has never declared or paid dividends and has no plans to do so in the foreseeable future.

Upon the effective date of the IPO, the Company began using the closing price of its common stock as the fair value of its common stock on the corresponding date.

Comprehensive Loss

Comprehensive loss is defined as a change in equity of a business enterprise during a period, resulting from transactions from nonowner sources. There have been no items qualifying as other comprehensive loss and, therefore, for all periods presented, the Company's comprehensive loss was the same as its reported net loss.

Net Loss Per Share

Basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period. Diluted net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common stock equivalents outstanding for the period determined using the treasury-stock and if-converted methods. Potentially dilutive common stock equivalents are comprised of redeemable convertible preferred stock, warrants for the purchase of redeemable convertible preferred and common stock and options outstanding under the Company's stock option plans. For the three and nine months ended September 30, 2020 and 2019, there is no difference in the number of shares used to calculate basic and diluted shares outstanding as the inclusion of the potentially dilutive securities would be antidilutive.

Potentially dilutive securities not included in the calculation of diluted net loss per share because to do so would be anti-dilutive are as follows (in common stock equivalent shares):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Warrants to purchase common stock	426,827	461,273	426,827	461,273
Common stock options	1,975,250	1,475,006	1,975,250	1,475,006
Total	2,402,077	1,936,279	2,402,077	1,936,279

Government Assistance Grant Income

Government assistance grants which are unconditional when received and intended to compensate for expenses incurred or replace lost revenue are recognized when those expenses are incurred or during the period that lost revenue is experienced, and are included in other income, net.

Segment Reporting

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. The Company views its operations as, and manages its business in, one operating segment.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (FASB), or other standard setting bodies and adopted by the Company as of the specified effective date. Under the Jumpstart Our Business Startups Act of 2012 (JOBS Act), the Company meets the definition of an emerging growth company. The Company has elected to use the extended transition period for complying with new or revised accounting standards pursuant to Section 107(b) of the JOBS Act. Unless otherwise discussed, the impact of recently issued standards that are not yet effective will not have a material impact on the Company's financial position or results of operations upon adoption.

In February 2016, the FASB issued Accounting Standards Update (ASU) 2016-02, *Leases* (Topic 842). The new topic supersedes Topic 840, *Leases*, and increases transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and requires disclosures of key information about leasing arrangements. In July 2018, the FASB issued ASU 2018-10, *Codification Improvements to Topic 842*, which provides narrow amendments to clarify how to apply certain aspects of the new lease standard, and ASU 2018-11, *Leases: Targeted Improvements*, which was issued to provide relief to companies from restating comparative periods. Pursuant to this ASU, in the period of adoption the Company will not restate comparative periods presented in its condensed financial statements. The effective date of this guidance for public companies is for reporting periods beginning after December 15, 2018. In June 2020, the FASB issued ASU 2020-05, which delays the adoption for ASU 2016-02 for non-public entities to fiscal years beginning after December 15, 2021, and interim periods beginning after December 15, 2022. As an emerging growth company as defined in the JOBS Act, the Company has elected to delay adoption of this ASU until January 1, 2022. Topic 842 mandates a modified retrospective transition method. The Company intends to adopt the new lease standard using a cumulative effect to accumulated deficit and will elect the package of practical expedients, which among other things will allow the Company to carry forward its historical lease classification. The Company is currently evaluating the impact of Topic 842 on its condensed financial statements.

Recently Adopted Accounting Standards

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement: Disclosure Framework--Changes to the Disclosure Requirements for Fair Value Measurement*, which adds and modifies certain disclosure requirements for fair value measurements. Under the new guidance, entities will no longer be required to disclose the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy, or valuation processes for Level 3 fair value measurements. However, public companies will be required to disclose the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements, and related changes in unrealized gains and losses included in other comprehensive income. The narrative description of measurement uncertainty should be applied prospectively for only the most recent interim or annual period presented in the initial fiscal year of adoption. All other amendments should be applied retrospectively to all period presented upon their effective date. This update is effective for annual periods beginning after December 15, 2019, and interim periods within those periods, and early adoption is permitted. The Company adopted this guidance on January 1, 2020, and the adoption did not have a material impact on its condensed financial statements.

Note 3. Other Financial Information

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following (in thousands):

	September 30, 2020	December 31, 2019
Diagnostic testing supplies	\$ 841	\$ 1,427
Prepaid product royalties	72	123
Prepaid maintenance and insurance contracts	897	1,768
Other prepaid and other current assets	14	133
Prepaid and other current assets	<u>\$ 1,824</u>	<u>\$ 3,451</u>

Property and Equipment

Property and equipment consist of the following (in thousands):

	September 30, 2020	December 31, 2019
Furniture and fixtures	\$ 44	\$ 25
Laboratory equipment	2,663	2,228
Computer equipment and software	927	851
Leasehold improvements	473	424
Construction in progress	438	247
Total property and equipment	4,545	3,775
Less: accumulated depreciation and amortization	(2,787)	(2,395)
Property and equipment, net	\$ 1,758	\$ 1,380

Depreciation and amortization expense for the three months ended September 30, 2020 and 2019 was approximately \$0.1 million, and for the nine months ended September 30, 2020 and 2019, was approximately \$0.4 million and \$0.5 million, respectively. At September 30, 2020 and December 31, 2019, the gross book value of assets under capital lease was \$1.2 million and \$0.8 million, respectively, and is classified in "Laboratory equipment" in the table above.

Accrued and Other Current Liabilities

Accrued and other current liabilities consist of the following (in thousands):

	September 30, 2020	December 31, 2019
Accrued payroll and related expenses	\$ 3,818	\$ 2,362
Accrued interest	142	145
Accrued purchases of goods and services	542	319
Accrued royalties	178	727
Accrued clinical study activity	139	40
Capital lease obligations, current portion	272	238
Other accrued liabilities	729	588
Accrued and other current liabilities	\$ 5,820	\$ 4,419

Note 4. Borrowings

2017 Term Loan

In September 2017, the Company executed a term loan agreement (the 2017 Term Loan) with Innovatus Life Sciences Lending Fund I, LP (Innovatus) and borrowed \$20.0 million, \$17.8 million of which was immediately used to repay the Company's existing loan with Capital Royalty Partners II L.P. and its affiliates. On December 7, 2018, the Company borrowed an additional \$5.0 million under the 2017 Term Loan. At September 30, 2020, no additional amounts remain available to borrow under the 2017 Term Loan.

In November 2019, the Company executed the First Amendment to the Loan and Security Agreement (the 2017 Loan Amendment). The interest rate on all borrowings under the Loan Amendment is 8.5%, of which 2.0% is paid in-kind in the form of additional term loans (PIK Loans) until December of 2022, after which interest accrues at an annual rate of 8.5%. The Company has estimated the effective interest rate of this loan to be approximately 10%. Accrued interest is due and payable monthly, unless the Company elects to pay paid-in-kind interest. The outstanding principal and accrued interest on the Loan Amendment will be repaid in twenty-four equal monthly installments commencing in December 2022. Upon repayment of the final installment under the Loan Amendment, the Company is required to pay an additional fee of \$1.0 million. This obligation is being accreted into interest expense over the term of Loan Amendment using the effective interest method. For the three months ended September 30, 2020 and 2019, the Company issued PIK Loans totaling \$0.1 million and \$0.2 million, respectively. For the nine months ended September 30, 2020 and 2019, the Company issued PIK Loans totaling \$0.4 million and \$0.5 million, respectively.

If the Loan Amendment is prepaid before November 19, 2020, the Loan Amendment requires a prepayment premium of 3% of the aggregate outstanding principal. The prepayment premium decreases by 1% during each subsequent twelve-month period after November 19, 2020.

The Loan Amendment is collateralized by a first priority security interest on substantially all of the Company's assets, including intellectual property. The affirmative covenants of the Loan Amendment require that the Company timely file taxes, maintain good standing and government compliance, maintain liability and other insurance, provide prompt notification of significant corporate events, and furnish audited financial statements within 150 days of fiscal year end without qualification as to the scope of the audit or as to going concern and without any other similar qualification.

The affirmative covenants require that the Company achieve a specified level of revenue, as measured quarterly on a rolling twelve-month basis, and commencing with the quarter ending December 31, 2019. The consequences of failing to achieve the performance covenant may be cured if, within sixty days of failing to achieve the performance covenant, the Company issues additional equity securities or subordinated debt with net proceeds sufficient to fund any cash flow deficiency generated from operations, as defined. The Company's revenues for the twelve-month period ended September 30, 2020 were lower than the specified targets, and as a result, subsequent to September 30, 2020, the Company and Innovatus agreed on a new management plan and target to bring the Company back into compliance with the Loan Amendment. The Loan Amendment requires that the Company maintain certain levels of minimum liquidity. The Company is required to maintain an unrestricted cash balance of \$2.0 million.

The negative covenants provide, among other things, that without the prior consent of Innovatus subject to certain exceptions, the Company may not dispose of certain assets, engage in certain business combinations or acquisitions, incur additional indebtedness or encumber any of the Company's property, pay dividends on the Company's capital stock or make prohibited investments. The Loan Amendment agreement provides that an event of default will occur if, among other triggers, (i) the Company defaults in the payment of any amount payable under the agreement when due, (ii) there occurs any circumstance(s) that could reasonably be expected to result in a material adverse effect on the Company's business, operations or condition, or on the Company's ability to perform its obligations under the agreement, (iii) the Company becomes insolvent, (iv) the Company undergoes a change in control or (v) the Company breaches any negative covenants or certain affirmative covenants in the agreement or, subject to a cure period, otherwise neglects to perform or observe any material item in the agreement.

At September 30, 2020, the Company was in compliance with all covenants of the Loan Amendment, other than as described above.

Upon an event of default in any of the Loan Amendment covenants, the repayment of the Loan Amendment may be accelerated and the applicable interest rate will be increased by 4.0% until the default is cured. Although repayment of the Loan Amendment can be accelerated under certain circumstances, the Company believes acceleration of this loan is not probable as of the date of these condensed financial statements. Accordingly, the Company has reflected the amounts of the Loan Amendment due beyond twelve months of the balance sheet date as non-current.

Future Minimum Payments on the Outstanding Borrowings

As of September 30, 2020, future minimum aggregate payments, including interest, for outstanding borrowings under the Loan Amendment are as follows (in thousands):

	September 30, 2020
2020 (remaining)	\$ 437
2021	1,755
2022	2,996
2023	15,619
2024	14,280
Total	35,087
Less:	
Unamortized debt discount and issuance costs	(320)
Interest	(8,314)
Total borrowings, net of discounts and debt issuance costs	\$ 26,453

Note 5. Commitments and Contingencies

Leases

As of September 30, 2020, the Company leases office and laboratory space in Vista, California, under leases that expire in January 2026, with an option to extend a portion of the lease for an additional 5-year period. In addition, the Company also leases additional office space in Vista, California, under a lease that expires in January 2026 with an option to extend the lease for an additional 5-year period. The Company's lease payments under each of these leases are subject to escalation clauses.

For the three months ended September 30, 2020 and 2019, rent expense was \$0.3 million and \$0.1 million, respectively. For the nine months ended September 30, 2020 and 2019, rent expense was \$0.5 million and \$0.3 million, respectively.

Acquisition-related liabilities

In connection with the acquisition of the medical diagnostics division of Cypress Bioscience, Inc. in 2010, the Company was required to pay certain amounts in the event that certain revenue milestones were achieved and upon the first commercial sale of a product associated with this acquisition. The acquisition also included amounts that may be due under several licensing agreements. All milestone payments other than one have been paid as of December 31, 2017. The remaining milestone obligation is for an additional \$2.0 million payment due to Prometheus Laboratories, Inc. (Prometheus) for which the fair value was determined to be zero at September 30, 2020 and December 31, 2019.

In addition, the Company has ongoing royalty payment obligations on net sales of products which incorporate certain acquired technologies ranging from 2.5% to 7.5%. Future royalties payable under these arrangements are limited to the lesser of an aggregate of \$4.2 million (including an upfront payment of \$100,000) or the total royalties earned through January 1, 2024.

Licensing Agreements

The Company has licensed technology for use in its diagnostic tests. In addition to the milestone payments required by these agreements as described above, individual license agreements generally provide for ongoing royalty payments on net sales of products which incorporate licensed technology, as defined, ranging from 2.0% to 20.0%. Royalties are accrued when earned and recorded in costs of revenue in the accompanying condensed statement of operations.

Supply Agreement

In September 2020, the Company entered into an amended supply agreement with one supplier for reagents which includes minimum annual purchase commitments of \$2.8 million, \$4.1 million and \$6.0 million for the years ended December 31, 2020, 2021 and 2022, respectively, with a 15% annual increase thereafter through the year ended December 31, 2025.

Contingencies

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications; including subpoenas and other civil investigative demands, from governmental agencies, Medicare or Medicaid payers and managed care organizations reviewing billing practices or requesting comment on allegations of billing irregularities that are brought to their attention through billing audits or third parties. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future, but have not yet been made or of which of the Company believes to be immaterial. The Company accrues a liability for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated.

Litigation

From time to time, the Company may be subject to various legal proceedings that arise in the ordinary course of business activities.

Note 6. Fair Value Measurements

The following table sets forth the Company's financial instruments that were measured at fair value on a recurring basis within the fair value hierarchy (in thousands):

	September 30, 2020			
	Total	Level 1	Level 2	Level 3
Assets:				
Money market funds	\$ 4,009	\$ 4,009	\$ —	\$ —

	December 31, 2019			
	Total	Level 1	Level 2	Level 3
Assets:				
Money market funds	\$ 70,760	\$ 70,760	\$ —	\$ —

The fair value of the Company's money market funds is based on quoted market prices.

Note 7. Redeemable Convertible Preferred Stock

Series G Financing

In January 2019, the Company entered into an agreement with new and certain existing preferred stockholders to issue shares of Series G redeemable convertible preferred stock in multiple separate closings at a per share price of \$0.078 in each closing. In conjunction with the issuance of the Series H redeemable convertible preferred stock, each share of issued and outstanding Series G redeemable convertible preferred stock was converted into shares of Series H redeemable convertible preferred stock.

Series H Financing

In July 2019, the Company entered into an agreement with a new investor to issue shares of Series H redeemable convertible preferred stock at a per share price of \$0.04712. The Company accounted for the difference between the effective conversion price of \$0.04712 and the fair value of the underlying common stock at the commitment date as a beneficial conversion feature, which was immediately accreted as a deemed dividend. As a result, the Company recognized a beneficial conversion feature in the amount of \$6.7 million in the third quarter of 2019, that was recorded as additional paid-in capital (in the absence of retained earnings) in the accompanying condensed statement of redeemable convertible preferred stock and stockholders' equity (deficit). Additionally, the Company concluded that the conversion of shares of Series G into shares of Series H redeemable convertible preferred stock in connection with the issuance of Series H redeemable convertible preferred stock represented an extinguishment of the Series G shares. As a result, the Company recognized a deemed dividend for the extinguishment charge in the amount of \$6.9 million in the third quarter of 2019, that was recorded as additional paid-in capital (in the absence of retained earnings) in the accompanying condensed statement of redeemable convertible preferred stock and stockholders' equity (deficit).

Initial Public Offering

Upon completion of the Company's IPO in September 2019, an aggregate of 7,816,643 shares of common stock, excluding warrant conversions, were issued to the holders of the Company's Series A-3, Series B-3, Series C, Series D, Series E, Series F and Series H redeemable convertible preferred stockholders upon the automatic conversion of all shares of redeemable convertible preferred stock to common stock. As a result, no shares of redeemable convertible preferred stock remain outstanding at December 31, 2019.

Note 8. Stockholders' Equity

Common Stock

On September 23, 2019, the Company closed its IPO of 4,140,000 shares of its common stock at a price to the public of \$14.00 per share, including the exercise in full by the underwriters of their option to purchase 540,000 additional shares of the Company's common stock. Including the exercise of the option to purchase additional shares, the aggregate net proceeds to the Company from the offering was approximately \$50.4 million, net of underwriting discounts, commissions and other estimated offering expenses, for aggregate expenses of approximately \$7.5 million. In addition, an aggregate of 7,816,643 shares of common stock, excluding warrant conversions, were issued to the holders of the Company's Series A-3, Series B-3, Series C, Series D, Series E, Series F and Series H redeemable convertible preferred stockholders upon the automatic conversion of all shares of redeemable convertible preferred stock to common stock.

Outstanding Warrants

The following equity classified warrants to purchase common stock were outstanding as of September 30, 2020:

	Shares	Exercise Price	Issuance date	Expiration date
Common stock warrants	252,798	\$ 1.84	January 19, 2016	January 19, 2026
Common stock warrants	69,176	1.84	March 31, 2016	March 31, 2026
Common stock warrants	131	1.84	April 1, 2016	April 1, 2026
Common stock warrants	83,778	14.32	September 8, 2017	September 8, 2024
Common stock warrants	20,944	14.32	December 7, 2018	December 7, 2025
	426,827			

During the nine months ended September 30, 2020, warrants to purchase common stock were exercised resulting in the issuance of 32,120 shares of the Company's common stock and cash proceeds of an immaterial amount.

Note 9. Stock Option Plan

In September 2019, the Company's Board of Directors adopted, and the Company's stockholders approved, the 2019 Incentive Award Plan (the 2019 Plan). A total of (i) 2,011,832 shares of common stock plus (ii) shares subject to awards granted under the 2013 Plan on or before the effective date of the 2019 Plan became available for issuance under the 2019 Plan and was initially reserved for issuance under the 2019 Plan. Under the 2019 Plan, the Company may grant stock options, stock appreciation rights, restricted stock, restricted stock units and other awards to individuals who are then employees, officers, non-employee directors or consultants of the Company or its subsidiaries. The options generally expire ten years after the date of grant and are exercisable to the extent vested. Vesting is established by the Board of Directors and is generally four years from the date of grant. As of September 30, 2020, 1,140,029 shares remained available for future awards.

Activity under the Company's stock option plans is set forth below:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding, December 31, 2019	1,375,542	\$ 8.33	9.16	\$ 23,654
Granted	901,531	\$ 16.14		
Exercised	(47,354)	\$ 0.27		
Forfeited	(244,749)	\$ 10.05		
Expired	(9,720)	\$ 29.11		
Outstanding, September 30, 2020	1,975,250	\$ 11.77	8.94	\$ 5,064
Vested and expected to vest, September 30, 2020	1,975,250	\$ 11.77	8.94	\$ 5,064
Options exercisable, September 30, 2020	394,739	\$ 6.51	8.25	\$ 2,430

The intrinsic value is calculated as the difference between the fair value of the Company's common stock and the exercise price of the stock options.

Stock-Based Compensation Expense

The fair value of employee stock options was estimated using the following assumptions to determine the fair value of stock options granted:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Expected volatility	52%	59%	47%-52%	59%
Risk-free interest rate	0.4%	2.0%	0.4%-1.7%	2.0%-2.6%
Dividend yield	—	—	—	—
Expected term (in years)	6.08	5.75-6.08	5.50-6.08	5.75-6.08

Total non-cash stock-based compensation expense recorded related to options granted in the condensed statement of operations is as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Cost of revenue	\$ 9	\$ 4	\$ 21	\$ 6
Selling, general and administrative	710	55	1,696	73
Research and development	80	3	160	6
Total	\$ 799	\$ 62	\$ 1,877	\$ 85

Stock-based compensation expense for the ESPP was immaterial for the three and nine months ended September 30, 2020.

As of September 30, 2020, total unrecognized compensation cost was \$9.3 million, which is expected to be recognized over a remaining weighted-average vesting period of 3.0 years.

Note 10. Related Parties

The closings of the Series G financing described in Note 7 were issued to existing holders of the Company's redeemable convertible preferred stock, including certain members of our Board of Directors.

Note 11. COVID-19

The current COVID-19 worldwide pandemic has presented substantial public health challenges and is affecting the Company's employees, patients, physicians and other healthcare providers, communities and business operations, as well as the U.S. and global economies and financial markets. International and U.S. governmental authorities in impacted regions are taking actions in an effort to slow the spread of COVID-19, including issuing varying forms of "stay-at-home" orders, and restricting business functions outside of one's home. As a result of these limitations and reordering of priorities across the U.S. healthcare system, which have resulted in a reduction in patient flow, the Company's test volumes began to decrease in the second half of March 2020. During the third quarter of 2020, the Company's AVISE[®] CTD volumes substantially recovered to pre-COVID-19 AVISE[®] CTD volumes in the first quarter. For the three months ended September 30, 2020 and for the nine months ended September 30, 2020 as compared to the same period a year ago, the Company has experienced AVISE[®] CTD test volumes decreases of approximately 4% and 8%, respectively. However, the continued spread of COVID-19 may adversely affect testing volumes in future periods, the extent of which is highly uncertain. In addition, the Company believes there are several other important factors that have impacted, and that it expects will impact its operating performance and results of operations, including shutdowns of its facilities and operations as well as those of its suppliers and courier services, disruptions to the supply chain of material needed for its tests, its sales and commercialization activities

and its ability to receive specimens and perform or deliver the results from its tests, delays in reimbursement and coverage decisions from Medicare and third-party payors and in interactions with regulatory authorities, as well its inability to achieve volume-based pricing discounts with its key suppliers and absorb fixed laboratory expenses. In addition, the Company has experienced delays in patient enrollment for ongoing and planned clinical studies involving its tests. The Company may also face increased competition for laboratory employees due to the increased demand in the industry for such personnel.

While the full impact COVID-19 will have on the Company's future business is unpredictable at this time, the Company expects it to have a material impact on its financial results for at least the next quarter and potentially beyond, depending upon the timing of any lifting or re-imposition of COVID-19 limitations on the U.S. healthcare system and general economic recovery. In response to the COVID-19 pandemic, the Company has curtailed non-essential employee travel and equipped most of its employees with the ability to work remotely with the exception of its clinical laboratory employees, and implemented measures to protect the health of its employees and to support the functionality of its clinical laboratory. In addition, in the second quarter of 2020 the Company's salesforce recommenced certain field-based interactions and scaled marketing spend, although access to healthcare providers remains limited and the use of virtual sales tools has increased. From March 2020 through September 30, 2020, as a result of the COVID-19 pandemic, the Company terminated temporary employees and 18 full-time employees, which included three employees at the vice president level. The termination of full-time employees resulted in the recognition of a restructuring charge for termination benefits of \$0.3 million which has been paid as of September 30, 2020. The restructuring charges were included in selling, general and administrative expenses in the condensed statements of operations. The full extent to which the COVID-19 pandemic will directly or indirectly continue to impact the Company's business, results of operations and financial condition, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain it or treat COVID-19, as well as the economic impact on local, regional, national and international markets.

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) was enacted in response to the COVID-19 pandemic. The CARES Act, among other things, permits NOL carryovers and carrybacks to offset 100% of taxable income for taxable years beginning before 2021. The CARES Act did not have a material impact on the Company's effective tax rate or income tax provision for the three months ended March 31, 2020. Under the Tax Cuts and Jobs Act (TCJA), NOLs generated post TCJA were allowed to be carried forward indefinitely but were only allowed to offset 80% of taxable income. As a result of the CARES Act and the change to permit NOLs generated in taxable years 2018, 2019 and 2020 to offset 100% of taxable income, the Company released valuation allowance against its deferred tax assets in the amount of \$0.1 million. The release of valuation allowance resulted in a discrete tax benefit of \$0.1 million in the first quarter of 2020.

In April 2020, the Company received \$0.7 million of funding under the CARES Act Provider Relief Fund, subject to the Company's agreement to comply with the Department of Health & Human Services' standard terms and conditions. The CARES Act Provider Relief Fund is a federal fund allocated for general distributions to Medicare facilities and providers impacted by the COVID-19 pandemic and is intended to support COVID-related expenses or lost revenue attributable to COVID-19. The funding received is considered a government grant which is recognized when there is reasonable assurance that the grant will be received and that conditions attached to the grant have been met. During the three and nine months ended September 30, 2020, the Company recognized \$0 and \$0.7 million, respectively, due to lost revenue attributable to COVID-19, which is reflected in other income, net, on its condensed statements of operations.

On April 16, 2020, the Company entered into a promissory note (the Note) with BOKF, NA dba Bank of Oklahoma (Bofo), the lender, evidencing an unsecured loan pursuant to the U.S. Small Business Administration (SBA) Paycheck Protection Program (PPP) of the CARES Act of approximately \$2.9 million (the PPP Loan). The Company applied for and received the PPP Loan pursuant to the then published PPP qualification and certification requirements. On April 23, 2020, the SBA, in consultation with the Department of Treasury, issued new guidance that created uncertainty regarding the qualification requirements for the PPP Loan (the "New Guidance"). In light of the New Guidance, on May 11, 2020, the Company paid off in full the principal and interest on the PPP Loan, resulting in the termination of the Note.

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

You should read the following discussion of our financial condition and results of operations in conjunction with the unaudited condensed financial statements and the notes thereto included elsewhere in this Quarterly Report on Form 10-Q and with our audited financial statements and notes thereto for the year ended December 31, 2019 included in our Annual Report on Form 10-K for the year ended December 31, 2019, filed on March 25, 2020.

Forward Looking Statements

The following discussion and other parts of this quarterly report contain forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All statements other than statements of historical facts contained in this quarterly report, including statements regarding our future results of operations and financial position, business strategy, the impact of the COVID-19 pandemic, current and future product offerings, reimbursement and coverage, our ability to implement an integrated testing and therapeutics strategy, the expected benefits from our partnerships or promotion arrangements with third-parties, research and development costs, timing and likelihood of success and plans and objectives of management for future operations, are forward-looking statements. These statements are often identified by the use of words such as "may," "will," "expect," "believe," "anticipate," "intend," "could," "should," "estimate," or "continue," and similar expressions or variations. The forward-looking statements in this quarterly report are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, operating results, business strategy, and short-term and long-term business operations and objectives. These forward-looking statements speak only as of the date of this quarterly report and are subject to a number of risks, uncertainties and assumptions, including those described in Part II, Item 1A, "Risk Factors." The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

Overview

We are dedicated to transforming the care continuum for patients suffering from debilitating and chronic autoimmune diseases by enabling timely differential diagnosis and optimizing therapeutic intervention. We have developed and are commercializing a portfolio of innovative testing products under our AVISE® brand, several of which are based on our proprietary CB-CAPs technology. Our goal is to enable rheumatologists to improve care for patients through the differential diagnosis, prognosis and monitoring of complex autoimmune and autoimmune-related diseases, including systemic lupus erythematosus, or SLE, and rheumatoid arthritis, or RA. Our strategy includes leveraging our portfolio of testing products to market therapeutics through our sales channel, targeting the approximately 5,000 rheumatologists across the United States. Our business model of integrating testing products and therapeutics positions us to offer targeted solutions to rheumatologists and, ultimately, better serve patients.

We currently market 10 testing products under our AVISE® brand that allow for the differential diagnosis, prognosis and monitoring of complex autoimmune and autoimmune-related diseases. Our lead testing product, AVISE® CTD, enables differential diagnosis for patients presenting with symptoms indicative of a wide variety of CTDs and other related diseases with overlapping symptoms. We commercially launched AVISE® CTD in 2012 and revenue from this product comprised 71% and 83% of our revenue for the nine months ended September 30, 2020 and 2019, respectively. There is an unmet need for rheumatologists to add clarity in their CTD clinical evaluation, and we believe there is a significant opportunity for our tests that enable the differential diagnosis of these diseases, particularly for potentially life-threatening diseases such as SLE. In order to advance our integrated testing and therapeutics strategy, in December 2018 we entered into the co-promotion agreement, or the Janssen Agreement, with Janssen Biotech, Inc., or Janssen, to exclusively promote SIMPONI® in the United States for the treatment of adult patients with moderate to severe RA and for other indicated rheumatic diseases. We began direct promotion of SIMPONI® in January 2019 and in support of these promotion efforts we have a salesforce of 50 representatives as of September 30, 2020 compared to 55 representatives as of September 30, 2019. Our SIMPONI® promotion efforts contributed approximately \$3.4 million and \$0.8 million in revenue for the nine months ended September 30, 2020 and 2019, respectively, with our quarterly tiered promotion fee based on the incremental increase in total prescribed units above a predetermined average baseline. In June 2020, due in part to COVID-19, we amended the Janssen

Agreement, pursuant to which the predetermined average baseline for total prescribed units of SIMPONI® for each remaining quarter in 2020, starting with the quarter ending June 30, 2020, was adjusted from approximately 29,000 to approximately 26,000 prescribed units per quarter, and subject to adjustment under certain circumstances. For each of the third and fourth quarters of 2020, we will receive a minimum promotion fee of \$0.3 million and the fee will be capped at 5% above the adjusted predetermined baseline. See "Janssen Promotion Agreement" below for additional terms of the agreement.

We also have additional agreements with other leading pharmaceutical companies and clinical research organizations, including GlaxoSmithKline plc., or GSK, Covance Inc. and Parexel that leverage our testing products and the information generated from such tests. We plan to pursue additional strategic partnerships with a focus on the commercialization of therapeutics that are synergistic with our testing products.

We perform all of our AVISE® tests in our approximately 8,000 square foot clinical laboratory, which is certified under the Clinical Laboratory Improvement Amendments of 1988, or CLIA, by the Centers for Medicare and Medicaid Services, or CMS, and accredited by the College of American Pathologists, or CAP, and located in Vista, California. Our laboratory is certified for performance of high-complexity testing by CMS in accordance with CLIA. We are approved to offer our products in all 50 states. Our clinical laboratory reports all AVISE® testing product results within five business days. In the second quarter of 2020, we began the build out of approximately 2,000 additional square feet to our clinical laboratory which is expected to be completed in the fourth quarter of 2020.

We market our AVISE® testing products using our specialized salesforce. Unlike many diagnostic salesforces that are trained only to understand the comparative benefits of their tests, the specialized backgrounds of our salesforce coupled with our comprehensive training enables our sales representatives to interpret results from our de-identified patient test reports and provide unique insights in a highly tailored discussion with rheumatologists. Our integrated testing and therapeutics strategy results in a unique opportunity to promote and sell targeted therapies in patient focused sales calls with rheumatologists, including those with whom we have a longstanding relationship and history using our portfolio of testing products.

Reimbursement for our testing services comes from several sources, including commercial third-party payers, such as insurance companies and health maintenance organizations, government payers, such as Medicare, and patients. Reimbursement rates vary by product and payer. We continue to focus on expanding coverage among existing contracted rheumatologists and to achieve coverage with commercial payers, laboratory benefit managers and evidence review organizations.

Since inception we have devoted substantially all our efforts developing and marketing products for the diagnosis, prognosis and monitoring of autoimmune diseases. Although our revenue has increased sequentially year over year, we have never been profitable and, as of September 30, 2020 we had an accumulated deficit of \$177.8 million. We incurred net losses of \$13.2 million and \$8.6 million for the nine months ended September 30, 2020 and 2019, respectively. We expect to continue to incur operating losses in the near term as our operating expenses will increase to support the growth of our business, as well as additional costs associated with being a public company. We have funded our operations primarily through equity and debt financings and revenue from sales of our products. Through the date of our initial public offering, or IPO, in September 2019, our operations were financed primarily from sales of our common and redeemable convertible preferred stock and borrowings under various debt financings. In September 2019, we completed our IPO of 4,140,000 shares of our common stock at a price to the public of \$14.00 per share, including the exercise in full by the underwriters of their option to purchase 540,000 additional shares of our common stock. Including the option exercise, the aggregate net proceeds to us from the offering was approximately \$50.4 million, net of underwriting discounts, commissions and other offering expenses, for aggregate expenses of approximately \$7.5 million. As of September 30, 2020, we had \$61.4 million of cash and cash equivalents.

Recent Developments

In June 2020, we entered into an exclusive worldwide license agreement with the Ohio State Innovation Foundation for the commercial diagnostic development and marketing rights for a novel blood test using vibrational spectroscopy and metabolic analysis to differentiate patients with fibromyalgia from RA, osteo arthritis, chronic lower back pain and SLE. Fibromyalgia is the most common cause of chronic widespread musculoskeletal pain in the United States, and approximately 90% of fibromyalgia sufferers are female. In the United States, there may be as many as 12 million undiagnosed patients with fibromyalgia. We are planning to start a multi-center clinical trial to clinically validate the fibromyalgia test with enrollment beginning in the fourth quarter of 2020.

In July 2020, we entered into an agreement with Humana Military, a managed care support provider for TRICARE East, to offer all AVISE® tests available on an in-network basis to approximately six million Humana Military members.

In September 2020, we entered into a preferred provider network agreement with Provider Network of America, or PNOA, to offer all AVISE® tests available on an in-network basis to approximately over eight million PNOA members.

In September 2020, we launched our AVISE® Vasculitis AAV test which utilizes a testing panel of individual analytes designed to provide physicians with rapid and reliable results in the assessment and monitoring of anti-neutrophil cytoplasmic antibody-associated vasculitis, or AAV. AAV is a group of autoimmune diseases characterized by vascular inflammation and damage. Early signs and symptoms vary greatly and are not always indicative of the severity of the disease. Rapid and accurate testing is essential to prevent death and long-term disability.

Recent Publications

In October 2020, a study in collaboration with leading health economic experts was published in the journal ACR Open Rheumatology, titled "Evaluation of the Economic Benefit of Earlier Systemic Lupus Erythematosus (SLE) Diagnosis using a Multivariate Assay Panel (MAP)". This was the first ever evaluation of the economics of diagnosing SLE with AVISE® Lupus (MAP) compared to standard diagnostic laboratory tests in a hypothetical cohort of 1,000 suspected SLE patients. Over the four-year time horizon AVISE® Lupus demonstrated an estimated total direct cost savings of approximately \$2.0 million or \$1,991 per patient. In addition, the year one savings was \$655,403 or \$655 per eligible patient, with the use of AVISE® Lupus, which aligns with early benefit to health plans looking for savings in the first year.

COVID-19

The current COVID-19 worldwide pandemic has presented substantial public health challenges and is affecting our employees, patients, physicians and other healthcare providers, communities and business operations, as well as the U.S. and global economies and financial markets. International and U.S. governmental authorities in impacted regions are taking actions in an effort to slow the spread of COVID-19, including issuing varying forms of "stay-at-home" orders, and restricting business functions outside of one's home. As a result of these limitations and reordering of priorities across the U.S. healthcare system, which have resulted in a reduction in patient flow, our test volumes began to decrease in the second half of March 2020. During the third quarter of 2020, our AVISE® CTD volumes have substantially recovered to pre-COVID-19 AVISE® CTD volumes in the first quarter. For the three months ended September 30, 2020 and for the nine months ended September 30, 2020 as compared to the same period a year ago, we have experienced AVISE® CTD test volumes decreases of 4% and 8%, respectively. However, the continued spread of COVID-19 may adversely affect testing volumes in future periods, the extent of which is highly uncertain. In addition, we believe there are several other important factors that have impacted, and that we expect will impact our operating performance and results of operations, including shutdowns of our facilities and operations as well as those of our suppliers and courier services, disruptions to the supply chain of material needed for our tests, our sales and commercialization activities and our ability to receive specimens and perform or deliver the results from our tests, delays in reimbursement and coverage decisions from Medicare and third-party payors and in interactions with regulatory authorities, as well our inability to achieve volume-based pricing discounts with our key suppliers and absorb fixed laboratory expenses. In addition, we have experienced delays in patient enrollment for ongoing and planned clinical studies involving our tests. We may also face increased competition for laboratory employees due to the increased demand in the industry for such personnel.

While the full impact COVID-19 will have on our future business is unpredictable at this time, we expect it to have a material impact on our financial results for at least the next quarter and potentially beyond, depending upon the timing of any lifting or re-imposition of COVID-19 limitations on the U.S. healthcare system and general economic recovery. In response to the COVID-19 pandemic, we have curtailed non-essential employee travel and equipped most of our employees with the ability to work remotely with the exception of our clinical laboratory employees, and implemented measures to protect the health of our employees and to support the functionality of our clinical laboratory. In addition, in the second quarter of 2020, our salesforce recommenced certain field-based interactions and scaled marketing spend, although access to healthcare providers remains limited and the use of virtual sales tools has increased. From March 2020 through September 30, 2020, as a result of the COVID-19 pandemic, we terminated our temporary employees and 18 full-time employees, which included three employees at the vice president level. The full extent to which the COVID-19 pandemic will directly or indirectly continue to impact our

business, results of operations and financial condition, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain it or treat COVID-19, as well as the economic impact on local, regional, national and international markets.

Factors Affecting Our Performance

In addition to the impact of COVID-19, we believe there are several important factors that have impacted, and that we expect will impact, our operating performance and results of operations, including:

- **Continued Adoption of Our Testing Products.** Since its launch in 2012, we have grown the number of our AVISE® CTD tests delivered at a compound annual growth rate of 81%, with limited incremental investment in our commercial infrastructure. Over 105,000 AVISE® CTD tests were delivered in 2019, representing 26% growth over 2018. Through the third quarter of 2020, 71,849 AVISE® CTD tests were delivered, representing approximately 8% decline over the same period in 2019, and the number of ordering healthcare providers in the third quarter of 2020 was 1,665, representing an approximate 5% increase over the same period in 2019. For the third quarter of 2020, we had 600 adopting healthcare providers (defined as those who had prescribed at least 11 diagnostic tests in the corresponding period) compared to 575 in the same period in 2019. A high percentage of adopting healthcare providers continue to order tests in subsequent quarters, as approximately 99% of adopting healthcare providers from the second quarter of 2020 ordered at least one diagnostic test in the third quarter of 2020. More than 459,000 AVISE® CTD tests have been delivered since launch. Revenue growth for our testing products will depend on our ability to continue to expand our base of ordering healthcare providers and increase our penetration with existing healthcare providers.
- **Reimbursement for Our Testing Products.** Our revenue depends on achieving broad coverage and reimbursement for our tests from third-party payers, including both commercial and government payers such as Medicare. Payment from third-party payers differs depending on whether we have entered into a contract with the payers as a "participating provider" or do not have a contract and are considered a "non-participating provider." Payers will often reimburse non-participating providers, if at all, at a lower amount than participating providers. We have received a substantial portion of our revenue from a limited number of third-party commercial payers, most of which have not contracted with us to be a participating provider. Historically, we have experienced situations where commercial payers proactively reduced the amounts they were willing to reimburse for our tests, and in other situations, commercial payers have determined that the amounts they previously paid were too high and have sought to recover those perceived excess payments by deducting such amounts from payments otherwise being made. When we contract to serve as a participating provider, reimbursements are made pursuant to a negotiated fee schedule and are limited to only covered indications. If we are not able to obtain or maintain coverage and adequate reimbursement from third-party payers, we may not be able to effectively increase our testing volume and revenue as expected. Additionally, retrospective reimbursement adjustments can negatively impact our revenue and cause our financial results to fluctuate.
- **Promotion of SIMPONI®.** We began promoting SIMPONI® in the United States under the Janssen Agreement in January 2019. Our SIMPONI® promotion efforts contributed approximately \$3.4 million and \$0.8 million in revenue for the nine months ended September 30, 2020 and 2019, respectively. Pursuant to the amended Janssen Agreement, for each of the third and fourth quarters of 2020, we will receive a minimum promotion fee of \$0.3 million and the fee will be capped at 5% above the adjusted predetermined baseline. We may continue to encounter difficulties in successfully promoting SIMPONI® and generating significant revenue under the Janssen Agreement. Our estimate of the total U.S. addressable market for SIMPONI®'s approved indications is approximately \$28 billion. Our ability to effectively promote SIMPONI® will require us to be successful in a range of activities, including creating demand for SIMPONI® through our own sales activities as well as those of Janssen. In interest of supporting these efforts we plan to continue to evaluate the reach and frequency of our salesforce. However, we may encounter difficulties being able to maintain meaningful co-promotion revenue based on sales over the predetermined baseline and we may not be successful in materially increasing market share, which would cause us to continue to rely on our existing testing products to drive revenue growth.
- **Development of Additional Testing Products.** We rely on sales of our AVISE® CTD test to generate the significant majority of our revenue. We expect to continue to invest in research and development in order to develop additional testing products and expect these costs to increase. Our success in developing new

testing products will be important in our efforts to grow our business by expanding the potential market for our testing products and diversifying our sources of revenue.

- **Margin Expansion.** We believe growth in our promotion of therapeutics will meaningfully improve our margin profile and further support our goal of achieving profitability. We realized an increase to our gross margins beginning in the first quarter of 2020 following the expiration of a 10% annual royalty on our CB-CAPs technology. In addition, we believe we are well positioned to drive further margin expansion through a continued focus on increasing operating leverage through the implementation of certain internal initiatives, such as conducting additional validation and reimbursement oriented clinical studies to facilitate payer coverage of our testing products, capitalizing on our growing reagent purchasing to negotiate improved volume-based pricing and automation in our clinical laboratory to reduce material and labor costs. However, these potential margin increases may be partially offset by expected decreases in Medicare reimbursement rates as a result of the Protecting Access to Medicare Act of 2014, or PAMA.
- **Timing of Our Research and Development Expenses.** Our spending on experiments and clinical studies may vary substantially from quarter to quarter. We also expend funds to secure clinical samples that can be used in discovery, product development, clinical validation, utility and outcome studies. The timing of these research and development activities is difficult to predict. If a substantial number of clinical samples are obtained in a given quarter or if a high-cost experiment is conducted in one quarter versus the next, the timing of these expenses will affect our financial results. We conduct clinical studies to validate our new testing products, as well as ongoing clinical and outcome studies to further expand the published evidence to support our commercialized AVISE® testing products. Spending on research and development for both experiments and studies may vary significantly by quarter depending on the timing of these various expenses.
- **How We Recognize Revenue.** We record revenue on an accrual basis based on our estimate of the amount that will be ultimately realized for each test upon delivery based on a historical analysis of amounts collected by test and by payer. Changes to such estimates may increase or decrease revenue recognized in future periods.

While each of these areas present significant opportunities for us, they also pose significant risks and challenges that we must address. We discuss many of these risks, uncertainties and other factors in the section entitled "Risk Factors."

Janssen Promotion Agreement

In December 2018, we entered into the Janssen Agreement, under which we are responsible for the costs associated with our salesforce in promoting SIMPONI® in the United States. Janssen is responsible for all other costs associated with our promotion of SIMPONI® under the Janssen Agreement. In exchange for our sales and co-promotional services, we are entitled to a quarterly tiered promotion fee based on the incremental increase in total prescribed units of SIMPONI® for that quarter over a predetermined baseline. For all periods presented, the tiered promotion fee ranged from \$750 to \$1,250 per prescription over a predetermined baseline. Due in part to COVID-19, in June 2020 we amended the Janssen Agreement, pursuant to which the predetermined average baseline for total prescribed units of SIMPONI® for each remaining quarter in 2020, starting with the quarter ending June 30, 2020, was adjusted to approximately 26,000 prescribed units per quarter, and subject to adjustment under certain circumstances. For each of the third and fourth quarters of 2020, we will receive a minimum promotion fee of \$0.3 million and the fee will be capped at 5% above the adjusted predetermined baseline. The predetermined baseline for 2021 will be agreed upon by us and Janssen no later than November 30, 2020. The Janssen Agreement expires on December 31, 2021, unless extended by us for an additional 12 months upon 180 days written notice prior to the end of the current term. If we elect to extend the term, the predetermined baseline for 2022 will be subject to future agreement by us and Janssen. Janssen may terminate the Janssen Agreement at any time for any reason upon 30 days' notice to us, and we may terminate the Janssen Agreement for any reason at the end of any calendar quarter upon 30 days' notice to Janssen. Either party may terminate the Janssen Agreement in the event of the other party's default of any of its material obligations under the agreement if such default remains uncured for a specified period of time following receipt of written notice of such default.

We recognized approximately \$1.3 million and \$0.4 million in revenue for the three months ended September 30, 2020 and 2019, respectively, and \$3.4 million and \$0.8 million in revenue for the nine months ended September 30, 2020 and 2019, respectively, for our promotional efforts under the Janssen Agreement.

Financial Overview

Revenue

To date, we have derived nearly all of our revenue from the sale of our testing products, most of which is attributable to our AVISE[®] CTD test. We primarily market our testing products to rheumatologists in the United States. The rheumatologists who order our testing products and to whom results are reported are generally not responsible for payment for these products. The parties that pay for these services, or payers, consist of healthcare insurers, government payers (primarily Medicare and Medicaid), client payers (i.e. hospitals, other laboratories, etc.), and patient self-pay. Our service is completed upon the delivery of test results to the prescribing rheumatologists which triggers billing for the service.

We recognize revenue in accordance with the provisions of ASC Topic 606, *Revenue from Contracts with Customers*. We record revenue on an accrual basis based on our estimate of the amount that will be ultimately realized for each test upon delivery based on a historical analysis of amounts collected by test and by payer. These assessments require significant judgment by management.

Our ability to increase our revenue will depend on our ability to further penetrate the market for our current and future testing products, and increase our reimbursement and collection rates for tests delivered, as well as our ability to successfully promote SIMPONI[®].

As discussed above, our test volumes in the third quarter of 2020 substantially recovered to pre-COVID-19 volume levels, however, the continued spread of COVID-19 may adversely affect testing volumes in future periods, the extent of which is highly uncertain.

Operating Expenses

Costs of Revenue

Costs of revenue represents the expenses associated with obtaining and testing patient specimens. The components of our costs of revenue include materials costs, direct labor, equipment and infrastructure expenses associated with testing specimens, shipping charges to transport specimens, blood specimen collections fees, royalties, depreciation and allocated overhead, including rent and utilities.

Each payer, commercial third-party, government, or individual, reimburses us at different amounts. These differences can be significant. As a result, our costs of revenue as a percentage of revenue may vary significantly from period to period due to the composition of payers for each month's billings.

Due to the COVID-19 pandemic, we expect that our costs of revenue will decrease in absolute dollars in 2020 as compared to 2019, related to the decrease in test volumes described above. We expect the decrease in test volumes may result in an increase in cost per test due to our inability to realize volume discounts on materials and absorb fixed laboratory expenses.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist of personnel costs, including stock-based compensation expense, direct marketing expenses, accounting and legal expenses, consulting costs, and allocated overhead including rent, information technology, depreciation and utilities.

We expect that our selling, general and administrative expenses will increase in absolute dollars in 2020 as compared to 2019, as we continue to evaluate the reach and frequency of our sales and sales support functions and incur expenses from operating as a public company for the entire year, including expenses related to compliance with the rules and regulations of the Securities and Exchange Commission, or SEC, and the Nasdaq Global Market, additional insurance, investor relations activities and other administrative and professional services such as accounting, legal, regulatory and tax.

Research and Development Expenses

Research and development expenses include costs incurred to develop our technology, testing products and product candidates, collect clinical specimens and conduct clinical studies to develop and support our testing products and product candidates. These costs consist of personnel costs, including stock-based compensation expense, materials, laboratory supplies, consulting costs, costs associated with setting up and conducting clinical studies and allocated overhead including rent and utilities. We expense all research and development costs in the periods in which they are incurred.

We expect that our research and development expenses will increase in absolute dollars in 2020 as compared to 2019, as we continue to invest in research and development activities related to our existing testing products and product candidates.

Interest Expense

Interest expense consists of cash and non-cash interest expense associated with our financing arrangements, including the borrowings under our loan agreement with Innovatus Life Sciences Lending Fund I, LP, or Innovatus.

We expect interest expense to decrease in 2020 as compared to 2019, due to the lower interest rates. Although, we expect interest expense to remain consistent thereafter until 2023.

Other Income, Net

Other income, net, consists primarily of interest income earned on our cash and cash equivalents and amount received under the CARES Act Provider Relief Fund.

Income Tax Benefit

Income taxes include federal and state income taxes in the United States.

Results of Operations

Comparison of the Three Months Ended September 30, 2020 and 2019:

	Three Months Ended September 30,		Change
	2020	2019	
	(unaudited, in thousands)		
Revenue	\$ 10,775	\$ 10,439	\$ 336
Operating expenses:			
Costs of revenue	4,341	4,783	(442)
Selling, general and administrative expenses	9,202	7,306	1,896
Research and development expenses	1,018	507	511
Total operating expenses	14,561	12,596	1,965
Loss from operations	(3,786)	(2,157)	(1,629)
Interest expense	(647)	(909)	262
Change in fair value of financial instruments	—	(200)	200
Other income, net	125	125	—
Loss before income taxes	(4,308)	(3,141)	(1,167)
Income tax benefit	—	—	—
Net loss	\$ (4,308)	\$ (3,141)	\$ (1,167)

Revenue

Revenue increased \$0.3 million, or 3.2%, for the three months ended September 30, 2020 compared to the three months ended September 30, 2019, primarily due to an increase in revenue to approximately \$1.3 million from the co-promotion of SIMPONI® during the three months ended September 30, 2020 compared to approximately \$0.4 million during the three months ended September 30, 2019. The increase in revenue was partially offset by a decrease in the number of diagnostic tests delivered due in part to COVID-19 impacts, coupled with a decrease in

average reimbursement per AVISE[®] CTD test. The number of AVISE[®] CTD tests, which accounted for 68% and 83% of revenue in the three months ended September 30, 2020 and 2019, respectively, decreased to 26,201 tests delivered in the three months ended September 30, 2020 compared to 27,159 tests delivered in the same 2019 period. The adoption of the AVISE[®] CTD test by rheumatologists for the three months ended September 30, 2020 increased to 1,665 ordering healthcare providers as compared to 1,591 ordering healthcare providers in the same 2019 period.

Costs of Revenue

Costs of revenue decreased \$0.4 million, or 9.2%, for the three months ended September 30, 2020 compared to the three months ended September 30, 2019. This decrease was primarily due to decreased royalty costs associated with the expiration of a royalty on our CB-CAPs technology during the three months ended September 30, 2020 compared to the same 2019 period.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased \$1.9 million, or 26.0%, for the three months ended September 30, 2020 compared to the three months ended September 30, 2019. This increase was due to increased employee related expenses, including stock-based compensation, of \$1.2 million, insurance expenses of \$0.3 million, legal fees of \$0.2 million and audit and professional services of \$0.1 million.

Research and Development Expenses

Research and development expenses increased \$0.5 million, or 100.8%, for the three months ended September 30, 2020 compared to the three months ended September 30, 2019. This increase was primarily due to increased employee related expenses, including stock-based compensation, of \$0.5 million.

Interest Expense

Interest expense decreased \$0.3 million, or 28.8%, for the three months ended September 30, 2020 compared to the three months ended September 30, 2019. This decrease was primarily due to the lower interest rate under our long-term borrowing arrangements for the three months ended September 30, 2020 compared to the prior year period.

Change in Fair Value of Financial Instruments

The change in fair value of financial instruments increased \$0.2 million for the three months ended September 30, 2020 compared to the three months ended September 30, 2019. This increase is due to the conversion of warrants to purchase preferred stock into warrants to purchase our common stock in connection with the completion of our IPO in September 2019. As a result, such warrants no longer require liability accounting which resulted in the recognition of income or expense.

Other Income, Net

Other income, net, remained consistent for the three months ended September 30, 2020 compared to the three months ended September 30, 2019.

Comparison of the Nine Months Ended September 30, 2020 and 2019:

	Nine Months Ended September 30,		Change
	2020	2019	
	(unaudited, in thousands)		
Revenue	\$ 29,307	\$ 30,173	\$ (866)
Operating expenses:			
Costs of revenue	12,224	14,217	(1,993)
Selling, general and administrative expenses	27,104	20,787	6,317
Research and development expenses	2,403	1,610	793
Total operating expenses	41,731	36,614	5,117
Loss from operations	(12,424)	(6,441)	(5,983)
Interest expense	(1,913)	(2,720)	807
Change in fair value of financial instruments	—	267	(267)
Other income, net	985	264	721
Loss before income taxes	(13,352)	(8,630)	(4,722)
Income tax benefit	118	—	118
Net loss	\$ (13,234)	\$ (8,630)	\$ (4,604)

Revenue

Revenue decreased \$0.9 million, or 2.9%, for the nine months ended September 30, 2020 compared to the nine months ended September 30, 2019, primarily due to a decrease in the number of diagnostic tests delivered due to COVID-19 impacts experienced from the second half of March through September 30, 2020 coupled with a decrease in average reimbursement per AVISE[®] CTD test. The number of AVISE[®] CTD tests, which accounted for 71% and 83% of revenue in the nine months ended September 30, 2020 and 2019, respectively, decreased to 71,849 tests delivered in the nine months ended September 30, 2020 compared to 78,237 tests delivered in the same 2019 period. The adoption of the AVISE[®] CTD test by rheumatologists for the nine months ended September 30, 2020 increased to 2,273 ordering healthcare providers as compared to 2,040 healthcare providers in the same 2019 period. The decrease in testing revenue was partially offset by an increase in revenue to approximately \$3.4 million from the co-promotion of SIMPONI[®] during the nine months ended September 30, 2020 compared to approximately \$0.8 million during the nine months ended September 30, 2019.

Costs of Revenue

Costs of revenue decreased \$2.0 million, or 14.0%, for the nine months ended September 30, 2020 compared to the nine months ended September 30, 2019. This decrease was primarily due to decreased direct costs such as materials and supplies associated with the decrease in test volume and decreased royalty costs associated with the expiration of a royalty on our CB-CAPs technology during the nine months ended September 30, 2020 compared to the same 2019 period.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased \$6.3 million, or 30.4%, for the nine months ended September 30, 2020 compared to the nine months ended September 30, 2019. This increase was due to increased employee related expenses, including stock-based compensation, of \$3.6 million and increases related to insurance expenses of \$0.9 million, legal fees of \$0.7 million and audit and professional services of \$0.6 million. The nine months ended September 30, 2020 included one-time restructuring charges of approximately \$0.2 million.

Research and Development Expenses

Research and development expenses increased \$0.8 million, 49.3%, for the nine months ended September 30, 2020 compared to the nine months ended September 30, 2019. This increase was primarily due to increased employee related expenses, including stock-based compensation, of \$0.7 million and professional service fees of \$0.2 million, partially offset by a decrease in clinical trial expenses of \$0.1 million.

Interest Expense

Interest expense decreased \$0.8 million, or 29.7%, for the nine months ended September 30, 2020 compared to the nine months ended September 30, 2019. This decrease was primarily due to the lower interest rate under our long-term borrowing arrangements for the nine months ended September 30, 2020 compared to the prior year period.

Change in Fair Value of Financial Instruments

The change in fair value of financial instruments decreased \$0.3 million for the nine months ended September 30, 2020 compared to the nine months ended September 30, 2019. This decrease is due to the conversion of warrants to purchase preferred stock into warrants to purchase our common stock in connection with the completion of our IPO in September 2019. As a result, such warrants no longer require liability accounting which resulted in the recognition of income or expense.

Other Income, Net

Other income, net, increased \$0.7 million for the nine months ended September 30, 2020 compared to the nine months ended September 30, 2019. The increase is primarily due to the \$0.7 million received under the CARES Act Provider Relief Fund due to lost revenues attributable to COVID-19 during the second quarter of 2020.

Income Tax Benefit

Income tax benefit increased \$0.1 million for the nine months ended September 30, 2020 compared to the nine months ended September 30, 2019 due to a change in tax law under the CARES Act.

Liquidity and Capital Resources

We have incurred net losses since our inception. For the nine months ended September 30, 2020 and 2019, we incurred a net loss of \$13.2 million and \$8.6 million, respectively, and we expect to incur additional losses and increased operating expenses in future periods. As of September 30, 2020, we had an accumulated deficit of \$177.8 million. To date, we have generated only limited revenue, and we may never achieve revenue sufficient to offset our expenses.

Through the date of our IPO in September 2019, our operations were financed primarily from sales of our common and redeemable convertible preferred stock and borrowings under various debt financings. In September 2019, we completed our IPO of 4,140,000 shares of its common stock at a price to the public of \$14.00 per share, including the exercise in full by the underwriters of their option to purchase 540,000 additional shares of our common stock. Including the option exercise, the aggregate net proceeds to us from the offering was approximately \$50.4 million, net of underwriting discounts, commissions and other offering expenses, for aggregate expenses of approximately \$7.5 million. As of September 30, 2020, we had \$61.4 million of cash and cash equivalents. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. Currently, our funds are held in cash and money market funds.

In September 2017, we entered into the loan and security agreement with Innovatus under which we immediately drew down \$20.0 million. In December 2018, we borrowed an additional \$5.0 million under the loan agreement. In November 2019, we amended the loan agreement, which we collectively refer to as the Amended Loan Agreement. Pursuant to the Amended Loan Agreement, the loan term is for five years with a final maturity date of November 2024. The Amended Loan Agreement accrues interest at an annual rate of 8.5%, of which 2.0%, during the first 36 months, will be treated as paid in-kind interest. Paid in-kind interest is added to the principal balance each period. After the initial 36 months of the loan, the entire 8.5% will be paid in cash at the end of each period. On or after the first anniversary of the Loan Amendment, but before the second anniversary of the Loan Amendment, we may, at our option, prepay the term loan borrowings by paying the lender a prepayment premium. Prepayment before the second anniversary of the Loan Amendment may only occur for specified reasons in the Amended Loan Agreement. The prepayment premium decreases by 1% during each subsequent twelve-month period after the first anniversary of the Loan Amendment.

Our obligations under the Amended Loan Agreement are secured by a security interest in substantially all of our assets, including our intellectual property. The Amended Loan Agreement contains customary conditions to borrowing, events of default, and covenants, including covenants requiring us to maintain certain levels of minimum liquidity of \$2.0 million and achieve certain minimum amounts of revenue, and limiting our ability to dispose of assets, undergo a change in control, merge with or acquire other entities, incur debt, incur liens, pay dividends or

other distributions to holders of our capital stock, repurchase stock and make investments, in each case subject to certain exceptions. The consequences of failing to achieve the performance covenant will be cured if, within sixty days of failing to achieve the performance covenant, we issue additional equity securities or subordinated debt with net proceeds sufficient to fund any cash flow deficiency generated from operations, as defined. Our revenues for the twelve-month period ended September 30, 2020 were lower than the specified targets, subsequent to September 30, 2020, we and Innovatus agreed on a new management plan and target to bring us back into compliance with the Loan Amendment. In addition, upon the occurrence of an event of default, Innovatus, among other things, can declare all indebtedness due and payable immediately, which would adversely impact our liquidity and reduce the availability of our cash flows to fund working capital needs, capital expenditures and other general corporate purposes.

In connection with the execution of the 2017 Term Loan Agreement, we issued the lender a seven-year warrant to purchase 15,384,615 shares of our Series F redeemable convertible preferred stock at an exercise price of \$0.078 per share, and in December 2018, in connection with the additional \$5.0 million borrowed under the 2017 Term Loan Agreement, we issued to the lender a seven-year warrant to purchase 3,846,154 shares of our Series F redeemable convertible preferred stock at an exercise price of \$0.078 per share. In connection with the completion of our IPO in September 2019, the warrants were automatically converted into warrants exercisable for an aggregate of 104,722 shares of common stock at an exercise price of \$14.32.

In April 2020, we received \$0.7 million of funding under the CARES Act Provider Relief Fund, subject to our agreement to comply with the Department of Health & Human Services' standard terms and conditions. The CARES Act Provider Relief Fund is a federal fund allocated for general distributions to Medicare facilities and providers impacted by the COVID-19 pandemic and is intended to support healthcare-related expenses or lost revenue attributable to COVID-19.

Funding Requirements

Our primary uses of cash are to fund our operations as we continue to grow our business. We expect to continue to incur operating losses in the near term as our operating expenses will be increased to support the growth of our business. We expect that our costs of revenue, selling, general and administrative expenses, and research and development expenses will continue to increase as we increase our test volume, expand our marketing efforts and increase our internal salesforce to drive increased adoption of and reimbursement for our AVISE[®] testing products, promote SIMPONI[®], prepare to commercialize new testing products, continue our research and development efforts and further develop our product pipeline. We believe we have sufficient laboratory capacity to support increased test volume. Other than the addition of laboratory equipment, we expect that we will not need to make material capital expenditures in the near term related to our laboratory facilities. Cash used to fund operating expenses is impacted by the timing of when we pay expenses, as reflected in the change in our outstanding accounts payable and accrued expenses.

We expect that our near- and longer-term liquidity requirements will continue to consist of working capital and general corporate expenses associated with the growth of our business, including payments we may be required to make upon the achievement of previously negotiated milestones associated with intellectual property we have licensed. Based on our current business plan, we believe that our existing cash and cash equivalents and our anticipated future revenue, will be sufficient to meet our anticipated cash requirements for at least the next 12 months.

Our estimate of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including:

- the impact of the recent COVID-19 pandemic on our business, including challenges resulting from social distancing and stay-at home orders through a reduction in testing volumes;
- our ability to maintain and grow sales of our AVISE[®] testing products, as well as the costs associated with conducting clinical studies to demonstrate the utility of our products and support reimbursement efforts;
- our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payers and adequate market share and revenue for our testing products;
- fluctuations in working capital;
- the costs of developing our product pipeline, including the costs associated with conducting our ongoing and future validation studies;

- the additional costs we may incur as a result of operating as a public company;
- the costs associated with our promotion of SIMPONI[®], including the expansion of our sales capabilities, and the extent and timing of generating revenue from such promotion; and
- the extent to which we establish additional partnerships or in-license, acquire or invest in complementary businesses or products.

Until such time, if ever, as we can generate revenue to support our costs structure, we expect to finance our operations through equity offerings, debt financings or other capital sources, including potentially collaborations, licenses and other similar arrangements. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders may be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. If additional funding is required or desired, there can be no assurance that additional funds will be available to us on acceptable terms on a timely basis, if at all, or that we will generate sufficient cash from operations to adequately fund our operating needs or achieve or sustain profitability. If we are unable to raise additional capital or generate sufficient cash from operations to adequately fund our operations, we will need to delay, reduce or eliminate some or all of our research and development programs, product portfolio expansion plans or commercialization efforts. Doing so will likely have an unfavorable effect on our ability to execute on our business plan and could have a negative impact on our relationships with parties such as Janssen. If we cannot expand our operations or otherwise capitalize on our business opportunities because we lack sufficient capital, our business, financial condition, and results of operations could be adversely affected.

Cash Flows

The following table summarizes our cash flows for the periods indicated:

	Nine Months Ended September 30,	
	2020	2019
(in thousands)	(unaudited)	
Net cash provided by (used in):		
Operating activities	\$ (10,185)	\$ (5,784)
Investing activities	(450)	(77)
Financing activities	(15)	70,525
Net change in cash, cash equivalents and restricted cash	<u>\$ (10,650)</u>	<u>\$ 64,664</u>

Cash Flows from Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2020 was \$10.2 million and primarily resulted from our net loss of \$13.2 million adjusted for non-cash charges of \$2.8 million related to stock-based compensation, non-cash interest, depreciation, amortization and deferred income taxes and changes in our net operating assets of \$0.3 million primarily related to net increases in account receivables, partially offset by net decreases in prepaid expenses and other current assets and net increases in accounts payables and accrued liabilities.

Net cash used in operating activities for the nine months ended September 30, 2019 was \$5.8 million and primarily resulted from our net loss of \$8.6 million adjusted for non-cash charges of \$1.4 million for depreciation, amortization, stock-based compensation, non-cash interest and the revaluation of our preferred stock liabilities, and changes in our net operating assets of \$1.5 million related to net increases in accounts payable and accrued liabilities.

Cash Flows from Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2020 and September 30, 2019 was \$0.5 million and \$0.1 million, respectively, and was due to net purchases of property and equipment.

Cash Flows from Financing Activities

Net cash used in financing activities for the nine months ended September 30, 2020 was \$15,000 and primarily resulted from principal payments on capital lease obligations, as well as proceeds from the Paycheck Protection Program loan, which were subsequently repaid in May 2020, partially offset by proceeds from Employee Stock Purchase Plan purchases.

Net cash provided by financing activities for the nine months ended September 30, 2019 was \$70.5 million and primarily resulted from net proceeds received from our IPO of \$52.2 million as well as net proceeds received from the issuance of our redeemable convertible preferred stock of \$18.4 million.

Critical Accounting Policies and Significant Management Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our condensed financial statements, which have been prepared in accordance with United States generally accepted accounting principles, or U.S. GAAP. The year-end condensed balance sheet data was derived from audited financial statements, but does not include all disclosures required by U.S. GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions, and any such differences may be material.

For a description of our critical accounting policies, please see the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations - Critical Accounting Policies and Significant Management Estimates" contained in the Annual Report on Form 10-K for the year ended December 31, 2019, filed on March 25, 2020. There have been no significant changes in our critical accounting policies and estimates during the three months ended September 30, 2020 as compared to the critical accounting policies and estimates disclosed in Management's Discussion and Analysis of Financial Condition and Operations included in the Annual Report on Form 10-K for the year ended December 31, 2019, filed on March 25, 2020, other than as set forth in Note 2 to the unaudited condensed financial statements included in this quarterly report.

Recent Accounting Pronouncements

Please see Note 2 of Part I, Item 1 of this Quarterly Report on Form 10-Q for a summary of changes in significant accounting policies.

Off-Balance Sheet Arrangements

During the periods presented we did not have, nor do we currently have any off-balance sheet arrangements, as defined under the rules and regulations of the SEC.

JOBS Act Accounting Election

The JOBS Act contains provisions that, among other things, reduce certain reporting requirements for an "emerging growth company." The JOBS Act permits an "emerging growth company" such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We have elected to use this extended transition period under the JOBS Act until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our audited financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

We will remain an emerging growth company until the last day of our fiscal year following the fifth anniversary of the date of the first sale of our common equity securities pursuant to an effective registration statement under the Securities Act, which such fifth anniversary will occur in 2024. However, if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, our annual gross revenues exceed \$1.07 billion or we issue more than \$1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Not applicable.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our periodic and current reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, control may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Our management, with the participation of our principal executive officer and our principal financial officer, evaluated, as of the end of the period covered by this quarterly report, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Based on that evaluation, our principal executive officer and principal financial officer have concluded that as of September 30, 2020, our disclosure controls and procedures were effective at the reasonable assurance level. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting during the three months ended September 30, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Part II. Other Information

Item 1. Legal Proceedings

We are currently not a party to any material legal proceedings. From time to time, we may be involved in legal proceedings or subject to claims incident to the ordinary course of business. Regardless of the outcome, such proceedings or claims can have an adverse impact on us because of defense and settlement costs, diversion of resources and other factors, and there can be no assurances that favorable outcomes will be obtained.

Item 1A. Risk Factors

There have been no material changes to the risk factors disclosed in Part I, Item 1A, "Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2019, other than as previously reported in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2020 and June 30, 2020 and changes to the risk factors set forth below:

Risks Related to Our Business and Strategy

Our business is subject to risks arising from epidemic diseases, such as the recent global pandemic of the COVID-19 coronavirus.

The current COVID-19 worldwide pandemic has presented substantial public health challenges and is affecting our employees, patients, physicians and other healthcare providers, communities and business operations, as well as the U.S. and global economies and financial markets. International and U.S. governmental authorities in impacted regions are taking actions in an effort to slow the spread of COVID-19, including issuing varying forms of "stay-at-home" orders, and restricting business functions outside of one's home. A pandemic, including COVID-19 or other public health epidemic, poses the risk that we or our employees, contractors, suppliers, third-party shipping carries, government and third-party payors and other partners may be prevented from conducting business activities for an indefinite period of time, including due to spread of the disease within these groups or due to shutdowns that may be requested or mandated by governmental authorities. As a result of current COVID-19 related limitations and reordering of priorities across the U.S. healthcare system, which have resulted in a reduction in patient flow, our test volumes began to decrease in the second half of March 2020. During the third quarter of 2020, our AVISE[®] CTD volumes substantially recovered to pre-COVID-19 AVISE[®] CTD volumes in the first quarter. For the three months ended September 30, 2020 and for the nine months ended September 30, 2020 as compared to the same period a year ago, we have experienced AVISE[®] CTD test volumes decreases of 4% and 8%, respectively. However, the continued spread of COVID-19 may adversely affect testing volumes in future periods, the extent of which is highly uncertain. In addition, we believe there are several other important factors that have impacted, and that we expect will impact our operating performance and results of operations, including shutdowns of our facilities and operations as well as those of our suppliers and courier services, disruptions to the supply chain of material needed for our tests, our sales and commercialization activities and our ability to receive specimens and perform or deliver the results from our tests, delays in reimbursement and coverage decisions from Medicare and third-party payors and in interactions with regulatory authorities, as well as our inability to achieve volume-based discounts with our key suppliers and to absorb fixed laboratory expenses. In addition, we have experienced delays in patient enrollment for ongoing and planned clinical studies involving our tests. We may also face increased competition for laboratory employees due to the increased demand in the industry for such personnel.

Our laboratory operations, including laboratory employees and medical directors, may be subject to closure or shut down, either due to the spread of the disease within these individuals, or as part of a larger scale government recommendation or mandate. Any disruption in our laboratory operations would have a material adverse effect on our business and would impede our ability to process tests in a timely manner, or at all. Additionally, as discussed above the demand for our testing products, and the demand for therapeutics, have significantly declined and may cease as COVID-19 continues to spread, including as a result of prioritization of hospital or clinical resources toward the pandemic or government imposed quarantines that impede patient flow or interrupt healthcare services or patients otherwise delaying or declining to seek treatment. The economic downturn may also result in closures of the practices of our primary customers. As it relates to our promotion efforts of SIMPONI[®], we may experience decreased demand for or discontinued treatment with SIMPONI[®] from patients who are infected by COVID-19 or who may be at higher risk of infection if it is determined that such patients should minimize exposure to immunosuppressant therapies. Additionally, if we are unable to renegotiate contract terms with our suppliers, we will not be able to utilize the volume-based price discounts due to the decrease in demand for our testing products.

The occurrence of any of the foregoing events could have a material adverse effect on our business, financial condition and results of operations. The COVID-19 pandemic and mitigation measures have had and may continue to have an adverse impact on global economic conditions which could have an adverse effect on our business and financial condition, including impairing our ability to raise capital on a timely basis or at all. The extent to which the COVID-19 pandemic impacts our results will depend on future developments that are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity of the virus and the actions to contain its impact. COVID-19 may also have the effect of heightening many of the other risks described in this section and in the "Risk Factors" section of our Annual Report on Form 10-K for the year ended December 31, 2019.

Our term loan contains restrictions that limit our flexibility in operating our business, and if we fail to comply with the covenants and other obligations under our loan agreement, the lenders may be able to accelerate amounts owed under the facility and may foreclose upon the assets securing our obligations.

In September 2017, we entered into the 2017 Term Loan Agreement, and in November 2019, we entered into the Amended Loan Amendment. The Amended Loan Agreement is collateralized by substantially all of our personal property, including our intellectual property. The Amended Loan Agreement also subjects us to certain affirmative and negative covenants, including limitations on our ability to transfer or dispose of assets, merge with or acquire other companies, make investments, pay dividends, incur additional indebtedness and liens and conduct transactions with affiliates. We are also subject to certain covenants that require us to maintain a minimum liquidity of at least \$2.0 million and achieve certain minimum amounts of annual revenue, and are required under certain conditions to make mandatory prepayments of outstanding principal. As a result of these covenants, we have certain limitations on the manner in which we can conduct our business, and we may be restricted from engaging in favorable business activities or financing future operations or capital needs until our current debt obligations are paid in full or we obtain the consent of Innovatus, which we may not be able to obtain. The Loan Amendment (i) decreased the interest rate on all borrowings to 8.5%, of which 2.0% is paid in-kind and capitalized to the principal amount of the outstanding term loan on a monthly basis under December 2022; after which interest accrues at an annual rate of 8.5%; (ii) extended the interest only period to December 2022 and the maturity date to November 19, 2024; (iii) revised the prepayment terms to (x) restrict prepayments for the initial year following the date of the Loan Amendment and (y) set the prepayment premium at 3% of the principal amount of any term loans prepaid prior to November 19, 2020, with such prepayment premium decreasing by 1% during each subsequent twelve-month period after November 2020; and (iv) replaced the interest-only milestones with a financial covenant requiring that we achieve a specified level of revenue, as measured on a rolling twelve-month basis, and commencing with the quarter ending December 31, 2019, subject to exceptions based on achievement of performance milestones and the ability to cure any default thereof with the issuance of equity securities or subordinated indebtedness. As of September 30, 2020, there was \$25.0 million in principal outstanding under the term loan and an additional \$1.6 million outstanding representing interest at 2.0% per annum payable in-kind by adding the amount to the outstanding principal balance of the term loans. Under the Amended Loan Agreement, we are required to repay any outstanding principal and capitalized interest in monthly installments over a two-year period commencing on December 1, 2022. Our revenues for the twelve-month period ended September 30, 2020 were lower than the specified targets in the Amended Loan Agreement, and as a result, subsequent to September 30, 2020, we and Innovatus agreed on a new management plan and target to bring us back into compliance with the Loan Amendment. We cannot be certain that we will be able to generate sufficient cash flow or revenue to meet the financial covenants or pay the principal and accrued interest on our debt.

In addition, upon the occurrence of an event of default, Innovatus, among other things, can declare all indebtedness due and payable immediately, which would adversely impact our liquidity and reduce the availability of our cash flows to fund working capital needs, capital expenditures and other general corporate purposes. An event of default includes, but is not limited to, our failure to pay any amount due and payable under the Amended Loan Agreement, the occurrence of a material adverse change in our business as defined in the Amended Loan Agreement, our breach of any representation or warranty in the Amended Loan Agreement, our breach of any covenant in the Amended Loan Agreement (subject to a cure period in some cases), a change in control as defined in the Amended Loan Agreement, our default on any debt payments to a third-party in an amount exceeding \$500,000 or any voluntary or involuntary insolvency proceeding. If an event of default occurs and we are unable to repay amounts due under the Amended Loan Agreement, Innovatus could foreclose on substantially all of our personal property, including our intellectual property. We cannot be certain that future working capital, borrowings or equity financings will be available to repay or refinance our debt to Innovatus or any other debt we may incur in the future.

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

Recent Sales of Unregistered Securities

None.

Use of Proceeds

On September 18, 2019, the SEC declared effective our registration statement on Form S-1 (File No. 333-233446), as amended, filed in connection with our IPO. At the closing of the offering on September 23, 2019, we issued and sold 4,140,00 shares of our common stock at the initial public offering price to the public of \$14.00 per share, which included the exercise in full of the underwriters' option to purchase additional shares. We received gross proceeds

from the IPO of \$58.0 million, before deducting underwriting discounts, commissions and other offering expenses, which resulted in net proceeds of approximately \$50.4 million and offering-related transaction costs of approximately \$7.5 million. Cowen and Company, LLC, Cantor Fitzgerald & Co and William Blair & Company, L.L.C. acted as joint book-running managers for the offering. No offering expenses were paid or are payable, directly or indirectly, to our directors or officers, to persons owning 10% or more of any class of our equity securities or to any of our affiliates.

As of September 30, 2020, we have used approximately \$12.8 million of the proceeds from our IPO primarily related to selling and marketing activities. There has been no material change in the planned use of such proceeds from that described in the final Prospectus filed by us with the SEC on September 20, 2019.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed/Furnished Herewith
		Form	File No.	Exhibit	Exhibit Filing Date	
3.1	Form of Amended and Restated Certificate of Incorporation.	8-K	001-39049	3.1	9/23/2019	
3.2	Form of Amended Restated Bylaws.	8-K	001-39049	3.2	9/23/2019	
4.1	Specimen stock certificate evidencing the shares of common stock.	S-1/A	333-233446	4.1	9/9/2019	
4.2	Amended and Restated Investors' Rights Agreement, dated July 12, 2019, by and among the Registrant and certain of its stockholders.	S-1/A	333-233446	4.2	9/9/2019	
4.3	Amended and Restated Stockholders' Agreement, dated July 12, 2019, by and among the Registrant and certain of its stockholders.	S-1/A	333-233446	4.3	9/9/2019	
4.4	Form of Common Stock Purchase Warrant issued to investors by the Registrant in connection with private placement financings.	S-1/A	333-233446	4.4	9/9/2019	
10.1	Acknowledgement Letter to Loan and Security Agreement, by and between Innovatus Life Sciences Lending I, LP and the Registrant.					X
31.1	Certificate of Principal Executive Officer, pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2	Certificate of Principal Financial Officer, pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
32.1*	Certifications Pursuant to U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Public Company Accounting Reform and Investor Protection Act of 2002.					X
101.SCH	XBRL Taxonomy Extension Schema Document.					X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.					X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.					X
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document.					X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.					X

* This certification is deemed not filed for purpose of section 18 of the Exchange Act or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.

Signatures

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

EXAGEN INC.

Date: November 10, 2020

by: /s/ Fortunato Ron Rocca
Fortunato Ron Rocca
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 10, 2020

by: /s/ Kamal Adawi
Kamal Adawi
Chief Financial Officer
(Principal Financial and Accounting Officer)

EXAGEN INC.
1261 Liberty Way
Vista, CA 92081

October 7, 2020

Innovatus Life Sciences Lending Fund I, LP
777 Third Avenue, 25th Floor
New York, NY 10017
Attention: Claes Ekstrom

Re: New Management Plan

Ladies and Gentlemen:

We refer to that certain Loan and Security Agreement, dated as of September 7, 2017 (as the same may from time to time be amended, modified, supplemented or restated, the “**Loan Agreement**”), among Innovatus Life Sciences Lending Fund I, LP (the “**Agent**”), the lenders party thereto (the “**Lenders**”), and Exagen Inc. (the “**Borrower**”). Any capitalized term used herein and not defined herein shall have the meaning assigned to such term in the Financing Agreement.

In accordance with the terms of the Loan Agreement, the Borrower intends to exercise its Equity Cure right as of the date hereof and replace the Management Plan with a New Management Plan (attached hereto as Annex I). By its signature below, the Agent and the Lenders each agree and acknowledge that, effective as of the date hereof, (i) the New Management Plan is approved in all respects, (ii) Annex Q (Management Plan) to the Loan Agreement is replaced with Annex I attached hereto and (iii) Section 6.15 of the Loan Agreement is amended to replace the percentage “seventy percent (70%)” with “one hundred percent (100%)”.

This letter agreement shall be construed under and governed by the laws of the State of New York, and may be executed in any number of counterparts and by different parties on separate counterparts. Each of such counterparts shall be deemed to be an original, and all of such counterparts, taken together, shall constitute but one and the same agreement. Delivery of an executed counterpart of this letter agreement by facsimile or electronic mail shall be equally effective as delivery of a manually executed counterpart.

IN WITNESS WHEREOF, the undersigned have caused this letter agreement to be executed by their respective officers thereunto duly authorized, as of the date first above written.

EXAGEN INC.

By: /s/ Kamal Adawi
Name: Kamal Adawi
Title: CFO

AGENT AND LENDER:

INNOVATUS LIFE SCIENCES LENDING FUND I, LP

By: Innovatus Life Sciences GP, LP

Its: General Partner

By: /s/ Andrew Dym
Name: Andrew Dym
Title: Authorized Signatory

EXAGEN INC.
CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Fortunato Ron Rocca, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Exagen Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) [paragraph omitted in accordance with Exchange Act Rule 13a-14(a)];
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

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

Date: November 10, 2020

/s/ Fortunato Ron Rocca

Fortunato Ron Rocca

President and Chief Executive Officer

(Principal Executive Officer)

EXAGEN INC.
CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Kamal Adawi, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Exagen Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) [paragraph omitted in accordance with Exchange Act Rule 13a-14(a)];
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

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

Date: November 10, 2020

/s/ Kamal Adawi

Kamal Adawi

Chief Financial Officer

(Principal Financial and Accounting Officer)

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Exagen Inc. (the "Company") hereby certifies, to such officer's knowledge, that:

1. The accompanying quarterly report on Form 10-Q of the Company for the quarterly period ended September 30, 2020 (the "Report") fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the periods presented therein.

Dated: November 10, 2020

/s/ Fortunato Ron Rocca

Fortunato Ron Rocca

President and Chief Executive Officer
(Principal Executive Officer)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. Section 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

CERTIFICATION OF CHIEF FINANCIAL OFFICER

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Exagen Inc. (the "Company") hereby certifies, to such officer's knowledge, that:

1. The accompanying quarterly report on Form 10-Q of the Company for the quarterly period ended September 30, 2020 (the "Report") fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the periods presented therein.

Dated: November 10, 2020

/s/ Kamal Adawi

Kamal Adawi

Chief Financial Officer (Principal Financial and Accounting Officer)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. Section 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.