Filed pursuant to Rule 424(b)(4)
Registration File No. 333-233446
Registration File No. 333-233832

PROSPECTUS

3,600,000 Shares

Common Stock

This is an initial public offering of common stock by Exagen Inc. We are offering 3,600,000 shares of our common stock. The initial public offering price is $14.00 per share.

Prior to this offering, there has been no public market for our common stock. Our common stock has been approved for listing on the Nasdaq Global Market under the symbol “XGN.”

We are an “emerging growth company” as that term is used in the Jumpstart Our Business Startups Act of 2012, and, as such, have elected to comply with certain reduced public company reporting requirements.

	Per share	*Total*
Initial public offering price	**$ 14.00**	**$50,400,000**
Underwriting discounts and commissions(1)	**$ 0.98**	**$ 3,528,000**
Proceeds to Exagen, before expenses	**$ 13.02**	**$46,872,000**

(1) See “Underwriting” for a description of the compensation payable to the underwriters.

We have granted the underwriters an option for a period of 30 days to purchase up to 540,000 additional shares of common stock.

Investing in our common stock involves a high degree of risk. See “Risk Factors” beginning on page 11.

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

Certain of our existing stockholders, including entities affiliated with certain of our directors, have indicated an interest in purchasing an aggregate of approximately $12.0 million in shares of our common stock in this offering at the initial public offering price per share and on the same terms as the other purchasers in this offering. However, because these indications of interest are not binding agreements or commitments to purchase, the underwriters may determine to sell more, less or no shares in this offering to any or all of these stockholders, or any or all of these stockholders may determine to purchase more, less or no shares in this offering. The underwriters will receive the same underwriting discount on any shares purchased by these stockholders as they will on any other shares sold to the public in this offering.

The underwriters expect to deliver the shares of common stock to purchasers on September 23, 2019.

Joint Book-running Managers

Cowen **Cantor** **William Blair**

September 18, 2019

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Neither we nor the underwriters have authorized anyone to provide you with information other than that contained in this prospectus or any free writing prospectus prepared by or on behalf of us or to which we have referred you. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We and the underwriters are offering to sell, and seeking offers to buy, common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus or any free writing prospectus is accurate only as of its date, regardless of its time of delivery or of any sale of shares of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

Through and including October 13, 2019 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This delivery is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

For investors outside of the United States: We have not, and the underwriters have not, done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than the United States. Persons outside of the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside of the United States.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus. This summary does not contain all of the information you should consider before investing in our common stock. You should read this entire prospectus carefully, especially the section in this prospectus entitled "Risk Factors" and our audited financial statements and the related notes thereto included elsewhere in this prospectus, before making an investment decision. As used in this prospectus, unless the context otherwise requires, references to "we," "us," "our," "our company" and "Exagen" refer to Exagen Inc.

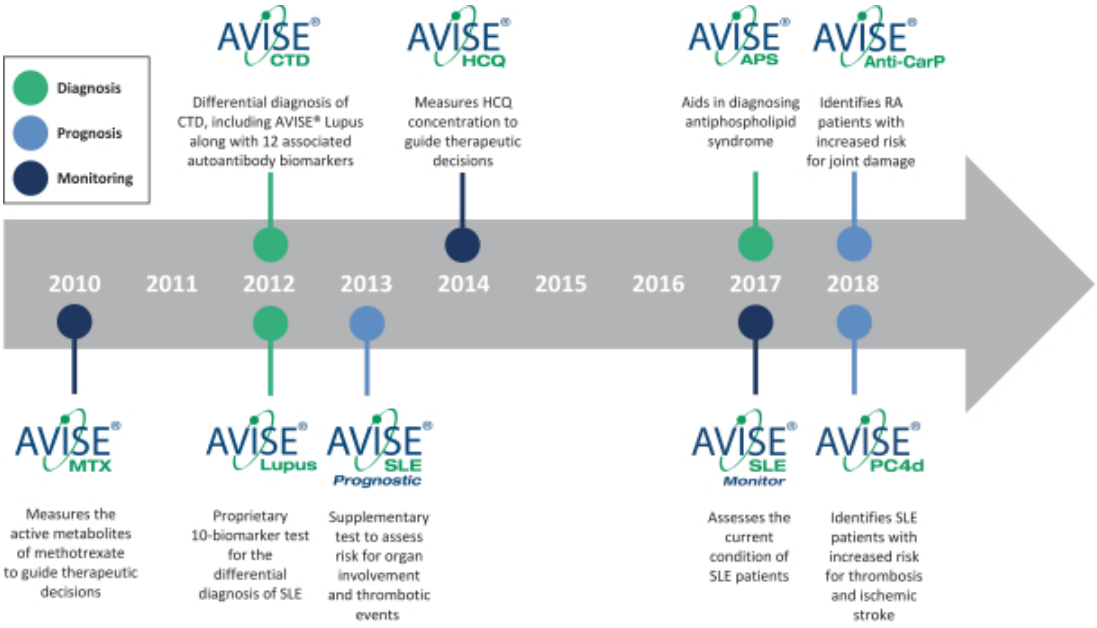
Company Overview

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 Cell-Bound Complement Activation Products, or CB-CAPs, technology. CB-CAPs assess the activation of the complement system, a biological pathway that is widely implicated across many autoimmune and autoimmune-related diseases, including systemic lupus erythematosus, or SLE. 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 SLE and rheumatoid arthritis, or RA. Our strategy includes leveraging our portfolio of testing products to market therapeutics through our sales channel and 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 nine testing products under our AVISE® brand, which we are leveraging to establish partnerships with leading pharmaceutical companies. In December 2018, we entered into a co-promotion agreement with Janssen Biotech, Inc., or the Janssen agreement, to exclusively promote SIMPONI® (golimumab), a subcutaneous, once-per-month, anti-tumor necrosis factor, or anti-TNF, biologic prescribed in combination with methotrexate, in the United States for the treatment of adult patients with moderate to severe RA and for other indicated rheumatic diseases. Combined U.S. sales of SIMPONI® and SIMPONI ARIA®, an intravenous formulation, were approximately $1.0 billion in 2018, of which we estimate approximately 50% was from sales of SIMPONI®. We began direct promotion of SIMPONI® in January 2019 and expanded our salesforce from 31 representatives as of December 31, 2018 to 55 representatives in August 2019 to support these promotion efforts. 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. We therefore believe our strategy of integrating the promotion of testing products and therapeutics uniquely positions us to expand SIMPONI®'s U.S. market share. We expect our SIMPONI® promotion efforts to contribute incremental revenue in 2019 with our quarterly tiered promotion fee based on the incremental increase in total prescribed units above a predetermined average baseline of approximately 29,000 prescribed units per quarter.

We believe our strategy of integrating the promotion of testing products and therapeutics differentiates us from other diagnostic and pharmaceutical companies, and provides our specialized salesforce greater access to rheumatologists. Our integrated testing and therapeutics strategy results in a unique opportunity to promote targeted therapies in patient focused sales calls with rheumatologists, including those with whom we have a longstanding relationship and who have a history using our portfolio of testing products.

Our lead testing product, AVISE® CTD, enables differential diagnosis for patients presenting with symptoms indicative of a wide variety of connective tissue diseases, or CTDs, and other related diseases with overlapping symptoms. The comprehensive nature of AVISE® CTD allows for the testing of a number of relevant biomarkers in one convenient blood draw, as opposed to testing serially for individual biomarkers, which adds time and cost to the diagnostic process. We believe AVISE® CTD may provide clinical utility for over 23 million patients in the United States suffering from these diseases, which include SLE, RA, Sjögren's syndrome, antiphospholipid syndrome, or APS, other autoimmune-related diseases such as autoimmune thyroid, and other disorders that mimic these diseases, such as fibromyalgia. There is an unmet need for rheumatologists to add clarity in their CTD clinical evaluations, 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. Our commitment to addressing this need is demonstrated by our strong track record of developing innovative testing products, as illustrated below:



AVISE® CTD leverages our proprietary CB-CAPs technology to differentially diagnose SLE. AVISE® CTD provides rheumatologists and their patients with sensitive and specific results that allow for potentially faster and more accurate differential diagnosis of SLE as compared to other currently-marketed testing methods. Beyond SLE, AVISE® CTD allows rheumatologists to accurately diagnose other overlapping autoimmune and autoimmune-related diseases, including RA, with the same blood sample.

Our AVISE® SLE Monitor testing product also leverages our proprietary CB-CAPs technology by measuring two CB-CAPs biomarkers that offer insight into a patient's disease activity. This test is designed to enable rheumatologists to effectively assess and optimize therapeutic intervention in patients diagnosed with SLE. Depending on disease severity, AVISE® SLE Monitor may be utilized by patients multiple times a year throughout their lives.

Our RA-focused testing products include AVISE® MTX and AVISE® Anti-CarP. AVISE® MTX is a drug monitoring test designed to aid in the optimization of methotrexate therapy, the standard of care and first-

line therapy for patients with RA. AVISE® MTX is based on our proprietary methotrexate polyglutamate, or MTXPG, technology that measures blood levels of MTXPGs, the active metabolite of methotrexate linked to disease control in RA patients. Measuring MTXPGs allows rheumatologists to identify patients presenting with inadequate exposure to methotrexate, enabling them to optimize dosing and achieve therapeutic levels commensurate with adequate disease control. AVISE® Anti-CarP, which measures anti-carbamylated protein antibody, or anti-CarP, was developed by the Leiden University Medical Center and we recently introduced it as a biomarker-driven RA prognostic test through a distribution agreement with Inova Diagnostics, Inc. with the goal of identifying patients prone to more severe disease.

We market our AVISE® testing products using our specialized salesforce. Since the launch of AVISE® CTD in 2012, we have delivered over 326,000 of these tests, representing a compound annual growth rate of 87% through December 31, 2018, with limited incremental investment in our commercial infrastructure. Approximately 83,000 AVISE® CTD tests were delivered in 2018, representing 18% growth over 2017, and the number of ordering physicians in the fourth quarter of 2018 reached 1,298, representing 18% growth over the same period in 2017. In the first half of 2019, 50,792 AVISE® CTD tests were delivered, representing approximately 30% growth over the same period in 2018, and the number of ordering physicians in the first half of 2019 reached 1,711. In the first half of 2019, we achieved a record number of 766 adopting physicians, which we classify as those who had previously prescribed at least 11 tests in a quarter, compared to 635 in the same period in 2018. Nearly 100% of adopting physicians continue to order tests in subsequent quarters. From launch of our direct promotion of SIMPONI® in January 2019 to the end of the second quarter of 2019, weekly ordering from healthcare providers increased by approximately 10% and total weekly prescriptions increased by approximately 17%.

In addition, we continue to populate a growing proprietary database of over 300,000 de-identified patient test results. We believe the insight emerging from these results has the potential to unlock value for pharmaceutical and biotechnology companies in the commercialization of therapeutics. We believe we also have the ability to further leverage our database to optimize patient selection in clinical trials for companies developing therapeutics for autoimmune and autoimmune-related diseases. We plan to collaborate with our existing and future pharmaceutical and biotechnology partners to help maximize the full value of our in-house database.

We believe our strategy of integrating the promotion of testing products and therapeutics differentiates us from other diagnostic and pharmaceutical companies, and provides our specialized salesforce greater access to rheumatologists. 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 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 targeted therapies in patient focused sales calls with rheumatologists, including those with whom we have a longstanding relationship and who have a history using our portfolio of testing products.

We recently entered into the Janssen agreement for the promotion of SIMPONI® in order to advance our integrated testing and therapeutics strategy. To support the co-promotion of SIMPONI®, we expanded our salesforce from 31 representatives as of December 31, 2018 to 55 representatives in August 2019. This will enable us to conduct approximately 60,500 calls annually to rheumatologists, which we believe will enable us to achieve the optimal reach and frequency with rheumatologists. We also have agreements with other leading pharmaceutical companies, including GlaxoSmithKline LLC, or GSK, Horizon Pharma USA, Inc., or Horizon Therapeutics, and Corrona, LLC, that leverage our testing products and the data generated from such tests. We provide GSK, a leader in lupus therapeutics, our test result data to provide market insight into and help increase awareness of the

benefits of an early and accurate diagnosis of SLE. Our agreement with Horizon Therapeutics entails utilizing our AVISE® MTX test to report on levels of MTXPG in patients undergoing methotrexate therapy in combination with its anti-gout product KRYSTEXXA® in an ongoing Phase 4 clinical trial. We also provide Corrona, the operator of the largest real world observational database in RA containing data from over 40,000 patients, with testing services and support. We plan to pursue additional partnerships with a focus on integrating therapeutics that are synergistic with our evolving portfolio of testing products.

We are led by an experienced management team with unique capabilities to execute on our strategy of integrating the promotion of testing products and therapeutics. Our senior management has an average of over 20 years of experience in the healthcare industry and many were previously involved with successfully building Prometheus Laboratories Inc., or Prometheus, which was focused on integrating diagnostics and therapeutics, prior to its acquisition by Nestlé Health Science S.A. in 2011.

Our Strategy

We develop and commercialize next-generation testing products and promote synergistic therapeutics to ultimately improve the care continuum for patients suffering from debilitating and chronic autoimmune diseases. The key tenets of our business strategy include:

- Drive additional market penetration for our testing products.
- Integrate the promotion of testing products and therapeutics for autoimmune and autoimmune-related diseases.
- Continue our track record of developing innovative testing products.
- Establish additional therapeutic partnerships.
- Achieve meaningful margin expansion.

Risks Related to Our Business

Our ability to execute our business strategy is subject to numerous risks, as more fully described in the section entitled “Risk Factors” immediately following this prospectus summary. These risks include, among others:

- We have a history of losses, we expect to incur net losses in the future and we may not be able to generate sufficient revenue to achieve and maintain profitability.
- In the near-term, we expect that our financial results will depend primarily on sales of our testing products, and we will need to generate sufficient revenue from these testing products to grow our business.
- Our future growth depends, in part, on our ability to execute on our strategy of integrating the promotion of our existing and future proprietary testing products with the promotion of therapeutics, and we may be unsuccessful in our promotion efforts for SIMPONI®, which could adversely affect our ability to implement this strategy.
- We may be unable to manage our ongoing and future growth effectively, which could make it difficult to execute our business strategy.
- If we lose or are unable to secure partners for our integrated testing and therapeutics strategy, or if our partners do not apply adequate resources to their relationships with us or are unable to provide, on a timely basis, an adequate and reliable supply of the therapeutics that we promote, our potential for profitability may be adversely affected.

- Our commercial success depends upon attaining and maintaining significant market acceptance of our testing products and promoted therapeutics among rheumatologists, patients, third-party payers and others in the medical community.
- We rely on sole suppliers for some of the reagents, equipment and other materials used in our testing products, and we may not be able to find replacements or transition to alternative suppliers.
- If we are unable to support demand for our current testing products or any of our future testing products or solutions, our business could suffer.
- If third-party payers do not provide coverage and adequate reimbursement for our testing products, or they breach, rescind or modify their contracts or reimbursement policies or delay payments for our testing products or promoted therapeutics, or if we or our partners are unable to successfully negotiate payer contracts, our commercial success could be compromised.
- Developing new testing products involves a lengthy and complex process, and we may not be able to commercialize on a timely basis, or at all, other testing products we are developing.
- We conduct business in a heavily regulated industry, and any changes in regulations or the U.S. Food and Drug Administration's, or FDA, enforcement discretion, or violations of regulations by us, could adversely affect our business, prospects, results of operations or financial condition.
- If we are unable to maintain intellectual property protection or if we infringe the intellectual property of others, our competitive position could be harmed.

Corporate Information

We were incorporated under the laws of the state of New Mexico in 2002, under the name Exagen Corporation. In 2003, we changed our state of incorporation from New Mexico to Delaware by merging with and into Exagen Diagnostics, Inc., pursuant to which we changed our name to Exagen Diagnostics, Inc. In January 2019, we changed our name to Exagen Inc. Our principal executive offices are located at 1261 Liberty Way, Suite C, Vista, California 92081. Our telephone number is (760) 560-1501. Our website address is www.exagen.com. The information contained in, or accessible through, our website does not constitute part of this prospectus.

We use our trademarks in this prospectus as well as trademarks, tradenames and service marks that are the property of other organizations. Solely for convenience, certain trademarks and tradenames referred to in this prospectus appear without the ® and ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or that the applicable owner will not assert its rights, to these trademarks and tradenames.

Implications of Being an Emerging Growth Company and a Smaller Reporting Company

As a company with less than $1.07 billion in revenue during our last fiscal year, we qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act, or the JOBS Act, enacted in April 2012. An emerging growth company may take advantage of reduced reporting requirements that are otherwise applicable to public companies. These provisions include, but are not limited to:

- being permitted to present only two years of audited financial statements and only two years of related Management's Discussion and Analysis of Financial Condition and Results of Operations in this prospectus;

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act;
- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We may take advantage of these provisions 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 of 1933, as amended, or 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 Securities Exchange Act of 1934, or 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.

We have elected to take advantage of certain of the reduced disclosure obligations in the registration statement of which this prospectus is a part and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. We have elected to avail ourselves of this exemption and, therefore, we may not be subject to the same implementation timing for new or revised accounting standards as other public companies that are not emerging growth companies, which may make comparison of our financials to those of other public companies more difficult.

We are also a “smaller reporting company” as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

The Offering

Common stock offered by us	3,600,000 shares.
Option to purchase additional shares	We have granted the underwriters an option exercisable for a period of 30 days after the date of this prospectus to purchase up to 540,000 additional shares of our common stock.
Common stock to be outstanding after this offering	11,494,770 shares (or 12,034,770 shares if the underwriters exercise their option to purchase additional shares of our common stock in full).
Use of proceeds	We intend to use the net proceeds from this offering for working capital purposes and other general corporate purposes, including for selling and marketing activities, research and development activities and capital expenditures. See “Use of Proceeds” for a more complete description of the intended use of proceeds from this offering.
Risk factors	You should read the “Risk Factors” section of this prospectus and the other information in this prospectus for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.
Nasdaq Global Market symbol	“XGN”

The number of shares of our common stock to be outstanding after this offering is based on 7,894,770 shares of our common stock outstanding as of June 30, 2019, after giving effect to the automatic conversion of all outstanding shares of our redeemable convertible preferred stock into 7,816,643 shares of our common stock (including the conversion of 479,967,595 shares of our Series H redeemable convertible preferred stock issued in July 2019 into 2,613,703 shares of our common stock) and the issuance of 15,072 shares of our common stock as a result of the expected net exercise of certain outstanding warrants, or the Net Exercise Warrants, in connection with the completion of this offering, based on the initial public offering price of $14.00 per share, which Net Exercise Warrants will terminate if not exercised prior to the completion of this offering, and excludes:

- 662,987 shares of our common stock issuable upon the exercise of stock options outstanding as of June 30, 2019, with a weighted-average exercise price of $1.24 per share;
- 812,745 shares of our common stock issuable upon the exercise of stock options, or the IPO grants, to be granted under our 2019 Incentive Award Plan, or the 2019 Plan, which became effective in connection with the completion of this offering with an exercise price that is equal to the initial public offering price;
- 1,013,107 shares of our common stock issuable upon the exercise of outstanding warrants (which number does not include the Net Exercise Warrants) as of June 30, 2019, with a weighted-average exercise price of $3.13 per share;

- 2,011,832 shares of our common stock reserved for future issuance under our 2019 Plan, which became effective in connection with the completion of this offering (which number includes the IPO grants, but does not include any potential annual evergreen increases pursuant to the terms of the 2019 Plan); and
- 120,000 shares of our common stock reserved for future issuance under our 2019 Employee Stock Purchase Plan, or ESPP, which became effective on the day the ESPP was adopted by our board of directors (which number does not include any potential annual evergreen increases pursuant to the terms of the ESPP).

Unless otherwise indicated, this prospectus reflects and assumes the following:

- the filing and effectiveness of our amended and restated certificate of incorporation and the adoption of our amended and restated bylaws, each of which will occur immediately prior to the completion of this offering;
- the issuance of 479,967,595 shares of our Series H redeemable convertible preferred stock in July 2019 (including the conversion of 148,928,337 shares of our Series G redeemable convertible preferred stock into 246,521,076 shares of our Series H redeemable convertible preferred stock in July 2019);
- the automatic conversion of all outstanding shares of our redeemable convertible preferred stock into 7,816,643 shares of our common stock (including the conversion of 479,967,595 shares of our Series H redeemable convertible preferred stock issued in July 2019 into 2,613,703 shares of our common stock), which will occur in connection with the completion of this offering;
- the net exercise of certain outstanding warrants to purchase shares of our common stock we issued in 2013 that have an exercise price of $1.84 per share, resulting in the issuance of an aggregate of 15,072 shares of our common stock;
- the termination of warrants to purchase 128,825 shares of our common stock outstanding as of June 30, 2019, with exercise prices that are higher than the initial public offering price of this offering and which will terminate if not exercised prior to the completion of this offering;
- the adjustment of outstanding warrants to purchase 19,230,769 shares of our Series F redeemable convertible preferred stock into warrants to purchase 104,722 shares of our common stock, which will occur in connection with the completion of this offering;
- no exercise of the outstanding options and warrants described above, other than the Net Exercise Warrants;
- a one-for-183.635 reverse stock split of our common stock which we effected on September 6, 2019; and
- no exercise by the underwriters of their option to purchase 540,000 additional shares of our common stock.

Certain of our existing stockholders, including entities affiliated with certain of our directors, have indicated an interest in purchasing an aggregate of approximately $12.0 million in shares of our common stock in this offering at the initial public offering price per share and on the same terms as the other purchasers in this offering. However, because these indications of interest are not binding agreements or commitments to purchase, the underwriters may determine to sell more, less or no shares in this offering to any or all of these stockholders, or any or all of these stockholders may determine to purchase more, less or no shares in this offering. The underwriters will receive the same underwriting discount on any shares purchased by these stockholders as they will on any other shares sold to the public in this offering.

Summary Financial Data

The following tables set forth a summary of our historical financial data as of, and for the periods ended on, the dates indicated. We have derived the summary statements of operations data for the years ended December 31, 2017 and 2018 from our audited financial statements included elsewhere in this prospectus. The statements of operations data for the six months ended June 30, 2018 and 2019 and the balance sheet data as of June 30, 2019 have been derived from our unaudited financial statements included elsewhere in this prospectus. You should read this data together with our audited financial statements and the related notes included elsewhere in this prospectus and the sections of this prospectus entitled “Selected Financial Data” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” Our historical results for any prior period are not indicative of our future results.

	Years Ended December 31,		Six Months Ended June 30,	
	2017	2018[1][3]	2018[1]	2019
(in thousands, except share and per share data)		**(As Revised)**	**(Unaudited)**	
Statements of Operations Data:				
Revenue	$ 26,807	$ 32,440	$ 14,576	$ 19,734
Operating expenses:				
Costs of revenue (excluding amortization of purchased technology)	14,137	15,379	7,524	9,434
Selling, general and administrative expenses	18,820	19,675	9,487	13,481
Research and development expenses	1,551	2,125	1,067	1,103
Amortization of intangible assets	186	141	94	–
Change in fair value of acquisition-related liabilities	(51)	–	–	–
Total operating expenses	34,643	37,320	18,172	24,018
Loss from operations	(7,836)	(4,880)	(3,596)	(4,284)
Interest expense	(2,948)	(2,868)	(1,394)	(1,811)
Loss on extinguishment of share purchase rights and 2013 Term Loan	(6,050)	–	–	–
Change in fair value of financial instruments	(9,391)	(318)	–	467
Other income, net	45	112	51	139
Loss before income taxes	(26,180)	(7,954)	(4,939)	(5,489)
Income tax (benefit) expense	(549)	58	–	–
Net loss	(25,631)	(8,012)	(4,939)	(5,489)
Accretion of redeemable convertible preferred stock	(5,353)	(9,318)	(3,694)	(4,302)
Deemed dividend recorded in connection with financing transactions	(1,790)	(1,152)	(1,152)	–
Net loss attributable to common stockholders	$ (32,774)	$ (18,482)	$ (9,785)	$ (9,791)
Net loss per share attributable to common stockholders, basic and diluted[2]	$ (520.18)	$ (293.34)	$ (155.31)	$ (155.33)
Weighted-average number of shares used to compute net loss per share attributable to common stockholders, basic and diluted[2]	63,005	63,005	63,005	63,033
Pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)[2]		$ (1.46)		$ (1.02)
Pro forma weighted-average number of shares used to compute pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)[2]		5,277,265		5,831,017

(1) We adopted ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)*, as of January 1, 2018. See Note 3 to our audited financial statements included elsewhere in this prospectus for further discussion.

(2) See Note 2 to our audited financial statements included elsewhere in this prospectus for an explanation of the method used to calculate the historical net loss and the historical and pro forma net loss per share attributable to common stockholders, basic and diluted, and the number of shares used in the computation of these per share amounts.

(3) See Note 16 to our audited financial statements included elsewhere in this prospectus for a summary of the amounts and financial statement line items impacted by the revision.

	As of June 30, 2019		
	Actual	Pro Forma(1)	Pro Forma As Adjusted(2)
	(unaudited, in thousands)		
Balance Sheet Data:			
Cash and cash equivalents	$ 16,237	$ 27,237	$ 71,809
Working capital(3)	18,210	29,210	73,782
Total assets	33,088	44,088	88,660
Borrowings, including current portion, net of discounts and debt issuance costs	25,331	25,331	25,331
Capital lease obligations, including current portion	602	602	602
Redeemable convertible preferred stock warrant liabilities	1,036	–	–
Redeemable convertible preferred stock	121,026	–	–
Total stockholders' equity (deficit)	(121,734)	11,328	55,900

(1) The pro forma balance sheet data gives effect to:

- the receipt of $11.0 million in gross proceeds from the sale of 233,446,519 shares of our Series H redeemable convertible preferred stock in July 2019;
- the conversion of 148,928,337 shares of our Series G redeemable convertible preferred stock into 246,521,076 shares of our Series H redeemable convertible preferred stock in July 2019;
- the automatic conversion of all outstanding shares of our redeemable convertible preferred stock into an aggregate of 7,816,643 shares of our common stock (including the conversion of 479,967,595 shares of our Series H redeemable convertible preferred stock issued in July 2019 into 2,613,703 shares of our common stock) and the resultant reclassification of (i) the carrying value of the redeemable convertible preferred stock to permanent equity and (ii) our Series F redeemable convertible preferred stock warrant liabilities to additional paid-in capital, and Series D and Series E redeemable convertible preferred stock warrant liabilities to net loss, a component of accumulated deficit, in connection with such conversion, all of which will occur in connection with the completion of this offering; and
- the issuance of 15,072 shares of our common stock as a result of the expected net exercise of the Net Exercise Warrants in connection with the completion of this offering, based on the initial public offering price of $14.00 per share, which Net Exercise Warrants will terminate if not exercised prior to the completion of this offering.

(2) The pro forma as adjusted balance sheet data gives effect to (i) the pro forma adjustments set forth in footnote (1) above and (ii) the issuance and sale of 3,600,000 shares of our common stock in this offering at the initial public offering price of $14.00 per share, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

(3) We define working capital as current assets less current liabilities. See our audited financial statements and the related notes included elsewhere in this prospectus for further details regarding our current assets and current liabilities.

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information in this prospectus, including our audited financial statements and related notes included elsewhere in this prospectus, before making an investment decision. If any of the following risks are realized, our business, financial condition, results of operations and prospects could be materially and adversely affected. In that event, the trading price of our common stock could decline and you could lose part or all of your investment.

Risks Related to Our Business and Strategy

We have a history of losses, we expect to incur net losses in the future and we may not be able to generate sufficient revenue to achieve and maintain profitability.

We have incurred net losses since our inception. For the years ended December 31, 2017 and 2018 and the six months ended June 30, 2019, we have incurred net losses of $25.6 million, $8.0 million (as revised) and $5.5 million, respectively, and we expect to incur additional losses this year and in future years. As of June 30, 2019, we had an accumulated deficit of $158.1 million. Over the next several years, we expect to continue to devote substantially all of our resources to increase adoption of, and reimbursement for, our testing products, to promote SIMPONI®, to develop future testing products and to continue to execute our integrated testing and therapeutics strategy. We may not be able to generate sufficient revenue to achieve and maintain profitability. Our failure to achieve and maintain profitability in the future could cause the market price of our common stock to decline.

We only recently began transitioning toward an integrated testing and therapeutics strategy. Consequently, any predictions about our future success, performance or viability may not be as accurate as they could be if we had a longer history of utilizing an integrated testing and therapeutics strategy in addition to the sale of our testing products.

In the near-term, we expect that our financial results will depend primarily on sales of our testing products, and we will need to generate sufficient revenue from these testing products to grow our business.

A significant majority of our historical revenue has been derived from the sale of our AVISE® CTD testing product, which we commercially launched in 2012. In the near term, we expect to continue to derive a majority of our revenue from sales of AVISE® CTD. We are in various stages of research and development with respect to other testing products that we may offer, but there can be no assurance that we will be able to commercialize these testing products.

The demand for our testing products may decrease or may not continue to increase at historical rates for a number of reasons. In addition, at any point in time we may decide to no longer commercialize any of our testing products for any number of reasons. While we have experienced revenue growth from the sale of our testing products, we may not be able to sustain this growth or maintain existing revenue levels. Further, we cannot ensure the continued availability of our testing products in commercial quantities at acceptable costs. If we are unable to increase sales of our testing products, expand reimbursement for our testing products, or successfully develop and commercialize additional testing products, our revenue and our ability to achieve and sustain profitability would be impaired, and the market price of our common stock could decline.

Our future growth depends, in part, on our ability to execute on our strategy of integrating the promotion of our existing and future proprietary testing products with the promotion of therapeutics, and we may be unsuccessful in our promotion efforts for SIMPONI®, which could adversely affect our ability to implement this strategy.

We are in the process of integrating our historical testing products business with the promotion of therapeutics in an integrated testing and therapeutics strategy. Our integrated testing and therapeutics strategy leverages our sales and marketing efforts, targeting rheumatologists for the commercialization of our testing products to promote therapeutics. As a result, our future growth is dependent, in part, on our ability to leverage our unique commercial model of offering testing products combined with therapeutics, including with respect to the Janssen agreement, which we entered into in December 2018 to exclusively promote SIMPONI® in the United States. Pursuant to the Janssen Agreement, we are entitled to receive a tiered promotion fee based on the total number of incremental prescriptions written above an established baseline. Our ability to effectively co-promote SIMPONI® will require us to be successful in a range of activities, including hiring, training and deploying additional sales representatives and creating demand for SIMPONI® through our commercial and sales activities as well as those of Janssen Biotech, Inc., or Janssen. If we encounter difficulties promoting SIMPONI®, our ability to generate significant revenue under the Janssen Agreement will be harmed. Janssen also has the right to terminate the Janssen agreement with or without cause after 30-days' notice. If Janssen were to exercise this right, we may be unable to recoup substantial investments we have made and intend to make in order to support the promotion of SIMPONI®. We have a limited history partnering with pharmaceutical companies for the promotion of therapeutics. Consequently, any predictions made about our future success or viability with respect to our promotion activities may not be as accurate as they could be if we had a history of successfully co-promoting therapeutics.

If we fail to successfully promote SIMPONI®, our ability to implement our integrated testing and therapeutics strategy and generate sufficient revenue to grow and sustain our business, and our business, financial condition and results of operations, will be materially adversely affected.

We may be unable to manage our ongoing and future growth effectively, which could make it difficult to execute our business strategy.

In addition to the need to scale our testing capacity, our future growth plans will also impose significant added responsibilities on management, including the need to identify, recruit, train and integrate additional employees and the need to manage additional relationships with various partners, suppliers and other third parties. In particular, we expanded our salesforce from 31 representatives as of December 31, 2018 to 55 representatives in August 2019 to help increase reach and frequency and support our integrated promotion of testing products and therapeutics. In addition, rapid and significant growth may strain our administrative and operational infrastructure and require us to expand our financial, development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. Our ability to manage our business and growth, as well as function as a public company, will require us to continue to improve our operational, financial and management controls, reporting systems and procedures. The time and resources required to optimize these systems is uncertain, and failure to complete optimization in a timely and efficient manner could adversely affect our operations. If we are unable to manage our ongoing and future growth effectively, it may be difficult for us to execute our business strategy and our business could be harmed.

If we lose or are unable to secure partners for our integrated testing and therapeutics strategy, or if our partners do not apply adequate resources to their relationships with us or are unable to provide, on a timely basis, an adequate and reliable supply of the therapeutics that we promote, our potential for profitability may be adversely affected.

In addition to the Janssen agreement, we plan to opportunistically evaluate, and may continue to enter into, additional agreements with pharmaceutical companies to integrate the promotion of our

testing products with their therapeutics. We have also entered into, and may continue to enter into, other agreements that leverage our testing products and data generated from such tests. For example, we provide GSK our test result data to provide market insight into and help increase awareness of the benefits of an early and accurate diagnosis of SLE; and our AVISE® MTX test data is used by Horizon Therapeutics to report on levels of MTXPG in patients undergoing methotrexate therapy in combination with its anti-gout product, KRYSTEXXA®, in an ongoing Phase 4 clinical trial.

The amount and timing of resources applied by our current or potential future partners are largely outside of our control. For example, we have limited control over, and rely on Janssen for, numerous activities that are critical to our ability to successfully promote SIMPONI®, such as pricing decisions, manufacture and supply of SIMPONI®, reimbursement support, marketing materials, the prosecution and enforcement of patents and other intellectual property rights related to SIMPONI® and public communications and presentations regarding SIMPONI®. We likewise have limited control of how our other partners use the information provided by our testing products.

If any of our current or future partners breaches or terminates our agreements, or fails to conduct the activities contemplated by our agreements in a timely manner, our success promoting the applicable therapeutics, testing products or information provided thereby could be diminished or blocked completely. It is possible that partners will change their strategic focus, pursue alternative technologies or develop alternative products, either on their own or in collaboration with others. For example, under the Janssen agreement, Janssen is not prohibited from developing or commercializing products that are competitive with SIMPONI®. If Janssen commercializes any competing products, it may provide lower levels of support to SIMPONI® or may terminate our agreement entirely. The effectiveness of our partners, if any, in marketing the applicable therapeutics will also affect our revenue and earnings. In addition, if our other partners encounter problems with our testing products or information provided by our testing products that they rely on as part of their efforts, our reputation and that of our testing products could be damaged, and it could impair our ability to enter into future agreements to promote therapeutics.

We rely on Janssen to provide, on a timely basis, an adequate and reliable supply of SIMPONI®. Any delay or interruption of supply or Janssen's failure to comply with regulatory or other requirements could limit its ability to make, or cause it to cease sales, of SIMPONI®. Any manufacturing defect or error discovered after SIMPONI® has been produced and distributed could result in even more significant consequences, including costly recall procedures. In addition, the importation of pharmaceutical products into the United States is subject to regulation by the FDA, and the FDA can refuse to allow an imported product into the United States if it appears that the product fails to comply with applicable laws or regulations. Moreover, Janssen and its third-party manufacturers and suppliers may experience difficulties related to their overall business and financial stability. To the extent Janssen faces manufacturing difficulties or is unable to provide an adequate and reliable supply of SIMPONI® on a timely basis, our reputation could be harmed and our business could suffer.

We do not have the capability and do not intend to discover or develop therapeutics on our own. Therefore, the success of our integrated testing and therapeutics strategy depends in part on our ability to acquire additional rights to promote therapeutics from new or existing partners. Other companies, many of which have substantially greater financial, marketing and sales resources than we do, also compete with us for the acquisition of rights to therapeutics. In addition, under the Janssen agreement, we are prohibited from selling or promoting certain types of products that are used to treat the same indications that SIMPONI® is used to treat. We may not be able to successfully negotiate any additional agreements to promote therapeutics and, if established, these relationships may not be successful. For example, potential partners, particularly those that are actively marketing their own therapeutics, may be unwilling to license commercialization rights to us or otherwise enter into terms that allow us to meaningfully participate in sales growth for their products, which could limit the

potential availability and value to us of additional agreements to promote therapeutics. The inability to enter into agreements for additional therapeutics could limit the overall growth of our business and adversely affect our business, financial condition and results of operations. Disputes could also arise between us and our existing or future partners, as to a variety of matters, including financial and intellectual property matters or other obligations under our agreements. These disputes would be both expensive and time-consuming and may result in delays in the success of therapeutics or could damage our relationship with a partner.

We may experience limits on our revenue if rheumatologists decide not to order our testing products or our promoted therapeutics or if we are otherwise unable to create or maintain demand for our testing products and promoted therapeutics.

If we are unable to create or maintain demand for either our testing products or promoted therapeutics in sufficient volume, we may not generate sufficient revenue to become profitable. To generate increased demand, we will need to continue to educate rheumatologists about the benefits of our testing products through publications in peer-reviewed medical journals, presentations at medical conferences and other similar means. We will also need to generate demand for both our testing products and promoted therapeutics through one-on-one education by our salesforce. We also plan to focus on educating patients about the benefits of these testing products and therapeutics, which we believe will be necessary to generate further demand. In addition, our inability to obtain and maintain coverage and adequate reimbursement from third-party payers may limit adoption by rheumatologists. With respect to SIMPONI® in particular, if we are unable to generate sales above certain thresholds agreed to with Janssen, we will not receive any payments under the Janssen agreement.

Rheumatologists may rely on guidelines issued by industry groups regarding the diagnosis, prognosis, treatment and monitoring of autoimmune and autoimmune-related diseases, and the monitoring of the effectiveness of therapeutic drugs used to treat such diseases before utilizing any diagnostic test or monitoring solution.

Our commercial success depends upon attaining and maintaining significant market acceptance of our testing products and promoted therapeutics among rheumatologists, patients, third-party payers and others in the medical community.

Our success depends on our ability to continue to develop and market testing products and promote therapeutics that are recognized and accepted as safe, effective, reliable and cost effective, and any testing product or promoted therapeutic that we offer may not gain or maintain market acceptance among rheumatologists, third-party payers, patients and the medical community. Market acceptance of our testing products and promoted therapeutics depends on a number of factors, including:

- the perceived accuracy of our test results by rheumatologists and patients;
- the potential and perceived advantages of our testing products and promoted therapeutics over alternative products and therapeutics;
- the demonstration in clinical studies of the performance and clinical validity of our testing products, the results of which studies may not replicate the positive results from earlier studies;
- the demonstration of clinical efficacy and safety of our promoted therapeutics compared to other more-established products;
- the introduction of new tests or therapeutics products that compete with our testing products or our promoted therapeutics or the introduction of generic versions of our promoted therapeutics;
- the product cost in relation to alternative products;
- the prevalence and severity of any adverse effects from our promoted therapeutics;
- the willingness of the target patient population to try new therapies and of rheumatologists to prescribe these therapies;

- any restrictions on the use of our promoted therapeutics, if approved, together with other medications
- publicity concerning our testing products and promoted therapeutics or competing products and treatments;
- the availability of coverage and adequate reimbursement by third-party payers, including government authorities;
- relative convenience and ease of administration; and
- the effectiveness of our sales and marketing efforts.

In addition, if we or our partners had to withdraw a product from the market, it could harm our business and could impact market acceptance of our other testing products or promoted therapeutics. If our testing products and promoted therapeutics do not achieve an adequate level of acceptance by rheumatologists, hospitals, third-party payers or patients, we may not generate sufficient revenue from that testing product or therapeutic and may not become or remain profitable. Our efforts to educate the medical community and third-party payers regarding the benefits of our testing products and promoted therapeutics may require significant resources and may never be successful.

The sizes of the markets for our testing products and promoted therapeutics have not been established with precision, and may be smaller than we estimate.

Our estimates of the annual total addressable markets for our current and potential future testing products and promoted therapeutics are based on a number of internal and third-party estimates. These include, without limitation, the number of patients with autoimmune and autoimmune-related diseases and the assumed prices at which we can sell testing products and our partners can sell therapeutics in markets that have not been established. While we believe our assumptions and the data underlying our estimates are reasonable, these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors. As a result, our estimates of the annual total addressable market for our current and potential future testing products and promoted therapeutics may prove to be incorrect. If the actual number of patients who would benefit from our testing products and promoted therapeutics, the price at which we and our partners can sell future testing products, or the annual total addressable market for our testing products and promoted therapeutics is smaller than we have estimated, it may impair our sales growth and have an adverse impact on our business.

We may expend our limited resources to pursue a particular testing product or promoted therapeutic and fail to capitalize on other testing products or promoted therapeutics that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on specific testing products and promoted therapeutics. As a result, we may forego or delay pursuit of opportunities with others that could have had greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. In addition, our spending on current and future research and development programs for testing products may not yield any commercially viable testing products. If we do not accurately evaluate the commercial potential or target market for a potential testing product or promoted therapeutic, we may forego other similar arrangements which would have been more advantageous for us to pursue.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or any guidance we may provide.

Our quarterly and annual operating results may fluctuate significantly, which makes it difficult for us to predict our future operating results. These fluctuations may occur due to a variety of factors, many of which are outside of our control, including, but not limited to:

- our ability to successfully market and sell our AVISE® testing products and continue to promote SIMPONI®;
- the extent to which our current testing and future testing products, if any, are eligible for coverage and reimbursement from third-party payers;
- the timing and cost of, and level of investment in, research, development, regulatory approval and commercialization activities relating to our testing products, which may change from time to time, and our ability to successfully commercialize new testing products;
- the cost of supplies, equipment and materials used for our testing products and laboratory operations, which may vary depending on the quantity of production and the terms of our agreements with third-party suppliers and manufacturers;
- expenditures that we may incur to acquire, develop or commercialize additional testing products and technologies;
- the level of demand for our testing products and promoted therapeutics, which may vary significantly;
- the receipt, timing and mix of revenue for our testing products and promoted therapeutics;
- future accounting pronouncements or changes in our accounting policies;
- the rate and extent to which payers make an overpayment determination and require us to return all or some portion of payments which we received in a prior period; and
- the timing and success or failure of competing products, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance.

This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, it could have a material adverse effect on our business, financial condition and results or operations.

We rely on sole suppliers for some of the reagents, equipment and other materials used in our testing products, and we may not be able to find replacements or transition to alternative suppliers.

We rely on sole suppliers for critical supply of reagents, equipment and other materials that we use to perform the tests that comprise our testing products. We also purchase components used in our testing product transportation kits from sole-source suppliers. Some of these items are unique to these suppliers and vendors. While we have developed alternate sourcing strategies for many of these materials and vendors, we cannot be certain whether these strategies will be effective or the alternative sources will be available when we need them. We are not a major customer of some of our suppliers, and these suppliers may therefore give other customers' needs higher priority than ours. If our suppliers can no longer provide us with the materials we need to perform the tests that comprise our testing products, if the materials do not meet our quality specifications, or if we cannot obtain

acceptable substitute materials, an interruption in test processing could occur and, in certain circumstances, we may be required to amend or cancel test results we have issued.

In addition, if we should encounter delays or difficulties in securing the quality and quantity of equipment we require for our testing products, we may need to reconfigure our test processes, which could result in an interruption in sales. Any such interruption may significantly affect our future revenue and harm our customer relations and reputation. In addition, in order to mitigate these risks, we may need to maintain inventories of these supplies at higher levels than would be the case if multiple sources of supply were available.

If we are unable to support demand for our current testing products or any of our future testing products or solutions, our business could suffer.

If demand for our testing products or any of our future testing products or solutions grows, we will need to continue to scale our testing capacity and processing technology, expand customer service, billing and systems processes and enhance our internal quality assurance program. We may also need additional certified laboratory scientists and other scientific and technical personnel to process higher volumes of our testing products. We cannot assure you that any increases in scale, related improvements and quality assurance will be successfully implemented or that appropriate personnel will be available. We will also need to purchase additional equipment, some of which can take several months or more to procure, setup and validate, and increase our software and computing capacity to meet increased demand. Failure to implement necessary procedures, transition to new processes, hire the necessary personnel, obtain any necessary additional equipment and increase software and computing capacity could result in higher costs of processing tests or inability to meet demand. There can be no assurance that we will be able to perform our testing on a timely basis at a level consistent with demand, or that our efforts to scale our operations, expand our personnel, equipment, software and computing capacities, or implement process enhancements will be successfully implemented and will not negatively affect the quality of test results. In addition, there can be no assurance that we will have adequate space in our laboratory facility to accommodate such required expansion. We are also currently collaborating with third parties in an effort to implement multiplex technology in our laboratory. We may experience difficulties securing a partner for this technology and integrating such technology into our existing laboratory operations, which could affect our ability to meet demand for our testing products. If we encounter difficulty meeting market demand or quality standards, our reputation could be harmed and our future prospects and our business could suffer.

If third-party payers do not provide coverage and adequate reimbursement for our testing products, or they breach, rescind or modify their contracts or reimbursement policies or delay payments for our testing products or promoted therapeutics, or if we or our partners are unable to successfully negotiate payer contracts, our commercial success could be compromised.

Successful commercialization of our testing products depends, in large part, on the availability of coverage and adequate reimbursement from third-party payers, including government payers, such as Medicare and Medicaid and private insurers. For the testing products that we develop and commercialize as well as the therapeutics we promote, each third-party payer decides whether to cover the product, the amount it will reimburse for a covered product and the specific conditions for reimbursement.

Reimbursement by third-party payers may depend on a number of factors, including the payer’s determination that tests using our technologies are:

- not experimental or investigational;
- medically necessary;
- demonstrated lead to improved patient outcomes;
- appropriate for the specific patient;

- cost-saving or cost-effective;
- supported by peer-reviewed medical journals; and
- included in clinical guidelines.

If we are unable to provide third-party payers with sufficient evidence of the clinical utility and validity of our test, they may not provide coverage, or may provide limited coverage, which will adversely affect our revenue and our ability to succeed. In addition, clinicians may be less likely to order a test unless third-party payers pay a substantial portion of the test price. Therefore, coverage determinations and reimbursement levels and conditions are critical to commercial success, and if we are not able to secure positive coverage determinations and reimbursement levels, our business will be materially adversely affected.

Third-party payers and other entities also conduct technology assessments of new medical tests and devices and provide and/or sell the results of their assessments to other parties. These assessments may be used by third-party payers and health care providers as grounds to deny coverage for or refuse to use a test or procedure. In addition, third-party payers, have increased their efforts to control the cost, utilization and delivery of healthcare services. These measures have resulted in reduced payment rates and decreased utilization for the diagnostics industry.

Effective April 25, 2012, Palmetto GBA, the Medicare molecular diagnostic services program's, or MolDx Program's, contractor, assigned the AVISE® MTX assay a unique identifier and determined that the test meets the applicable Medicare coverage criteria to support dose optimization and therapeutic decision making for patients diagnosed with RA on methotrexate. Our current Medicare contractor, Noridian, has adopted this coverage policy. Other third-party payers make their own decisions as to whether to establish a policy to reimburse our testing products, however, and because approvals must be sought on a payer by payer basis, establishing broad coverage is a time-consuming and costly process. There are many third-party payers who have not yet established a coverage policy applicable to our testing products. In addition, several Blue Cross Blue Shield plans and Aetna issued non-coverage policies with respect to AVISE® Lupus, determining that AVISE® Lupus does not meet the medical criteria for coverage and is considered investigational and/or experimental.

While our testing products are reimbursed by a number of third-party payers, we do not currently have contracts with significant private payers. We have in the past, and will likely in the future, experience delays and temporary interruptions in the receipt of payments from third-party payers due to changes in their internal processes, documentation requirements and other issues, which could cause our revenue to fluctuate from period to period.

If we are not successful in reversing existing non-coverage policies, or if other third-party payers issue negative coverage policies, these policies could have a material adverse effect on our business and operations. Even if many third-party payers currently reimburse for our testing products, such payers may withdraw coverage at any time, review and adjust the rate of reimbursement, require co-payments from patients or stop paying for our testing products altogether, any of which would reduce our revenue.

Billing for our testing products is complex, and we must dedicate substantial time and resources to the billing process to be paid for our testing products.

Billing for our testing products is complex, time consuming and expensive. Depending on the billing arrangement and applicable law, we bill various third-party payers, including Medicare and private insurance companies, as well as patients, all of which have different billing requirements. We generally bill third-party payers for our testing products and pursue reimbursement on a case-by-case basis where pricing contracts are not in place. We may also face increased risk in our collection efforts,

including long collection cycles and potential delays in claims processing, which could adversely affect our business, results of operations and financial condition.

Several factors contribute to the complexity of the billing process, including:

- differences between the list price for our testing products and the reimbursement rates of third-party payers;
- compliance with complex federal and state regulations related to billing Medicare;
- disputes among third-party payers as to which party is responsible for payment;
- differences in coverage among third-party payers;
- the effect of patient deductibles, co-payments or co-insurance;
- differences in information and billing requirements among third-party payers;
- changes to billing codes used for our testing products;
- risk of government audits related to billing;
- incorrect or missing billing information; and
- the resources required to manage the billing and claims appeals process.

We use standard industry billing codes, known as CPT codes, to bill for our testing products. If these codes were to change, there is a risk of an error being made in the claim adjudication process. Such errors can occur with claims submission, third-party transmission or in the processing of the claim by the payer. Claim adjudication errors may result in a delay in payment processing or a reduction in the amount of the payment received.

As we introduce new testing products, we will need to add new codes to our billing process as well as our financial reporting systems. Failure or delays in effecting these changes in external billing and internal systems and processes could negatively affect our collection rates, revenue and cost of collecting.

Our billing activities require us to implement compliance procedures and oversight, train and monitor our employees, and undertake internal audits to evaluate compliance with applicable laws and regulations as well as internal compliance policies and procedures. When payers deny our claims, in order to obtain reimbursement for services that we provide, we may challenge coverage and payment denials. Payers also conduct external audits to evaluate payments, which add further complexity to the billing process. If the payer makes an overpayment determination, there is a risk that we may be required to return all or some portion of prior payments we have received. Additionally, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, collectively the Affordable Care Act, or ACA, established a requirement for providers and suppliers to report and return any overpayments received from government payers under the Medicare and Medicaid programs within 60 days of identification. Failure to identify and return such overpayments exposes the provider or supplier to liability under federal false claims laws.

Additionally, from time to time, third-party payers change processes that may affect timely payment. These changes may result in uneven cash flow or impact the timing of revenue recognized with these payers. With respect to payments received from governmental programs, factors such as a prolonged government shutdown could cause significant regulatory delays or could result in attempts to reduce payments made to us by federal government healthcare programs. In addition, third-party payers may refuse to ultimately make payment if their processes and requirements have not been met on a timely basis. These billing complexities, and the related uncertainty in obtaining payment for our testing products could negatively affect our revenue and cash flow, our ability to achieve profitability, and the consistency and comparability of our results of operations.

In 2018, Noridian posted the final Medicare Physician Fee Schedule, or MPFS, and Clinical Laboratory Fee Schedule, or CLFS, which establishes the reimbursement rates to be paid by Medicare for our coverage area for tests performed after January 1, 2019. We have estimated that the implementation of these reimbursement rates will result in an approximate 10.1% reduction in anticipated reimbursements from Medicare from our AVISE® CTD testing product from levels experienced in 2018. Revenue from Medicare comprised 30% and 27% of our revenue in the year ended December 31, 2018 and the six months ended June 30, 2019, respectively. Revenue from the sale of our AVISE® CTD testing products comprised 82% and 83% of our revenue in the year ended December 31, 2018 and the six months ended June 30, 2019, respectively.

We also rely on a third-party provider to provide revenue cycle management software systems for certain processing and collection functions. In the past, we have experienced delays in claims processing as a result of our third-party provider making changes to its invoicing system, as well as not submitting claims to payers within the timeframe required. If claims for our testing products are not submitted to payers on a timely basis, or if we are required to switch to a different systems provider, it could have an adverse effect on our revenue and our business.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

At times, we share our proprietary technology and confidential information, including trade secrets, with third parties that conduct studies and other services on our behalf. We seek to protect our proprietary technology, in part, by entering into confidentiality agreements, consulting agreements or other similar agreements with our advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are intentionally or inadvertently incorporated into the technology of others or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets and despite our efforts to protect our trade secrets, a competitor's discovery of our proprietary technology and confidential information or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business, financial condition, results of operations and prospects.

Significant safety or efficacy issues could arise for our promoted therapeutics, which could have an adverse effect on our revenue and financial condition.

Pharmaceutical products receive regulatory approval based on data obtained in controlled clinical trials of limited duration. Following regulatory approval, these products will be used over longer periods of time in many patients. Investigators may also conduct additional, and perhaps more extensive, studies. If new safety or efficacy issues are reported or if new scientific information becomes available (including results of post-marketing Phase 4 trials), or if governments change standards regarding safety, efficacy or labeling, our partners may be required to amend the conditions of use for a therapeutic. For example, a partner may voluntarily provide or be required to provide updated information on a therapeutic's label or narrow its approved indication, either of which could reduce the therapeutic's market acceptance. If safety or efficacy issues with a partner's therapeutic arise, sales of the therapeutic could be halted by the partner or by regulatory authorities. Safety or efficacy issues affecting suppliers' or competitors' products also may reduce the market acceptance of one of our partner's therapeutics.

New data about a partner's therapeutics, or products similar to a partner's therapeutics, could negatively impact demand for such therapeutics due to real or perceived safety issues or uncertainty

regarding efficacy and, in some cases, could result in product withdrawal. Furthermore, new data and information, including information about therapeutic misuse, may lead government agencies, professional societies, practice management groups or organizations involved with various diseases to publish guidelines or recommendations related to the use of such therapeutics or the use of related therapies or place restrictions on sales. Such guidelines or recommendations may lead to lower sales of the applicable therapeutics and reduce our revenue or otherwise adversely affect our business, prospects, results of operations or financial condition.

If we are unable to maintain or expand our sales and marketing force to adequately address our customers' and current or future partners' needs, our business may be adversely affected.

We sell our testing products through our own specialized salesforce and have recently increased our salesforce in order to achieve the optimal reach and frequency and support our strategy of integrating the promotion of testing products and therapeutics. Our testing products compete in a concentrated specialty market, that of autoimmune and autoimmune-related diseases, and utilizing a specialized salesforce is integral to our integrated testing and therapeutics strategy. As such, we believe it is necessary to maintain a salesforce that includes sales representatives with specific technical backgrounds and industry expertise. For example, to support the co-promotion of SIMPONI®, we expanded our salesforce from 31 representatives as of December 31, 2018 to 55 representatives in August 2019. Additional agreements for the promotion of therapeutics may require us to further expand our specialized salesforce. Training of additional sales representatives can be costly and time consuming, particularly given the level of experience and sophistication we seek in our salesforce. In addition, until recently, not all of our sales representatives have promoted therapeutics, including SIMPONI®, as part of our organization, and they will need to complete additional training in order to effectively promote SIMPONI® and any other therapeutics that we promote through additional agreements. If we are unable to effectively retain, train and integrate additional sales representatives, it may adversely affect our ability to effectively market and sell our testing products. In addition, competition for highly specialized sales personnel is intense, and we may not be able to attract and retain personnel or be able to maintain an efficient and effective sales and marketing force.

Our future sales will depend in large part on our ability to maintain an effective salesforce. If we are unsuccessful in this regard, it could negatively impact our revenue growth and potential profitability.

If we are unable to compete successfully, we may be unable to increase or sustain our revenue or achieve profitability.

Our principal competition for our testing products is traditional methods used by healthcare providers to test patients with CTD-like symptoms. Such traditional methods include testing for a broad range of diagnostic, immunology and chemistry biomarkers, such as anti-nuclear antibodies, or ANA, and anti-double-stranded DNA, or anti-dsDNA, and serum complement biomarkers, such as C3 and C4. We also face competition from commercial laboratories, such as Laboratory Corporation of America Holdings, Quest Diagnostics Incorporated, ARUP Laboratories, Inc. and the Mayo Clinic, all of which have existing infrastructures to support the commercialization of diagnostic services. Large, multispecialty group medical clinics, health systems and academic medical university-based clinics may provide in-house clinical laboratories offering autoimmune and autoimmune-related disease testing services. Additionally, we compete against regional clinical laboratories providing testing in the autoimmune and autoimmune-related disease field, including Rheumatology Diagnostics Laboratories, Inc. Other potential competitors include companies that might develop diagnostic or disease or drug monitoring products, such as Myriad Genetics, Inc., Progentec Diagnostics Inc., Kypha, LLC, Genalyte Inc., Protagen AG, DxTerity Diagnostics Inc., HealthTell, Inc. and Immunovia AB. In the future, we may also face competition from companies developing new products or technologies.

Direct competition for the promotion of SIMPONI® includes all other companies with anti-TNF biologics and the marketing companies supporting their distribution and promotion. These products include HUMIRA® and RINVOQ™ from Abbvie Inc., ENBREL® from Amgen Inc., CIMZIA® from UCB, INFLECTRA® from Pfizer, (biosimilar REMICADE®) and RENFLEXIS® from Merck & Co. (biosimilar REMICADE®). Additional competitors include companies with other biologic drugs indicated for RA that have significant sales or sales potential. Specifically, these include ORENCIA® from Bristol-Myers Squibb Company, ACTEMRA® from Roche, RITUXAN® from Roche, XELJANZ® from Pfizer, KEVZARA® from Sanofi S.A. and OLUMIANT® from Eli Lilly and Company. There are also several late-stage RA drug and biosimilar development programs and several additional RA products that have minimal sales to date or that are indicated for other rheumatic indications competitive to SIMPONI® such as psoriatic arthritis and ankylosing spondylitis.

We believe the principal competitive factors in our target market include: quality and strength of clinical and analytical validation data; confidence in diagnostic results; safety and efficacy with respect to promoted therapeutics; sales and marketing capabilities; the extent of reimbursement; inclusion in clinical guidelines; cost-effectiveness; and ease of use.

Many of our potential competitors have widespread brand recognition and substantially greater financial, technical and research and development resources and selling and marketing capabilities than we do. Others may develop products with prices lower than ours that could be viewed by rheumatologists and payers as functionally equivalent to our solution or offer solutions at prices designed to promote market penetration, which could force us to lower the list price of our products and affect our ability to achieve profitability. If we are unable to change clinical practice in a meaningful way or compete successfully against current and future competitors, we may be unable to increase market acceptance and sales of our products, which could prevent us from increasing our revenue or achieving profitability and could cause the market price of our common stock to decline.

To compete successfully we must be able to demonstrate, among other things, that our testing products are accurate and cost effective and that we are effective in promoting therapeutics.

Developing new testing products involves a lengthy and complex process, and we may not be able to commercialize on a timely basis, or at all, other testing products we are developing.

We will continue to devote considerable resources to the research and development of our planned future testing products and enhancements to our current testing products. We may not be able to develop testing products with the clinical utility necessary to be useful and commercially successful. There are certain products for which a commercial launch would trigger additional payment obligations to licensors of the technology. In these cases, if the economic projections of the product do not outweigh the additional obligations, we may not launch these products. In order to develop and commercialize testing products, we need to:

- expend significant funds to conduct substantial research and development;
- conduct successful validation studies;
- develop and scale our laboratory processes to accommodate different tests;
- achieve and maintain required regulatory certifications;
- develop and scale our infrastructure to be able to analyze increasingly large amounts of data; and
- build the commercial infrastructure to market and sell new testing products.

Our testing product development process involves a high degree of risk and may take several years. Our testing product development efforts may fail for many reasons, including:

- failure to identify additional biomarkers to incorporate into our testing products;

- failure or sub-optimal performance of the testing product at the research or development stage;
- difficulty in accessing archival patient blood specimens, especially specimens with known clinical results; or
- failure of clinical validation studies to support the effectiveness of the test.

Typically, few research and development projects result in commercial products, and success in early clinical studies often is not replicated in later studies. At any point, we may abandon development of a testing product candidate or we may be required to expend considerable resources repeating clinical studies, which would adversely affect the timing for generating potential revenue from a new testing product and our ability to invest in other products in our pipeline. In addition, as we develop testing products, we will have to make significant investments in product development, marketing and selling resources. If a clinical validation study fails to demonstrate the prospectively defined endpoints of the study, we might choose to abandon the development of the testing product or product feature that was the subject of the clinical study, which could harm our business. Additionally, competitors may develop and commercialize competing products or technologies faster than us or at a lower cost.

Developing new testing products and enhancements to our existing technologies is expensive and time consuming, and there is no assurance that such activities will result in significant new marketable testing products, enhancements to our current technologies, design improvements, cost savings, revenue or other expected benefits. If we spend significant resources on research and development and are unable to generate an adequate return on our investment or divert resources away from other, more attractive growth opportunities, our business and results of operations may be materially and adversely affected.

If we cannot enter into new clinical study collaborations, our product development and subsequent commercialization could be delayed.

In the past, we have entered into clinical study collaborations, and our success in the future depends in part on our ability to enter into additional collaborations with highly regarded institutions. This can be difficult due to internal and external constraints placed on these organizations. Some organizations may limit the number of collaborations they have with any one company so as to not be perceived as biased or conflicted. Organizations may also have insufficient administrative and related infrastructure to enable collaborations with many companies at once, which can extend the time it takes to develop, negotiate and implement a collaboration. Additionally, organizations often insist on retaining the rights to publish the clinical data resulting from the collaboration. The publication of clinical data in peer-reviewed medical journals is a crucial step in commercializing and obtaining reimbursement for testing products such as our testing products, and our inability to control when and if results are published may delay or limit our ability to derive sufficient revenue from any solution.

We may acquire businesses or assets, form joint ventures or make investments in other companies or technologies that could harm our operating results, dilute our stockholders' ownership, increase our debt or cause us to incur significant expense.

As part of our business strategy, we may pursue acquisitions of complementary businesses or assets, as well as technology licensing arrangements and other strategic transactions or collaborations with third parties. We also may pursue strategic alliances that leverage our core technology and industry experience to expand our offerings or distribution, make investments in other companies or acquire ownership rights to therapeutics that are synergistic with our testing products. To date, other than our acquisition of the medical diagnostics division of Cypress Bioscience, Inc. in 2010, we have not acquired other companies or therapeutics and, except with respect to certain collaboration agreements executed in connection with our integrated testing and therapeutics strategy, we have limited experience with respect to the formation of strategic alliances and joint ventures. If we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing

business, and we could assume unknown or contingent liabilities. Any future acquisitions by us also could result in significant write-offs or the incurrence of debt and contingent liabilities, any of which could harm our operating results. Integration of an acquired company, business or assets also may require management resources that otherwise would be available for ongoing development of our existing business. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any acquisition, technology license, strategic alliance, joint venture or investment.

To finance any acquisitions or investments, we may choose to issue shares of our stock as consideration, which would dilute the ownership of our stockholders. Once we become a public company, if the price of our common stock is low or volatile, we may not be able to acquire other companies for stock. Alternatively, it may be necessary for us to raise additional funds for these activities through public or private financings or through the issuance of debt. Additional funds may not be available on terms that are favorable to us, or at all, and any debt financing may involve covenants limiting or restricting our ability to take certain actions.

Also, the anticipated benefit of any strategic alliance, joint venture or acquisition may not materialize or such strategic alliance, joint venture or acquisition may be prohibited. In addition, our loan agreement restricts our ability to pursue certain mergers, acquisitions, amalgamations or consolidations that we may believe to be in our best interest. Additionally, future acquisitions or dispositions could result in potentially dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities or amortization expenses or write-offs of goodwill, any of which could harm our financial condition. We cannot predict the number, timing or size of future joint ventures or acquisitions, or the effect that any such transactions might have on our operating results.

The diagnostics and therapeutics industries are subject to rapidly changing technology, which could make our testing products, promoted therapeutics and other testing products we develop obsolete.

Our industry is characterized by rapid technological changes, frequent new product introductions and enhancements and evolving industry standards. These advances require us to continuously develop our technology and work to develop new solutions to keep pace with evolving standards of care. Our testing products could become obsolete unless we continually innovate and expand our testing product offerings to include new clinical applications. If we are unable to develop new testing products or to demonstrate the applicability of our testing products for other diseases, our sales could decline and our competitive position could be harmed. In addition, if our promoted therapeutics become obsolete and we are unable to expand such agreements or find new partners, our sales could decline and our competitive position could be harmed. For example, with respect to SIMPONI® and the treatment of RA, active psoriatic arthritis, or active ankylosing spondylitis, there are many novel therapeutic approaches in development and we expect that the competition in this market will increase dramatically. If new therapeutics make SIMPONI® obsolete or diminish the degree to which rheumatologists prescribe it, our ability to generate revenue under the Janssen agreement will be harmed.

Our failure to maintain relationships or build new relationships with key opinion leaders could materially adversely impact our business and prospects.

Key opinion leaders are able to influence clinical practice by publishing research and determining whether new tests should be integrated into clinical guidelines. We rely on key opinion leaders early in the development process to help ensure our clinical studies are designed and executed in a way that clearly demonstrates the benefits of our testing products to physicians and payers. Our failure to maintain or build new relationships with such key opinion leaders could affect rheumatologist and patient perception of our testing products and result in a loss of existing and future customers and therefore materially adversely impact our business and prospects.

If we are sued for errors and omissions or professional liability, we could face substantial liabilities that exceed our resources.

The marketing, sale and use of our testing products could lead to liability claims if someone were to allege that any such testing product failed to perform as it was designed. We may also be subject to liability for errors in the results we provide to rheumatologists or for a misunderstanding of, or inappropriate reliance upon, the information we provide. We may also be subject to similar types of claims related to testing products we may develop in the future. An errors and omissions or professional liability claim could result in substantial damages and be costly and time consuming for us to defend. Although we maintain professional liability insurance, we cannot assure you that our insurance would fully protect us from the financial impact of defending against these types of claims or any judgments, fines or settlement costs arising out of any such claims. Any errors or omissions or professional liability claim brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage in the future. Additionally, any product liability lawsuit could cause injury to our reputation or cause us to suspend sales of our testing products. Similarly, any product liability lawsuit affecting our partners could also cause injury to our reputation or cause the applicable partner to suspend sales of its therapeutics. We may also initiate a correction or removal for one of our testing products, issue a safety alert or undertake a field action or recall to reduce a risk to health posed by potential failure of our products to perform as designed, which could lead increase costs and lead to increased scrutiny by regulatory authorities and our customers regarding the quality and safety of our testing products and to negative publicity, including safety alerts, press releases or administrative or judicial actions. The occurrence of any of these events could have an adverse effect on our business and results of operations.

The loss of members of our senior management team or our inability to attract and retain highly skilled scientists, technicians and salespeople could adversely affect our business.

Our success depends largely on the skills, experience and performance of key members of our executive management team, including Fortunato Ron Rocca, our President and Chief Executive Officer, and others in key management positions. The efforts of each of these persons will be critical to us as we continue to develop our technologies and test processes and focus on our growth. If we were to lose one or more of these key employees, we may experience difficulties in competing effectively, developing our technologies and implementing our business strategy.

In addition, our research and development programs and commercial laboratory operations depend on our ability to attract and retain highly skilled scientists, including licensed clinical laboratory scientists and biostatisticians. We may not be able to attract or retain qualified scientists and technicians in the future due to the intense competition for qualified personnel among life science businesses, particularly in Southern California. Because it is expected that there will be a shortage of clinical laboratory scientists in coming years, it may become more difficult to hire sufficient numbers of qualified personnel. We also face competition from universities and public and private research institutions in recruiting and retaining highly qualified scientific personnel. Additionally, our success depends on our ability to attract and retain qualified and highly-specialized salespeople. We may have difficulties locating, recruiting or retaining qualified salespeople, which could cause a delay or decline in the rate of adoption of our testing products and the sale of promoted therapeutics. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that could adversely affect our ability to support our research and development, clinical laboratory and sales efforts. All of our employees are at-will, which means that either we or the employee may terminate their employment at any time. We do not carry key man insurance for any of our employees.

If our sole laboratory facility becomes damaged or inoperable, we are required to vacate our existing facility or we are unable to expand our existing facility as needed, we will be unable to perform our testing services and our business will be harmed.

We currently derive all of our revenue from tests conducted at a single laboratory facility located in Vista, California. Vista is situated on or near earthquake fault lines. Our facility and equipment could be harmed or rendered inoperable by natural or man-made disasters, including earthquake, fire, flood, power loss, communications failure or terrorism. In particular, we store all of our flow cytometers, the instrument we use to detect CB-CAPs on cells, at our Vista facility. If all of our flow cytometers were rendered inoperable simultaneously pursuant to a natural or man-made disaster, we would be unable to perform these key tests as we do in the ordinary course of our business. The inability to perform the tests contained in our testing products or to reduce the backlog of analyses that could develop if our facility is inoperable, for even a short period of time, may result in the loss of customers or harm to our reputation, and we may be unable to regain those customers or repair our reputation in the future. Additionally, we store our bio-repository of specimens, which were collected in collaboration with leading academic institutions and help us to further validate our testing products, at our Vista facility. If these specimens were destroyed pursuant to a natural or man-made disaster or otherwise become unavailable, our ability to develop new testing products may be delayed. Furthermore, our facility and the equipment we use to perform our research and development work could be unavailable or costly and time-consuming to repair or replace. It would be difficult, time-consuming and expensive to rebuild our facility or license or transfer our proprietary technology to a third-party, particularly in light of the licensure and accreditation requirements for a commercial laboratory like ours. Even in the unlikely event we are able to find a third party with such qualifications to enable us to conduct the tests contained in our testing products, we may be unable to negotiate commercially reasonable terms.

In order to rely on a third party to perform the tests contained in our testing products, we would need to engage another facility with established state licensure and Clinical Laboratory Improvement Amendments of 1988, or CLIA, accreditation under the scope of which tests could be performed following validation and other required procedures. We cannot assure you that we would be able to find another CLIA-certified facility willing to comply with the required procedures, that any such facility would be willing to perform the tests contained in our testing products for us on commercially reasonable terms, or that it would be able to meet our quality standards.

In order to establish an additional clinical reference laboratory facility, we would have to spend considerable time and money securing adequate space, constructing the facility, recruiting and training employees, and establishing the additional operational and administrative infrastructure necessary to support a second facility. We may not be able, or it may take considerable time, to replicate our testing processes or results in a new facility. Additionally, any new clinical reference laboratory facility opened by us would be subject to certification under CLIA and licensing by several states, including California and New York, which could take a significant amount of time and result in delays in our ability to begin operations.

We believe we have the capacity to meet our projected needs for at least the next 12 months, although we may grow at a rate that is faster than we expect. Beyond this time frame, we may need to further expand our laboratory space. Any future expansion could disrupt laboratory operations, resulting in an inability to meet customer turnaround time expectations, and could be delayed, resulting in slower realization of laboratory efficiencies anticipated from the use of the expanded facilities. Adverse consequences resulting from a delay in the laboratory expansion could harm our relationships with our customers and our reputation, and could affect our ability to generate revenue.

We carry insurance for damage to our property and the disruption of our business, but this insurance may not cover all of the risks associated with damage or disruption to our business, provide

coverage in amounts sufficient to cover our potential losses or continue to be available to us on acceptable terms, if at all.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or manmade disasters or business interruptions, for which we are predominantly self-insured. We rely on third- party manufacturers to produce our testing products. Our ability to obtain clinical supplies of our testing products could be disrupted if the operations of these suppliers were affected by a man-made or natural disaster or other business interruption. In addition, our corporate headquarters is located in Vista, California near major earthquake faults and fire zones, and the ultimate impact on us of being located near major earthquake faults and fire zones and being consolidated in a certain geographical area is unknown. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

Our testing process involves the use of sophisticated state-of-the-art equipment that requires precise calibration, and issues affecting such equipment may delay delivery or impact the quality of the test results to rheumatologists or otherwise adversely affect our operations.

As part of our process of determining CB-CAPs, which is part of our AVISE® Lupus product, we utilize a number of flow cytometers that require calibration and performance validation according to the requirements of the College of American Pathologists, or CAP, at specified time intervals. While we believe we have implemented appropriate controls and metrics in our laboratory to meet such requirements, we cannot provide any assurance that our instruments will not fall out of specification, in which case we would be required to re-calibrate them. Failure to timely re-calibrate our instruments could negatively impact the test results, which could result in liability and harm our reputation. Patient specimens degrade and become unusable generally within 48 hours of collection. Therefore, if we do not have other sufficient properly functioning flow cytometers due to failure to meet specifications or they otherwise become inoperable, our ability to process patient specimens in the required timeframe would be compromised and our business could be harmed.

If we use hazardous materials in a manner that causes contamination or injury, we could be liable for resulting damages.

We are subject to federal, state and local laws, rules and regulations governing the use, discharge, storage, handling and disposal of biological material, chemicals and waste. We cannot eliminate the risk of accidental contamination or injury to employees or third parties from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages, remediation costs and any related penalties or fines, and any liability could exceed our resources or any applicable insurance coverage we may have. The cost of compliance with these laws and regulations may become significant, and our failure to comply may result in substantial fines or other consequences, either of which could negatively affect our operating results.

Failure in our information technology, telephone or other systems could significantly disrupt our operations and adversely affect our business and financial condition.

Information technology and telephone systems are used extensively in virtually all aspects of our business, including laboratory testing, sales, billing, customer service, logistics and management of medical data. The success of our business depends on the ability to obtain, process, analyze, maintain and manage this data. Our management relies on our information systems because:

- patient specimens must be received, tracked and processed on a timely basis;

- test results must be reported on a timely basis;
- billings and collections for all customers must be managed efficiently and accurately;
- third party ancillary billing services require proper tracking and reporting;
- pricing and other information related to our services is needed by our salesforce and other personnel in a timely manner to conduct business;
- patient-identifiable health information must be securely held and kept confidential;
- regulatory compliance requires proper tracking and reporting; and
- proper recordkeeping is required for operating our business, managing employee compensation and other personnel matters.

Our business, results of operations and financial condition may be adversely affected if, among other things:

- our information technology, telephone or other systems fail or are interrupted for any extended length of time;
- services relating to our information technology, telephone or other systems are not kept current;
- our information technology, telephone or other systems do not have the capacity to support expanded operations and increased levels of business;
- data is lost or unable to be restored or processed; or
- data is corrupted due to a breach of security.

Despite the precautionary measures we have taken to prevent breakdowns in our information technology, telephone and other systems, sustained or repeated system failures that interrupt our ability to process test orders, deliver test results or perform testing in a timely manner or that cause us to inadvertently disclose or lose patient information could adversely affect our business, results of operations and financial condition.

Security breaches, loss of data and other disruptions to us, our third-party service providers or our partners could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.

In the ordinary course of our business, we and our partners, and our respective third-party service providers collect and store sensitive data, such as legally protected health information, including de-identified test reports, personally identifiable information about our patients, credit card information, intellectual property, and our proprietary business and financial information. We manage and maintain our applications and data utilizing a combination of on-site and vendor-owned systems. We face a number of risks related to our protection of, and our service providers' protection of, this critical information, including loss of access, unauthorized disclosure and unauthorized access, as well as risks associated with our ability to identify and audit such events. In addition, we have limited control over the storage of sensitive data by our third-party therapeutics partners as well as risks related to the transfer and sale of de-identified data files to such partners.

The secure processing, storage, maintenance and transmission of this critical information is vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure, and that of our third-party billing and collections provider, may be vulnerable to attacks by hackers or viruses or otherwise breached due to employee error, malfeasance or other activities. While we have not experienced any such attack or breach, if such an event were to occur, our networks would be compromised and the information we

store on those networks could be accessed by unauthorized parties, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, such as the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Exonomic and Clinical Health Act, or the HITECH Act, and their implementing regulations and regulatory penalties. Unauthorized access, loss or dissemination could also disrupt our operations, including our ability to process tests, provide test results, bill payers or patients, process claims and appeals, provide customer assistance services, conduct research and development activities, collect, process and prepare company financial information, provide information about our products and other patient and rheumatologist education and outreach efforts through our website and manage the administrative aspects of our business and could damage our reputation, any of which could adversely affect our business.

In addition, the interpretation and application of federal and state consumer, health-related and data protection laws in the United States are often uncertain, contradictory and in flux. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices, systems and compliance procedures in a manner adverse to our business.

Performance issues, service interruptions or price increases by our shipping carrier could adversely affect our business, results of operations and financial condition, and harm our reputation and ability to provide testing services on a timely basis.

Expedited, reliable shipping is essential to our operations. While we have recently begun working with United Parcel Service, we still rely extensively on a single carrier, Federal Express Corporation for reliable and secure point-to-point transport of patient specimens to our laboratory and enhanced tracking of these patient specimens. Should Federal Express, or any other carrier we may use in the future, encounter delivery performance issues such as loss, damage or destruction of a specimen, it may be difficult to replace our patient specimens in a timely manner and such occurrences may damage our reputation and lead to decreased utilization from rheumatologists for our testing services and increased cost and expense to our business. In addition, any significant increase in shipping time could adversely affect our ability to receive and process patient specimens on a timely basis.

If we or Federal Express were to terminate our relationship, we would be required to find another party to provide expedited, reliable point-to-point transport of our patient specimens. There are only a few other providers of such nationwide transport services, and there can be no assurance that we will be able to enter into arrangements with such other providers on acceptable terms, if at all. Finding a new provider of transport services would be time-consuming and costly and result in delays in our ability to provide our testing services. Even if we were to enter into an arrangement with any such provider, there can be no assurance that they will provide the same level of quality in transport services currently provided to us by Federal Express. If any new provider does not provide, or if Federal Express does not continue to provide, the required quality and reliability of transport services at the same or similar costs, it could adversely affect our business, reputation, results of operations and financial condition.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an “ownership change” (generally defined as a greater than 50 percentage-point change (by value) in its equity ownership by “5-percent shareholders,” as defined in the Code, over a three-year period), the corporation’s ability to use its pre-change net operating loss, or NOL,

carryforwards and other pre-change tax attributes to offset its post-change federal taxable income and taxes, as applicable, may be limited. Under recently enacted U.S. tax legislation, federal NOL carryforwards generated in periods after December 31, 2017, may be carried forward indefinitely but may only be used to offset 80% of our taxable income annually. Our ability to use a portion of our NOL carryforwards is subject to limitation under Section 382 of the Code as a result of a prior ownership change. If we undergo an ownership change in connection with this offering, or as a result of subsequent shifts in our stock ownership, our ability to utilize our NOL carryforwards and other pre-change tax attributes could be further limited by Sections 382 and 383 of the Code. Similar provisions of state tax law may also apply. As a result, if we earn net taxable income, our ability to use such pre-change NOL carryforwards and other pre-change tax attributes to offset taxable income and taxes, as applicable, may be limited.

Recent U.S. tax legislation may materially adversely affect our financial condition, results of operations and cash flows.

Recently enacted U.S. tax legislation, known as the Tax Cuts and Jobs Act of 2017, has significantly changed the U.S. federal income taxation of U.S. corporations, including by reducing the U.S. corporate income tax rate and revising the rules governing NOLs. Many of these changes are effective immediately, without any transition periods or grandfathering for existing transactions. The legislation is unclear in many respects and could be subject to potential amendments and technical corrections, as well as interpretations and implementing regulations by the U.S. Treasury and U.S. Internal Revenue Service, any of which could lessen or increase certain adverse impacts of the legislation. In addition, it is unclear how these U.S. federal income tax changes will affect state and local taxation, which often uses federal taxable income as a starting point for computing state and local tax liabilities. Based on our current evaluation of this legislation, the reduction of the U.S. corporate income tax rate required a provisional write-down of our deferred income tax assets (including the value of our NOL carryforwards and our tax credit carryforwards).

There may be other material adverse effects resulting from the legislation that we have not yet identified. While some of the changes made by the tax legislation may adversely affect us in one or more reporting periods and prospectively, other changes may be beneficial on a going forward basis. We continue to work with our tax advisors to determine the full impact that the recent tax legislation as a whole will have on us. We urge our investors to consult with their legal and tax advisors with respect to such legislation and the potential tax consequences of investing in our common stock.

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 a loan and security agreement, or the loan agreement, with Innovatus Life Sciences Lending Fund I, LP, or Innovatus. The loan agreement is collateralized by substantially all of our personal property, including our intellectual property. The 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. On December 7, 2018, we borrowed an additional $5.0 million under the loan

agreement, as a result of meeting the requisite trailing twelve-month revenue and gross margin milestones. As of June 30, 2019, there was $25.0 million in principal outstanding under the term loan and an additional $1.0 million outstanding representing interest at 2.5% per annum payable in-kind by adding the amount to the outstanding principal balance of the term loans. Under the loan agreement, we are required to repay any outstanding principal and capitalized interest in monthly installments over a two-year period commencing on October 1, 2020. 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 loan agreement, the occurrence of a material adverse change in our business as defined in the loan agreement, our breach of any representation or warranty in the loan agreement, our breach of any covenant in the loan agreement (subject to a cure period in some cases), a change in control as defined in the 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 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.

We may require substantial additional capital to finance our planned operations, which may not be available to us on acceptable terms or at all. Our failure to obtain additional financing when needed on acceptable terms, or at all, could force us to delay, limit, reduce or eliminate our product development programs, commercialization efforts or other operations.

We expect capital expenditures and operating expenses to increase over the next several years as we expand our infrastructure, commercial operations and research and development activities. We believe, based on our current plan, that the net proceeds from this offering, together with our current cash and cash equivalents and anticipated future revenue, will be sufficient to meet our anticipated cash requirements for at least the next 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Our operating plans and other demands on our cash resources may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings or other sources, such as strategic collaborations. If our available cash balances, net proceeds from this offering and anticipated future revenue are insufficient to satisfy our liquidity requirements, including because of lower demand for our testing products or promoted therapeutics or lower-than-expected rates of reimbursement from commercial third-party payers and government payers, or other risks described in this “Risk Factors” section, we may seek to raise additional capital through equity offerings, debt financings, collaborations or licensing arrangements. In the case of the incurrence of further indebtedness, the loan agreement, subject to certain customary exceptions, restricts our ability to incur additional indebtedness or encumber any of our property without the prior consent of Innovatus. Under the loan agreement, we are required to make monthly interest payments at a rate equal to 11% (provided that 2.50% of the 11% is payable in-kind by adding the amount to the outstanding principal balance of the term loans). We may also consider raising additional capital in the future to expand our business, pursue strategic investments, take advantage of financing opportunities, or for other reasons. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. The timing and amounts of our future capital requirements are difficult to forecast and will depend on numerous factors, including: our ability to maintain and grow sales of our testing products, as well as the costs associated with conducting

clinical studies to demonstrate the utility of our testing products and support reimbursement efforts; our ability to successfully promote therapeutics; fluctuations in working capital; the costs to expand our sales and marketing capabilities; 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 and the extent to which we in-license, acquire or invest in complementary businesses or products.

Additional funding may not be available to us on acceptable terms, or at all. If we raise funds by issuing equity securities, dilution to our stockholders could result, and the market price of our common stock could decline. Any equity securities issued also may provide for rights, preferences or privileges senior to those of holders of our common stock. The incurrence of additional indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and could also result in restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire or license intellectual property rights, and other operating restrictions that could adversely affect our ability to conduct our business. In addition, our current loan agreement restricts our ability to incur additional indebtedness or encumber any of our property without the prior consent of Innovatus, subject to certain exceptions. In the event that we enter into collaborations or licensing arrangements to raise capital, we may be required to accept unfavorable terms. These agreements may require that we relinquish or license to a third party on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves, or reserve certain opportunities for future potential arrangements when we might be able to achieve more favorable terms. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of or eliminate one or more research and development programs or selling and marketing initiatives. In addition, we may have to work with a partner on one or more of our testing products, promoted therapeutics or market development programs, which could lower the economic value of those programs to our company.

The FDA may modify its enforcement discretion policy with respect to LDTs in a risk-based manner, and we may become subject to extensive regulatory requirements and may be required to conduct additional clinical trials prior to continuing to sell our existing tests or launching any other tests we may develop, which may increase the cost of conducting, or otherwise harm, our business.

If the FDA ends its policy of enforcement discretion with respect to LDTs, and our testing products become subject to the FDA's requirements for premarket review of medical devices, we may be required to cease commercial sales of our testing products and conduct additional clinical testing prior to making submissions to the FDA to obtain premarket clearance or approval. If we are required to conduct such clinical trials, delays in the commencement or completion of clinical testing could significantly increase our test development costs and delay commercialization of any currently-marketed tests that we may be required to cease selling or the commercialization of any future tests that we may develop. Many of the factors that may cause or lead to a delay in the commencement or completion of clinical trials may also ultimately lead to delay or denial of regulatory clearance or approval. The commencement of clinical trials may be delayed due to insufficient patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites and the eligibility criteria for the clinical trial.

We may find it necessary to engage contract research organizations to perform data collection and analysis and other aspects of our clinical trials, which might increase the cost and complexity of our trials. We may also depend on clinical investigators, medical institutions and contract research organizations to perform the trials, and would control only certain aspects of their activities. Nevertheless, we would be responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on these third parties would not relieve us of our regulatory responsibilities.

We and our third party contractors are required to comply with good clinical practices, or GCPs, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area, or EEA, and comparable foreign regulatory authorities for products in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any third party contractor fails to comply with applicable GCPs, the clinical data generated in clinical trials may be deemed unreliable and the FDA, Competent Authorities of the Member States of the EEA or comparable foreign regulatory authorities may require us to perform additional clinical trials before clearing or approving our marketing applications. A failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory clearance or approval process. In addition, if these parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, or if the quality, completeness or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or for other reasons, our clinical trials may have to be extended, delayed or terminated. Many of these factors would be beyond our control. We may not be able to enter into replacement arrangements without undue delays or considerable expenditures. If there are delays in testing or clearances or approvals as a result of the failure to perform by third parties, our research and development costs would increase, and we may not be able to obtain regulatory clearance or approval for our testing products. In addition, we may not be able to establish or maintain relationships with these parties on favorable terms, if at all. Each of these outcomes would harm our ability to market our testing products, or to achieve sustained profitability.

The FDA requires medical device manufacturers to comply with, among other things, current good manufacturing practices for medical devices, known as the Quality System Regulation, which requires manufacturers to follow elaborate design, testing, control, documentation and other quality assurance procedures during the manufacturing process; the medical device reporting regulation, which requires that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur; labeling regulations, including the FDA's general prohibition against promoting products for unapproved or "off-label" uses; and the reports of corrections and removals regulation, which requires manufacturers to report to the FDA if a device correction or removal was initiated to reduce a risk to health posed by the device or to remedy a violation of the FDCA caused by the device which may present a risk to health.

Even if we were able to obtain FDA clearance or approval for one or more of our testing products, if required, a testing product may be subject to limitations on the indications for which it may be marketed or to other regulatory conditions. In addition, such clearance or approval may contain requirements for costly post-market testing and surveillance to monitor the safety or efficacy of the product.

The FDA has broad post-market enforcement powers, and if unanticipated problems with our testing products arise, or if we or our suppliers fail to comply with regulatory requirements following FDA clearance or approval, we may become subject to enforcement actions such as:

- adverse publicity, warning letters, untitled letters, fines, injunctions, consent decrees and civil penalties;
- repair, replacement, refunds, recalls, termination of distribution, administrative detention or seizures of our testing products;
- operating restrictions, partial suspension or total shutdown of production;
- customer notifications or repair, replacement or refunds;
- refusing our requests for 510(k) clearance or PMA approvals or foreign regulatory approvals of new testing products, new intended uses or modifications to existing testing products;

- withdrawals of current 510(k) clearances or PMAs or foreign regulatory approvals, resulting in prohibitions on sales of our testing products;
- FDA refusal to issue certificates to foreign governments needed to export testing products for sale in other countries; and
- criminal prosecution.

Any of these sanctions could also result in higher than anticipated costs or lower than anticipated sales and have a material adverse effect on our reputation, business, results of operations and financial condition.

In addition, the FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approvals. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing authorization that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

Risks Related to Regulatory and Compliance Matters

Healthcare policy and payment changes may have a material adverse effect on our financial condition and results of operations.

Reimbursement to healthcare providers, such as specialized diagnostic service providers like us, is subject to continuing change in policies by third-party payers including governmental payers, such as Medicare and Medicaid, private insurers and other private payers, such as hospitals and private medical groups. Statutory and regulatory changes, retroactive rate adjustments and administrative rulings, and other policy changes may be implemented with little or no prior notice, all of which could materially decrease the range of services for which we are reimbursed or the reimbursement rates paid for our testing products.

On April 1, 2014, the Protecting Access to Medicare Act of 2014, or PAMA, was signed into law, which, among other things, implemented a new payment system for clinical laboratory tests reimbursed under the CLFS. Under the law, clinical laboratories must report laboratory test payment data for each Medicare-covered clinical diagnostic lab test that it furnishes. The reported data must include the payment rate and the volume of each test that was paid by each private third-party payer. Laboratories that fail to report the required payment information may be subject to substantial civil monetary penalties. We bill Medicare for our testing products, and therefore we are subject to reporting requirements under PAMA.

The final PAMA ruling was issued June 17, 2016. Data for reporting for the new PAMA process began in 2017, and in 2018, the Medicare payment rate for each clinical diagnostic lab test, with some exceptions, equaled the weighted median of the reported private third-party payer payment for the test, as calculated using data collected by applicable laboratories during the data collection period and reported to the Centers for Medicare and Medicaid Services, or CMS, during a specified data reporting period. These revisions to the CLFS have altered payment rates for clinical diagnostic lab tests under the CLFS, with estimated reductions in Medicare reimbursement rates for AVISE® CTD of 3.2% and 10.1% in 2018 and 2019, respectively. We cannot be sure how revisions to the CLFS will effect reimbursement rates in the future.

Other laws make changes impacting clinical laboratories, many of which have already gone into effect. The ACA, enacted in March 2010, requires each medical device manufacturer to pay an excise tax in an amount equal to 2.3% of the price for which such manufacturer sells its medical devices that

are listed with the FDA. This excise tax has been temporarily suspended until December 31, 2019, unless additional congressional action is taken. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, or Texas District Court Judge, ruled that the entire ACA is invalid based primarily on the fact that the Tax Cuts and Jobs Act of 2017 repealed the tax-based shared responsibility payment imposed by the ACA, on certain individuals who fail to maintain qualifying health coverage for all or part of a year, which is commonly referred to as the "individual mandate". While the Texas District Court Judge, as well as the current presidential administration and CMS, have stated that this ruling will have no immediate effect, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA and our business.

Other significant measures contained in the ACA include, for example, coordination and promotion of research on comparative clinical effectiveness of different technologies and procedures, initiatives to revise Medicare payment methodologies, such as bundling of payments across the continuum of care by providers and physicians, and initiatives to promote quality indicators in payment methodologies. The ACA also includes significant new fraud and abuse measures, including required disclosures of financial arrangements with physician customers, lower thresholds for violations and increasing potential penalties for such violations. There have been judicial and Congressional challenges to certain aspects of the ACA, as well as efforts by the current presidential administration to repeal and replace the ACA, and we expect that there will be additional challenges and amendments to the ACA in the future. We are monitoring the impact of the ACA in order to enable us to determine the trends and changes that may be necessitated by the legislation and that, in turn, may potentially impact our business over time.

Additionally, the Budget Control Act of 2011, among other things, resulted in aggregate reductions to Medicare payments to providers of 2% per fiscal year, beginning April 1, 2013, and due to additional legislative amendments to the statute, these reductions will remain in effect through 2027 unless additional congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Some of our flow cytometry tests are reimbursed by the Medicare program under the MPFS. On April 16, 2015, President Obama signed the Medicare Access and CHIP Reauthorization Act of 2015, or MACRA, which, among other actions, repealed the previous statutory formula by which CMS established annual updates to MPFS rates. MACRA created the Merit-Based Incentive Payment System which, beginning in 2019, more closely aligns physician payments with composite performance on performance metrics similar to three existing incentive programs (i.e., the Physician Quality Reporting System, the Value-based modifier program and the Electronic Health Record Meaningful Use program) and incentivizes physicians to enroll in alternative payment methods. At this time, we do not know whether these changes to the physician payment systems will have any impact on orders or payments for our testing products.

Medicare payments are significant to our business, not only because approximately 28% and 27% of the total payments we received from payers in the year ended December 31, 2018 and the six months ended June 30, 2019, respectively, were derived from the Medicare program, but also because other payers often use the MPFS and CLFS amounts as a benchmark to develop their payment rates. We cannot predict whether Medicare and other third-party payer reimbursement rates that mirror Medicare's will be sufficient to make our testing products commercially attractive.

In addition, some third-party payers have implemented, or are in the process of implementing, laboratory benefit management programs, often using third-party benefit managers to manage these programs. The stated goals of these programs are to help improve the quality of outpatient laboratory services, support evidence-based guidelines for patient care and lower costs. The impact on

laboratories, such as ours, of active laboratory benefit management by third parties is unclear, and we expect that it could have a negative impact on our revenue in the short term. It is possible that third-party payers will resist reimbursement for testing products that we offer in favor of less expensive tests, may require pre-approval for our testing products or may impose additional pricing pressure on and substantial administrative burden for reimbursement for our testing products.

Product pricing by companies is currently, and is expected to continue to be, under close scrutiny. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and patient programs, and reform government program reimbursement methodologies for products. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures.

We also cannot predict whether future healthcare initiatives will be implemented at the federal or state level or in countries outside of the United States in which we may do business in the future, or the effect any future legislation or regulation will have on us. Although we cannot predict the full effect of the recent legislative changes discussed above, including taxes imposed by the ACA, cost reduction measures, the expansion in government's role in the U.S. healthcare industry and PAMA's changes to the reimbursement methodology under the CLFS, such changes individually or in the aggregate may result in decreased profits to us and/or lower reimbursement by third-party payers for our testing products, which may adversely affect our business, financial condition and results of operations.

Complying with numerous regulations pertaining to our business is an expensive and time-consuming process, and any failure to comply could result in substantial penalties.

We are subject to CLIA, a federal law that regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. CLIA regulations mandate specific standards in the areas of personnel qualifications, administration, and participation in proficiency testing, patient test management, quality control, quality assurance and inspections. We have a current certificate of accreditation under CLIA to perform testing through our accreditation by CAP. To renew this certificate, we are subject to survey and inspection every two years. Moreover, CLIA inspectors may make random inspections of our clinical reference laboratory.

Although we are required to hold a certificate of accreditation or compliance under CLIA that allows us to perform high complexity testing, we are not required to hold a certificate of accreditation through CAP. We could alternatively maintain a certificate of accreditation from another accrediting organization or a certificate of compliance through inspection by surveyors acting on behalf of the CLIA program. If our accreditation under CAP were to terminate, either voluntarily or involuntarily, we would need to convert our certification under CLIA to a certificate of compliance (or to a certificate of accreditation with another accreditation organization) in order to maintain our ability to perform clinical testing and to continue commercial operations. Whether we would be able to successfully maintain operations through either of these alternatives would depend upon the facts and circumstances surrounding termination of our CAP accreditation, such as whether any deficiencies were identified by CAP as the basis for termination and, if so, whether these were addressed to the satisfaction of the surveyors for the CLIA program (or another accrediting organization).

The failure to comply with CLIA requirements can result in enforcement actions, including the revocation, suspension, or limitation of our CLIA certificate of accreditation, as well as a directed plan of correction, state on-site monitoring, civil money penalties, civil injunctive suit and/or criminal penalties. We must maintain CLIA compliance and certification to be eligible to bill for tests provided to

Medicare beneficiaries. If we were to be found out of compliance with CLIA program requirements and subjected to sanctions, our business and reputation could be harmed. Even if it were possible for us to bring our laboratory back into compliance, we could incur significant expenses and potentially lose revenue in doing so.

We are also required to maintain a license to conduct testing in California. California laws establish standards for day-to-day operation of our clinical reference laboratory, including the training and skills required of personnel and quality control. In addition, our clinical reference laboratory is licensed on a product-specific basis by New York as an out of state laboratory and our testing products, as LDTs, must be approved by the New York Department of Health, or NYDOH, on a product-by-product basis before they are offered in New York. We are also be subject to periodic inspection by the NYDOH and required to demonstrate ongoing compliance with NYDOH regulations and standards. To the extent NYDOH identified any non-compliance and we are unable to implement satisfactory corrective actions to remedy such non-compliance, the State of New York could withdraw approval for our testing products. New York law also mandates proficiency testing for laboratories licensed under New York state law, regardless of whether or not such laboratories are located in New York. Moreover, several other states require that we hold licenses to test specimens from patients in those states. Other states may have similar requirements or may adopt similar requirements in the future. Although we have obtained licenses from states where we believe we are required to be licensed, we may become aware of other states that require out-of-state laboratories to obtain licensure in order to accept specimens from the state, and it is possible that other states currently have such requirements or will have such requirements in the future.

If we were to lose our CLIA accreditation or California license, whether as a result of a revocation, suspension or limitation, we would no longer be able to sell our testing products, which would limit our revenue and harm our business. If we were to lose our license or fail to obtain or maintain NYDOH approval for our laboratory developed tests in New York or if we were to lose our license in other states where we are required to hold licenses, we would not be able to test specimens from those states which would limit our revenue.

If we fail to comply with healthcare laws and regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected.

We and our partners, including those with whom we may enter into co-promotion or co-marketing arrangements, are also subject to healthcare fraud and abuse regulation by both the federal government and the states in which we or our partners conduct our business. These laws include, without limitation, state and federal anti-kickback, self-referral, fraud and abuse, false claims, and physician sunshine laws and regulations.

The Federal Anti-kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any good, facility, item or service, including laboratory services, reimbursable, in whole or in part, under Medicare, Medicaid or other federally financed healthcare programs. The term “remuneration” has been broadly interpreted to include anything of value. The Federal Anti-kickback Statute has been interpreted to apply to arrangements between manufacturers on one hand and prescribers, purchasers and formulary managers on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor, however, does not make the conduct per se illegal under the Federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Several courts have interpreted the

statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the Federal Anti-Kickback Statute has been violated. Further, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it. in order to have committed a violation In addition, the government may assert that a claim including items or services resulting from a violation of the Federal Anti-kickback Statute constitutes a false or fraudulent claim for purposes of the false claims laws.

On June 25, 2014, the Office of Inspector General of the Department of Health and Human Services, or the OIG, released a Special Fraud Alert, expressing concern regarding laboratory payments made to referring physicians and physician group practices for blood specimen collection, processing, and packaging. Specifically, the OIG expressed concern that such arrangements may implicate the Federal Anti-Kickback Statute when laboratories make payments to physicians for services that are already covered and reimbursed by Medicare, or are not commercially reasonable or exceed fair market value, all in order to induce physicians to order tests from such laboratory. Because the choice of laboratory and the decision to order laboratory tests is made or strongly influenced by the physician, with little or no input from patients, such payment may induce physicians to order more laboratory tests than are medically necessary, particularly when the payments are tied to, or take into account, the volume or value of business generated by the physician. We had entered into certain arrangements with physicians for services related to specimen collection, transporting and handling. Effective August 2015, we terminated all such agreements. To date, no regulatory authorities have contacted us regarding these arrangements. To the extent our prior arrangements are found to be inconsistent with applicable laws, we may be subject to significant penalties, including criminal penalties, and exclusion from participation in U.S. federal or state health care programs.

The Federal civil and criminal false claims law, including the False Claims Act, prohibit, among other things, any person from knowingly presenting or causing to be presented a false claim for payment to the federal government, or knowingly making or causing to be made a false statement to get a false or fraudulent claim paid by the federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. In addition, private individuals have the ability to bring actions under these false claims laws in the name of the government alleging false and fraudulent claims presented to or paid by the government (or other violations of the statutes) and to share in any amounts paid by the entity to the government in fines or settlement. Such suits, known as qui tam actions, have increased significantly in the healthcare industry in recent years. In addition, the federal civil monetary penalties statute imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. The majority of states also have statutes or regulations similar to the federal anti-kickback and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer.

We are also subject to the federal physician self-referral prohibitions, commonly known as the Stark Law, which prohibits, among other things, physicians who have a financial relationship, including an investment, ownership or compensation relationship with an entity, from referring Medicare patients for designated health services, which include clinical laboratory services, unless an exception applies. Similarly, entities may not bill Medicare or any other party for services furnished pursuant to a prohibited referral. Many states have their own self-referral laws as well, which in some cases apply to all third-party payers, not just Medicare and Medicaid.

In addition, under the federal civil monetary penalties statute, a person is prohibited from offering or transferring to a Medicare or Medicaid beneficiary any remuneration, including waivers of co-payments and deductible amounts (or any part thereof), that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of Medicare or Medicaid

payable items or services. Moreover, in certain cases, providers who routinely waive copayments and deductibles for Medicare and Medicaid beneficiaries can also be held liable under the Federal Anti-kickback Statute and civil False Claims Act. One of the statutory exceptions to the prohibition is non-routine, unadvertised waivers of copayments or deductible amounts based on individualized determinations of financial need or exhaustion of reasonable collection efforts. The OIG emphasizes, however, that this exception should only be used occasionally to address special financial needs of a particular patient. Although this prohibition applies only to federal healthcare program beneficiaries, the routine waivers of copayments and deductibles offered to patients covered by commercial payers may implicate applicable state laws related to, among other things, unlawful schemes to defraud, excessive fees for services, tortious interference with patient contracts and statutory or common law fraud. To the extent our patient assistance programs are found to be inconsistent with applicable laws, we may be required to restructure or discontinue such programs, or be subject to other significant penalties.

The ACA, among other things, also imposed new reporting requirements on manufacturers of certain devices, drugs and biologics for certain payments and transfers of value by them and in some cases their distributors to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Manufacturers must submit reports by the 90th day of each calendar year. Because we manufacture our own LDTs solely for use by or within our own laboratory, we believe that we are exempt from these reporting requirements. We cannot assure you, however, that our regulators, principally the federal government, will agree with our determination, and a determination that we have violated these laws and regulations, or a public announcement that we are being investigated for possible violations, could adversely affect our business, prospects, results of operations or financial condition.

It is possible that some of our business activities could be subject to challenge under one or more of such laws, including our promotion of SIMPONI®, which is subject to restriction of off-label use discussions Such a challenge, regardless of the outcome, could have a material adverse effect on our business, business relationships, reputation, financial condition and results of operations. Although an effective compliance program can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with these laws may prove costly. If we or our operations, or any of the rheumatologists or entities with whom we do business are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to significant penalties, including administrative, civil and/or criminal penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in U.S. federal or state health care programs, such as Medicare and Medicaid in the U.S. and similar programs outside the U.S., a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could materially adversely affect our ability to operate our business and our financial results. To the extent that any of our testing products are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

Failure to comply with HIPAA, the HITECH Act, their implementing regulations, and similar comparable state laws and regulations affecting the transmission, security and privacy of health information could result in significant penalties.

Numerous federal and state laws and regulations, including HIPAA and the HITECH Act, govern the collection, dissemination, security, use and confidentiality of individually identifiable health information. HIPAA and the HITECH Act require us to comply with standards for the use and disclosure

of individually identifiable health information within our company and with third parties. The Standards for Privacy of Individually Identifiable Health Information, or Privacy Standards, and the Security Standards for the Protection of Electronic Protected Health Information, or Security Standards, under HIPAA establish a set of basic national privacy and security standards for the protection of individually identifiable health information by health plans, healthcare clearinghouses and certain healthcare providers, referred to as covered entities, and the business associates with whom such covered entities contract for services. Notably, whereas HIPAA previously directly regulated only these covered entities, the HITECH Act, which was signed into law as part of the stimulus package in February 2009, made certain of the Security Standards directly applicable to business associates. Further, the HITECH Act and the Final HIPAA Omnibus Rule that was promulgated in 2013, made additional parts of HIPAA directly applicable to business associates. As a result, both covered entities and business associates are now subject to significant civil and criminal penalties for failure to comply with the Privacy Standards and/or the Security Standards.

HIPAA and the HITECH Act also include standards for common healthcare electronic transactions and code sets, such as claims information, plan eligibility, payment information and the use of electronic signatures, and privacy and electronic security of individually identifiable health information. Covered entities, such as certain health care providers, are required to conform to such transaction set standards, known as the Standards for Electronic Transactions, pursuant to HIPAA.

HIPAA requires covered entities to develop and maintain policies and procedures with respect to individually identifiable health information that is used or disclosed, including the adoption of administrative, physical and technical safeguards to protect such information. The HITECH Act expands the notification requirement for breaches of individually identifiable health information, restricts certain disclosures and sales of individually identifiable health information and provides a tiered system for civil monetary penalties for HIPAA violations. The Final HIPAA Omnibus Rule modifies the breach reporting standard in a manner that will likely make more data security incidents qualify as reportable breaches. The HITECH Act also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorney fees and costs associated with pursuing federal civil actions. Additionally, certain states have adopted comparable privacy and security laws and regulations, some of which may be more stringent than HIPAA.

If we do not comply with the requirements of HIPAA, the HITECH Act or applicable state privacy and security laws, we could be subject to criminal or civil sanctions that could adversely affect our financial condition. The costs of complying with privacy and security related legal and regulatory requirements are burdensome and could have a material adverse effect on our business. These laws are subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us, as well as our physician clients. In addition, we are unable to predict what changes to the HIPAA Privacy Standards and Security Standards might be made in the future or how those changes could affect our business. Any new legislation or regulation in the area of privacy and security of personal information, including individually identifiable health information, could also adversely affect our business operations.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions

regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, or FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties to sell our testing products outside the United States, to conduct clinical trials, and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

Our future growth may depend, in part, on our ability to operate in foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future growth may depend, in part, on our ability to develop and commercialize our testing products and promote therapeutics in foreign markets. We are not permitted to market or promote any of our testing products or promote therapeutics before we or our partners receive regulatory approval from applicable regulatory authorities in foreign markets, and we or they may never receive such regulatory approvals for any of our testing products or promoted therapeutics. To obtain separate regulatory approval in many other countries parties must comply with numerous and varying regulatory requirements regarding safety and efficacy and governing, among other things, clinical trials, commercial sales, pricing and distribution of our testing products. If we or our partners obtain regulatory approval of our testing products and promoted therapeutics, and ultimately commercialize our testing products or promoted therapeutics in foreign markets, we would be subject to additional risks and uncertainties, including:

- different regulatory requirements for approval of drugs in foreign countries;
- reduced protection for intellectual property rights;
- the existence of additional third-party patent rights of potential relevance to our business;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- foreign reimbursement, pricing and insurance regimes;
- workforce uncertainty in countries where labor unrest is common;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

Risks Related to our Intellectual Property

If we are unable to maintain intellectual property protection our competitive position could be harmed.

Our ability to protect our technologies such as CB-CAPs and methotrexate polyglutamates, or MTXPGs, affects our ability to compete and to achieve sustained profitability. We rely on a combination of U.S. and foreign patents and patent applications, copyrights, trademarks and trademark applications, and contractual restrictions to protect our intellectual property rights. We cannot be certain that the claims in our granted patents and pending patent applications covering our AVISE® testing products will be considered patentable or enforceable by the United States Patent and Trademark Office, or the USPTO, courts in the United States, or by patent offices and courts in foreign countries. If we fail to protect our intellectual property, third parties may be able to compete more effectively against us and we may incur substantial litigation costs in our attempts to recover or restrict use of our intellectual property.

We apply for patents covering our testing products and technologies and uses thereof, as we deem appropriate, however we may fail to apply for patents on important testing products and technologies in a timely fashion or at all, or we may fail to apply for patents in potentially relevant jurisdictions, or we may cease our prosecution and maintenance of patents in potentially relevant jurisdictions. Currently, we have an exclusive license to 13 issued U.S. patents, and certain corresponding foreign counterpart patents, relevant to our AVISE® testing products. We also own two pending U.S. patent applications relevant to our AVISE® testing products. While we intend to pursue additional patent applications, it is possible that our pending patent applications and any future applications may not result in issued patents. Even if such patents do successfully issue, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Any successful opposition to our patents could deprive us of exclusive rights necessary for the further development of our AVISE® testing products. Furthermore, even if they are unchallenged, our patents may not adequately protect our intellectual property, provide exclusivity for our AVISE® testing products or prevent others from designing around our claims.

We might not have been the first to make the inventions covered by each of our pending patent applications and we might not have been the first to file patent applications for these inventions. To determine the priority of these inventions, we may have to participate in interference proceedings, derivation proceedings or other post-grant proceedings declared by the USPTO that could result in substantial cost to us. No assurance can be given that our patent applications will have priority over other patent applications. In addition, recent changes to the patent laws of the United States allow for various post-grant opposition proceedings that have not been extensively tested, and their outcome is therefore uncertain. Furthermore, if third parties bring these proceedings against our patents, we could experience significant costs and management distraction.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our AVISE® testing products and development processes that involve proprietary know-how, information or technology that is not covered by patents. However, trade secrets can be difficult to protect. While we use commercially reasonable efforts to protect our trade secrets, our licensors, employees, consultants, contractors and other advisors may unintentionally or willfully disclose such trade secret information to third parties and competitors. We attempt to protect our proprietary technology in large part by entering into confidentiality and non-disclosure agreements with our employees, consultants and other contractors. We cannot assure you, however, that these agreements will not be breached, that we will have adequate remedies for any breach or that competitors will not know of, or independently discover, our trade secrets. We cannot assure you that others will not independently

develop substantially equivalent proprietary information or be issued patents that may prevent the sale of our testing products, technologies, services or know-how or require licensing and the payment of significant fees or royalties by us in order to produce our testing products, technologies or services. Further, we cannot be certain that the steps we have taken will prevent the misappropriation of our trade secrets and other confidential information.

Monitoring unauthorized disclosure is difficult, and we do not know whether the steps we have taken to prevent such disclosure are, or will be, adequate. If we were to enforce a claim that a third party had illegally obtained and was using our trade secrets, it would be expensive and time consuming, and the outcome would be unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets. If we are unable to prevent unauthorized material disclosure of our trade secrets and other confidential information to third parties, and in particular in jurisdictions where we have not filed for patent protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results and financial condition.

Certain of our testing products utilize unpatented technology that is publicly available and can be used by our competitors.

Certain of our AVISE® testing products, such as AVISE® CTD, utilize both patented technology and publicly available technology that is not protected by patents or other intellectual property rights. We believe that using certain publicly available technology allows us to offer a better and more comprehensive testing product. However, the publicly available technology which we rely upon is also used in, and may continue to be used in, products which compete with our AVISE® testing products. Our competitors may independently develop competing diagnostic products and services that do not infringe our intellectual property.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our AVISE® testing products.

Our success is heavily dependent on intellectual property, particularly on obtaining and enforcing patents. Obtaining and enforcing patents in the diagnostics industry involves both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. The United States has enacted and is currently implementing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents. We may not develop additional proprietary products, methods and technologies that are patentable.

Some of our intellectual property has been discovered through government funded programs and thus may be subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for U.S.-based companies. Compliance with such regulations may limit our exclusive rights, and limit our ability to contract with non-U.S. manufacturers.

Some of the intellectual property rights we have acquired or licensed or may acquire or license in the future may have been generated through the use of U.S. government funding and may therefore be subject to certain federal regulations. For example, some of the research and development work related to our CB-CAPs technology was funded by government research grants. As a result, the U.S. government may have certain rights to intellectual property embodied in our testing products pursuant to the Bayh-Dole Act of 1980, or Bayh-Dole Act. These U.S. government rights include a non-exclusive,

non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right, under certain limited circumstances, to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations (also referred to as “march-in rights”). The U.S. government also has the right to take title to these inventions if the grant recipient fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the U.S. government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States. This preference for U.S. industry may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. industry may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property. To the extent any of our future intellectual property is also generated through the use of U.S. government funding, the provisions of the Bayh-Dole Act may similarly apply.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on our AVISE® testing products in all countries throughout the world would be prohibitively expensive. Moreover, we believe that obtaining foreign patents may be more difficult than obtaining domestic patents because of differences in patent laws and, accordingly, our patent position may be stronger in the United States than abroad. In addition, the laws of some foreign countries do not protect intellectual property rights in the same manner and to the same extent as laws in the United States. Various countries limit the subject matter that can be patented and limit the ability of a patent owner to enforce patents in the medical and other related fields. This may limit our ability to obtain or utilize those patents internationally. In order to manage our foreign patent costs and focus on the U.S. market, we made the decision to cease the prosecution and maintenance of certain of our foreign patents and patent applications related to our CB-CAPs technology, which is used in our AVISE® testing products. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection but enforcement of such patent protection is not as strong as that in the United States. These products may compete with our AVISE® testing products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

The patent protection and patent prosecution for some of our testing products may be dependent on third parties.

We or our licensors may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to strengthen our patent position. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. If we or our licensors, whether current or future, fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our licensors are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation, prosecution, or enforcement of our patents or patent applications, such patents may be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

As a licensee of third parties, we rely on third parties to file and prosecute patent applications and maintain patents and otherwise protect the licensed intellectual property under some of our license agreements. We have not had and do not have primary control over these activities for certain of our patents or patent applications and other intellectual property rights. We cannot be certain that such activities by third parties have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents or other intellectual property rights. Pursuant to the terms of the license agreements with some of our licensors, the licensors may have the right to control enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents and even if we are permitted to pursue such enforcement or defense, we will require the cooperation of our licensors. We cannot be certain that our licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it may permit other parties to compete with us If any of our licensors or any of our future licensors or future collaborators fail to appropriately prosecute and maintain patent protection for patents covering any of our testing products, our ability to develop and commercialize those testing products may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products.

In addition, even where we have the right to control patent prosecution of patents and patent applications we have acquired or licensed from third parties, we may still be adversely affected or prejudiced by actions or inactions of our predecessors or licensors and their counsel that took place prior to us assuming control over patent prosecution.

Our technology acquired or licensed from various third parties may be subject to retained rights. Our predecessors or licensors often retain certain rights under their agreements with us, including the right to use the underlying technology for noncommercial academic and research use, to publish general scientific findings from research related to the technology, and to make customary scientific and scholarly disclosures of information relating to the technology. It is difficult to monitor whether our predecessors or licensors limit their use of the technology to these uses, and we could incur substantial expenses to enforce our rights to our licensed technology in the event of misuse.

If we are limited in our ability to utilize acquired or licensed technologies, or if we lose our rights to critical in-licensed technology, we may be unable to successfully develop, out-license, market and sell our testing products, which could adversely affect our business. Our business strategy depends on the successful development of licensed and acquired technologies into commercial products. Therefore,

any limitations on our ability to utilize these technologies may impair our ability to develop, out-license or market and sell our testing products.

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

We are a party to a number of license agreements under which we are granted intellectual property rights that are important to our business. For example, certain patent rights related to AVISE® Lupus are licensed from the University of Pittsburgh, certain patent rights related to AVISE® MTX are licensed from Prometheus. Our existing license agreements as related to our AVISE® testing products impose various regulatory and/or commercial diligence obligations, payment of milestones and/or royalties and other obligations. If we fail to comply with our obligations under a license agreement, the license agreement may be terminated, in which event we would not be able to further develop or market certain AVISE® testing products. Additionally, we may not always have the first right to maintain, enforce or defend our licensed intellectual property rights and, although we would likely have the right to assume the maintenance, enforcement and defense of such intellectual property rights if our licensors do not, our ability to do so may be compromised by our licensors' acts or omissions.

Licensing of intellectual property rights is of critical importance to our business and involves complex legal, business and scientific issues. Disputes may arise between us and our licensors regarding intellectual property rights subject to a license agreement, including the scope of rights granted under the license agreement and other interpretation-related issues, and whether and the extent to which our technology and processes infringe on intellectual property rights of the licensor that are not subject to the licensing agreement. If disputes over intellectual property rights that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, our business, results of operations, financial condition and prospects may be adversely affected. We may enter into additional licenses in the future and if we fail to comply with obligations under those agreements, we could suffer adverse consequences.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent process. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on any issued patents and/or applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patents and/or applications. Our outside counsel has systems in place to monitor deadlines to pay these fees and to remind us of these fees, and our outside counsel employs an outside firm to pay these fees due to the USPTO and to foreign patent agencies based on our instructions. In the aggregate, these fees can be cost prohibitive for an early-stage company. Accordingly, we made a financially-driven decision to prioritize our payment of these fees and to allow certain of our applications to lapse, particularly with respect to our ex-U.S. rights licensed from the University of Pittsburgh related to our CB-CAPs technology. The permanent lapse of certain of these ex-U.S. rights may result in our patent position being stronger in the United States than abroad, such as in countries that are part of the European Patent Convention, and third parties may be able to compete more effectively against us in countries outside the United States, including in those countries that belong to the European Patent Convention. Additionally, while an inadvertent lapse may sometimes be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or

patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market earlier than should otherwise have been the case, which would have a material adverse effect on our business.

We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through acquisitions and in-licenses.

Presently we have intellectual property rights, through licenses from third parties and under patents that we own, related to our AVISE® testing products. Because our programs may involve additional products that require the use of proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to acquire, in-license or use these proprietary rights. We may be unable to acquire or in-license proprietary rights that we identify as being necessary for our AVISE® testing products, and our partner may be unable to acquire any necessary rights for our promoted therapeutics. Even if we are able to obtain a license to such proprietary rights, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology.

The licensing and acquisition of third-party proprietary rights is a competitive area, and companies, which may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party proprietary rights that we may consider necessary or attractive in order to further develop our AVISE® testing products or our partners consider necessary or attractive in order to promote their therapeutic. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us, either on reasonable terms, or at all. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment, or at all. If we or our partner are unable to successfully obtain rights to required third-party intellectual property rights on commercially reasonable terms, our ability to further develop our AVISE® testing products and promote therapeutics, and our business, financial condition and prospects for growth could suffer.

Third-party claims alleging intellectual property infringement may prevent or delay our development efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patents and other intellectual property rights in the diagnostics industry, as well as administrative proceedings for challenging patents, including interference and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. The Leahy-Smith America Invents Act introduced new procedures including inter partes review and post grant review. The implementation of these procedures bring the possibility of third party challenges to our patents and the outcome of such challenges could result in a loss or narrowing of our patent rights. In such an event, our competitors might be able to enter the market earlier than should otherwise have been the case, which would have a material adverse effect on our business. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our AVISE® testing products. As the diagnostics industry expands and more patents are issued, the risk increases that our activities related to our AVISE® testing products may give rise to claims of infringement of the patent rights of others.

We cannot assure you that any of our current or future AVISE® testing products will not infringe existing or future patents. Although we are not aware of any issued patents that will prevent us from

marketing our AVISE® testing products, there may be third-party patents of which we are currently unaware with claims to materials or methods of manufacture related to the use or manufacture of our AVISE® testing products. If a third party that owns such a patent asserts it successfully against one of our current or future AVISE® testing products, we may be unable to market our product, which could materially harm our business and because patent applications can take many years to issue and may be confidential for 18 months or more after filing, there may be currently pending third-party patent applications which may later result in issued patents that our AVISE® testing products or our technologies may infringe, or which such third parties claim are infringed by the use of our technologies.

Parties making claims against us for infringement or misappropriation of their intellectual property rights may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop one or more of our AVISE® testing products. Defense of these claims, regardless of their merit, would involve substantial expenses and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees if we are found to be willfully infringing a third party's patents, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or development of our AVISE® testing products. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop our AVISE® testing products, which could harm our business significantly. Even if we were able to obtain a license, the rights may be nonexclusive, which may give our competitors access to the same intellectual property.

In addition to infringement claims against us, if third parties have prepared and filed patent applications in the United States that also claim technology to which we have rights, we may have to participate in interference proceedings in the USPTO to determine the priority of invention. Third parties may also attempt to initiate reexamination, post grant review or inter partes review of our patents in the USPTO. We may also become involved in similar proceedings in the patent offices in other jurisdictions regarding our intellectual property rights with respect to our AVISE® testing products and technology.

We may be involved in proceedings to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.

Third parties may infringe, misappropriate or otherwise violate our existing patents, patents that may issue to us in the future, or the patents of our licensors that are licensed to us. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

In addition, if we or one of our licensors initiated legal proceedings against a third party to enforce a patent covering one of our AVISE® testing products, the defendant could counterclaim that the patent covering such AVISE® testing product is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Such proceedings could result in an invalidation of our patents. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or

unenforceability, we would lose at least part, and perhaps all, of the patent protection on our AVISE® testing products. Such a loss of patent protection could have a material adverse impact on our business.

Litigation proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties.

Because of the expense and uncertainty of litigation, we may conclude that even if a third party is infringing our patents or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our stockholders. We are not aware of any third party infringement of our intellectual property rights that would have a materially adverse impact on our business. In addition, there can be no assurance that our licensors will be willing to bring and enforce claims to prevent third parties from infringing intellectual property that is licensed to us, particularly if the affected intellectual property is less important to the licensor's business than to ours. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other companies in our industry. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise improperly used or disclosed confidential information of these third parties or our employees' former employers. Further, we may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our AVISE® testing products. We may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. Litigation may be necessary to defend against these and other claims challenging our right to and use of confidential and proprietary information. If we fail in defending any such claims, in addition to paying monetary damages, we may lose our rights therein. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees.

Risks Related to this Offering and Our Common Stock

An active, liquid and orderly market for our common stock may not develop, and you may not be able to resell your common stock at or above the public offering price. Our stock price may be volatile, and you may not be able to sell shares of our common stock at or above the price you paid.

Prior to this offering, there has been no public market for our common stock, and an active public market for our stock may not develop or be sustained after this offering. We and the representatives of the underwriters determined the initial public offering price of our common stock through negotiation. This price will not necessarily reflect the price at which investors in the market will be willing to buy and

sell our stock following this offering. In addition, the trading price of our common stock following this offering is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include:

- actual or anticipated variations in our and our competitors' financial condition and results of operations;
- announcements by us or our competitors of new products, strategic partnerships or capital commitments;
- changes in reimbursement by current or potential third-party payers;
- issuance of new securities analysts' reports or changed recommendations for our stock;
- actual or anticipated changes in regulatory oversight of our testing products;
- developments or disputes concerning our intellectual property or other proprietary rights;
- commencement of, or our involvement in, litigation;
- announced or completed acquisitions of businesses or technologies by us or our competitors;
- any major change in our management;
- changes in accounting principles;
- announcement or expectation of additional financing efforts;
- future sales of our common stock by our executive officers, directors and other stockholders; and
- general economic conditions and slow or negative growth of our markets.

In addition, the stock market in general, and the market for stock of life sciences companies in particular, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. Broad market and industry factors, as well as general economic, political and market conditions such as recessions or interest rate changes, may seriously affect the market price of our common stock, regardless of our actual operating performance. These fluctuations may be even more pronounced in the trading market for our stock shortly following this offering. If the market price of our common stock after this offering does not exceed the initial public offering price, you may not realize any return on your investment in us and may lose some or all of your investment.

In addition, in the past, following periods of volatility in the overall market and the market price of a particular company's securities, securities class action litigation has often been instituted against these companies. This litigation, if instituted against us, could result in substantial costs and a diversion of our management's attention and resources. Any adverse determination in any such litigation or any amounts paid to settle any such actual or threatened litigation could require that we make significant payments.

Our failure to meet the continued listing requirements of the Nasdaq Global Market, or Nasdaq, could result in a delisting of our common stock.

If, after listing, we fail to satisfy the continued listing requirements of Nasdaq, such as the corporate governance requirements or the minimum closing bid price requirement, Nasdaq may take steps to delist our common stock. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with Nasdaq's listing requirements.

If securities or industry analysts issue an adverse opinion regarding our stock or do not publish research or reports about our company, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that equity research analysts publish about us and our business. Currently, we do not have any analyst coverage and we may not obtain analyst coverage in the future. In the event we obtain analyst coverage, we would not have any control over such analysts or the content and opinions included in their reports. Securities analysts may elect not to provide research coverage of our company after the completion of this offering, and such lack of research coverage may adversely affect the market price of our common stock. The price of our common stock could also decline if one or more equity research analysts downgrade our common stock or if those analysts issue other unfavorable commentary or cease publishing reports about us or our business. If one or more equity research analysts cease coverage of our company, we could lose visibility in the market, which in turn could cause our stock price to decline.

Future sales of shares by existing stockholders could cause our stock price to decline.

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the lock-up and other legal restrictions on resale discussed in this prospectus lapse, the trading price of our common stock could decline. Based on the number of shares of common stock outstanding as of June 30, 2019, upon the completion of this offering, we will have outstanding a total of 11,494,770 shares of common stock, assuming the expected net exercise of the Net Exercise Warrants, no exercise of the underwriters' option to purchase additional shares and no exercise of outstanding options or warrants (other than the Net Exercise Warrants). Of these shares, all shares sold in this offering will be freely tradable, without restriction, in the public market immediately after the offering, except for any shares purchased by our affiliates. Each of our directors and officers and substantially all of our other stockholders has entered into a lock-up agreement with the underwriters described in "Underwriting" elsewhere in this prospectus, which restricts their ability to sell or transfer their shares. The lock-up agreements pertaining to this offering will expire 180 days from the date of this prospectus. The underwriters, however, may, in their sole discretion, waive the contractual lock-up prior to the expiration of the lock-up agreements. After the lock-up agreements expire, based on shares outstanding as of June 30, 2019, up to an additional 7,894,770 shares of common stock will be eligible for sale in the public market, of which 5,467,126 shares are held by directors, executive officers and other affiliates and will be subject to volume limitations under Rule 144 under the Securities Act.

In addition, 662,987 shares of common stock that are subject to outstanding options as of June 30, 2019 will become eligible for sale in the public market to the extent permitted by the provisions of various option agreements, the lock-up agreements and Rules 144 and 701 under the Securities Act. We intend to file a registration statement on Form S-8 under the Securities Act covering all of the shares of common stock subject to options outstanding and reserved for issuance under our employee benefit plans. This registration statement will become effective immediately upon filing, and shares covered by this registration statement will be eligible for sale in the public markets, subject to Rule 144 limitations applicable to affiliates, the terms of the applicable plan and the option agreements entered into with option holders, and any lock-up agreements described above. In addition, our directors and executive officers may establish programmed selling plans under Rule 10b5-1 of the Exchange Act for the purpose of effecting sales of our common stock. Any sales of securities by these stockholders, or the perception that those sales may occur, including the entry into such programmed selling plans, could have a material adverse effect on the trading price of our common stock.

In addition, the holders of 7,878,463 shares of common stock and holders of warrants to purchase an aggregate of 1,013,107 shares of common stock will be entitled to rights with respect to registration of such shares under the Securities Act pursuant to an investors' rights agreement between such

holders and us. See “Certain Relationships and Related Person Transactions—Investors’ Rights Agreement” below. If such holders, by exercising their registration rights, sell a large number of shares, they could adversely affect the market price for our common stock. If we file a registration statement for the purpose of selling additional shares to raise capital and are required to include shares held by these holders pursuant to the exercise of their registration rights, our ability to raise capital may be impaired.

We are an emerging growth company and a smaller reporting company, and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.

We are an emerging growth company, as defined in the JOBS Act, and may remain an emerging growth company until the last day of the fiscal year following the fifth anniversary of the completion of this offering. However, if certain events occur prior to the end of such five-year period, including if we become a “large accelerated filer,” our annual gross revenue exceeds $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. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced “Management’s discussion and analysis of financial condition and results of operations” disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We have taken advantage of reduced reporting burdens in this prospectus. In particular, in this prospectus, we have provided only two years of audited financial statements and have not included all of the executive compensation related information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be reduced or more volatile. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies. We have elected to avail ourselves of this exemption and, therefore, we may not be subject to the same implementation timing for new or revised accounting standards as other public companies that are not emerging growth companies, which may make comparison of our financials to those of other public companies more difficult.

We are also a “smaller reporting company” as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be

able to take advantage of these scaled disclosures for so long as our voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

We will incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. We will be subject to the reporting requirements of the Exchange Act, which will require, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. In addition, Sarbanes-Oxley, as well as rules subsequently adopted by the Securities and Exchange Commission, or the SEC, and Nasdaq to implement provisions of Sarbanes-Oxley, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, the SEC has adopted additional rules and regulations in these areas, such as mandatory “say on pay” voting requirements that will apply to us when we cease to be an emerging growth company. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition and results of operations. The increased costs will decrease our net income or increase our net loss, and may require us to reduce costs in other areas of our business or increase the prices of our testing products or services. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

Pursuant to Section 404 of Sarbanes-Oxley, our management will be required to report upon the effectiveness of our internal control over financial reporting beginning with the annual report for our fiscal year ending December 31, 2020. When we lose our status as an “emerging growth company” and reach an accelerated filer threshold, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Exchange Act, we will need to upgrade our information technology systems; implement additional financial and management controls, reporting systems and procedures; and hire additional accounting and finance staff. If we or, if required, our auditors are unable to conclude that our internal control over financial reporting is effective, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting once that firm begin its Section 404 reviews, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

Provisions in our charter documents and under Delaware law could discourage a takeover that stockholders may consider favorable and may lead to entrenchment of management.

Our amended and restated certificate of incorporation and amended and restated bylaws that will be in effect immediately prior to the consummation of this offering will contain provisions that could significantly reduce the value of our shares to a potential acquiror or delay or prevent changes in control or changes in our management without the consent of our board of directors. The provisions in our charter documents will include the following:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors, unless the board of directors grants such right to the stockholders, to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- the required approval of at least 66-2/3% of the shares entitled to vote to remove a director for cause, and the prohibition on removal of directors without cause;
- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror;
- the ability of our board of directors to alter our amended and restated bylaws without obtaining stockholder approval;
- the required approval of at least 66-2/3% of the shares entitled to vote to adopt, amend or repeal our amended and restated bylaws or repeal the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- an exclusive forum provision providing that the Court of Chancery of the State of Delaware will be the exclusive forum for certain actions and proceedings;
- the requirement that a special meeting of stockholders may be called only by the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of us.

We are also subject to the anti-takeover provisions contained in Section 203 of the Delaware General Corporation Law. Under Section 203, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the board of directors has approved the transaction.

Our amended and restated certificate of incorporation and amended and restated bylaws will provide that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation and amended and restated bylaws will provide that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine; provided, that, this provision would not apply to suits brought to enforce a duty or liability created by Securities Act or the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. To the extent that any such claims may be based upon federal law claims, Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. By agreeing to this provision, however, the stockholders will not be deemed to have waived our compliance with the Federal Securities laws and rules and regulations thereunder. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. If a court were to find the choice of forum provisions in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

We have broad discretion to use the net proceeds from this offering and our investment of these proceeds may not yield a favorable return. We may allocate the net proceeds from this offering in ways that you and other stockholders may not approve.

Our management will have broad discretion in the application of the net proceeds from this offering, including for any of the purposes described in the section titled "Use of Proceeds." Because of the number and variability of factors that will determine our use of the net proceeds from this offering, their ultimate use may vary substantially from their currently intended use. Our management might not apply our net proceeds in ways that ultimately increase the value of your investment, and the failure by our management to apply these funds effectively could harm our business. We may also use a portion of the net proceeds of this offering for acquisitions to bolster our product offerings. We have not entered into any agreements or commitments with respect to any specific acquisitions and have no understandings or agreements with respect to any such acquisition or investment at this time. Pending their use, we may invest the net proceeds from this offering in short- and intermediate-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government. These investments may not yield a favorable return to our stockholders. If we do not invest or apply the net proceeds from this offering in ways that enhance stockholder value, we may fail to achieve expected results, which could cause our stock price to decline.

Purchasers in this offering will experience immediate and substantial dilution in the book value of their investment.

The initial public offering price of our common stock is substantially higher than the net tangible book value per share of our common stock immediately after this offering. Therefore, if you purchase our common stock in this offering, you will incur immediate dilution of $9.62 in the net tangible book value per share from the price you paid, based on the initial public offering price of $14.00 per share. The exercise of outstanding options and warrants will result in further dilution. In addition, if we raise additional funds by issuing equity securities, our stockholders may experience further dilution. For a detailed description of the dilution that you will experience immediately after this offering, see “Dilution.”

After this offering, our executive officers, directors and principal stockholders, if they choose to act together, will continue to have the ability to control or significantly influence all matters submitted to stockholders for approval.

Following the completion of this offering, our executive officers, directors and greater than 5% stockholders, in the aggregate, will own approximately 50.4% of our outstanding common stock (assuming no exercise of the underwriters’ option to purchase additional shares and no exercise of outstanding options). As a result, such persons, acting together, will have the ability to control or significantly influence all matters submitted to our stockholders for approval, including the election and removal of directors and approval of any significant transaction, as well as our management and business affairs. This concentration of ownership may have the effect of delaying, deferring or preventing a change in control, impeding a merger, consolidation, takeover or other business combination involving us, or discouraging a potential acquiror from making a tender offer or otherwise attempting to obtain control of our business, even if such a transaction would benefit other stockholders. Moreover, certain of our existing stockholders, including certain affiliates of our directors, have indicated an interest in purchasing shares of our common stock in this offering at the initial public offering price. Based on the initial public offering price of $14.00 per share, if our greater than 5% stockholders purchase all of the shares they have indicated an interest in purchasing in this offering, the number of shares of our common stock beneficially owned by our executive officers, directors and greater than 5% stockholders will, in the aggregate, increase to approximately 57.5% of our outstanding common stock. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters may determine to sell more, less or no shares in this offering to any of these stockholders, or any of these stockholders may determine to purchase more, less or no shares in this offering.

We have never paid dividends on our capital stock, and we do not anticipate paying dividends in the foreseeable future. Your ability to achieve a return on your investment will depend on appreciation, if any, in the price of our common stock.

We have never declared or paid any cash dividends on our common stock and do not intend to pay any cash dividends in the foreseeable future. We currently intend to retain any future earnings to fund the growth of our business. In addition, our loan agreement restricts our ability to pay cash dividends on our common stock and we may also enter into credit agreements or other borrowing arrangements in the future that will restrict our ability to declare or pay cash dividends on our common stock. Any determination to pay dividends in the future will be at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, general business conditions and other factors that our board of directors may deem relevant. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for the foreseeable future.

If an active, liquid trading market for our common stock does not develop, you may not be able to sell your shares quickly or at or above the initial offering price.

There has not been a public market for our common stock. An active and liquid trading market for our common stock may not develop or be sustained following this offering. The lack of an active market

may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares. An inactive market may also impair our ability to raise capital to continue to fund operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration. You may not be able to sell your shares quickly or at or above the initial offering price. The initial public offering price was determined by negotiations with the representatives of the underwriters. This price may not be indicative of the price at which our common stock will trade after this offering, and our common stock could trade below the initial public offering price.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements. All statements other than statements of historical facts contained in this prospectus, including statements regarding our future results of operations and financial position, business strategy, current and future product offerings, reimbursement and coverage, our ability to implement an integrated testing with therapeutics strategy, the expected benefits from our partnership 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 involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplates,” “believes,” “estimates,” “predicts,” “potential” or “continue” or the negative of these terms or other similar expressions. The forward-looking statements in this prospectus 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 business, financial condition and results of operations. These forward-looking statements speak only as of the date of this prospectus and are subject to a number of risks, uncertainties and assumptions described under the sections in this prospectus entitled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this prospectus. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. 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. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. Except as required by applicable law, we undertake no obligation 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. The forward-looking statements contained in this prospectus are excluded from the safe harbor protection provided by the Private Securities Litigation Reform Act of 1995 and Section 27A of the Securities Act. You should, however, review the factors and risks we describe in the reports we will file from time to time with the SEC after the date of this prospectus. See “Where You Can Find More Information.”

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this prospectus, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and you are cautioned not to rely unduly upon these statements.

MARKET AND INDUSTRY DATA

We obtained the industry, market and competitive position data used throughout this prospectus from our own internal estimates and research, as well as from independent market research, industry and general publications and surveys, governmental agencies and publicly available information in addition to research, surveys and studies conducted by third parties. Internal estimates are derived from publicly available information released by industry analysts and third-party sources, our internal research and our industry experience, and are based on assumptions made by us based on such data and our knowledge of our industry and market, which we believe to be reasonable. In some cases, we do not expressly refer to the sources from which this data is derived. In that regard, when we refer to one or more sources of this type of data in any paragraph, you should assume that other data of this type appearing in the same paragraph is derived from the same sources, unless otherwise expressly stated or the context otherwise requires. In addition, while we believe the industry, market and competitive position data included in this prospectus is reliable and based on reasonable assumptions, such data involves risks and uncertainties and is subject to change based on various factors, including those discussed in “Risk Factors.” These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties or by us.

USE OF PROCEEDS

We estimate that the net proceeds to us from the sale of the common stock that we are offering will be approximately $44.6 million (or $51.6 million if the underwriters exercise their option to purchase additional shares in full), based on the initial public offering price of $14.00 per share, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

The principal purposes of this offering are to obtain additional capital to support our operations, to create a public market for our common stock and to facilitate our future access to the public equity markets.

We currently intend to use the net proceeds from this offering as follows:

- approximately $20.0 million for selling and marketing activities;
- approximately $11.0 million for research and development activities, including continued expansion of our AVISE® product portfolio, as well as clinical studies to demonstrate the utility of our AVISE® products and support reimbursement efforts; and
- the remainder for working capital purposes and other general corporate purposes.

We may also use a portion of the net proceeds and our existing cash and cash equivalents, to in-license, acquire, or invest in complementary businesses, technologies, products or assets. However, we have no current commitments or obligations to do so.

We believe, based on our current operating plan, that the net proceeds from this offering and our existing cash and cash equivalents and anticipated future product revenue, will be sufficient to fund our operations for at least the next 12 months, although there can be no assurance in that regard. The amounts and timing of our actual expenditures will depend on numerous factors, including the timing and amount of our cash receipts from the sale of our testing products and promotion of SIMPONI®, the development efforts for our testing products and other factors described under “Risk Factors” in this prospectus, as well as the amount of cash used in our operations. For example, if our research and development of new testing products requires more time or resources than we currently anticipate or if we are required to conduct additional studies to help secure reimbursement for our testing products, we may allocate additional proceeds of this offering to our research and development efforts. If our research and development efforts progress faster than we currently expect, or if our sales and marketing needs expand faster than we currently expect, we may elect to reallocate a portion of the proceeds of this offering from research and development to sales and marketing activities to support our integrated promotion of testing products and therapeutics strategy. Therefore, our actual expenditures may differ materially from the estimates described above. We may find it necessary or advisable to use the net proceeds for other purposes, and we will have broad discretion in the application of the net proceeds.

Pending the uses described above, we plan to invest the net proceeds from this offering in short- and intermediate-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government.

DIVIDEND POLICY

We have never declared or paid any cash dividends on our capital stock. We intend to retain future earnings, if any, to finance the operation of our business and do not anticipate paying any cash dividends in the foreseeable future. Any future determination related to dividend policy will be made at the discretion of our board of directors after considering our financial condition, results of operations, capital requirements, business prospects and other factors the board of directors deems relevant, and subject to the restrictions contained in any future financing instruments. In addition, our ability to pay cash dividends is currently prohibited by the terms of our loan agreement.

CAPITALIZATION

The following table sets forth our cash and cash equivalents, and our capitalization as of June 30, 2019 as follows:

- on an actual basis;
- on a pro forma basis to reflect (i) the issuance of 479,967,595 shares of our Series H redeemable convertible preferred stock in July 2019 and the receipt of $11.0 million in gross proceeds therefrom (including the conversion of 148,928,337 shares of our Series G redeemable convertible preferred stock into 246,521,076 shares of our Series H redeemable convertible preferred stock in July 2019), (ii) the automatic conversion of all outstanding shares of our redeemable convertible preferred stock into an aggregate of 7,816,643 shares of our common stock (including the conversion of 479,967,595 shares of our Series H redeemable convertible preferred stock issued in July 2019 into 2,613,703 shares of our common stock) and the resultant reclassification of (A) the carrying value of the redeemable convertible preferred stock to permanent equity and (B) our Series F redeemable convertible preferred stock warrant liabilities to additional paid-in capital, and Series D and Series E redeemable convertible preferred stock warrant liabilities to net loss, a component of accumulated deficit, in connection with such conversion, all of which will occur in connection with the completion of this offering, (iii) the issuance of 15,072 shares of our common stock as a result of the expected net exercise of the Net Exercise Warrants in connection with the completion of this offering, based on the initial public offering price of $14.00 per share, which Net Exercise Warrants will terminate if not exercised prior to the completion of this offering, and (iv) the filing and effectiveness of our amended and restated certificate of incorporation immediately prior to the completion of this offering; and
- on a pro forma as adjusted basis to give further effect to the issuance and sale of 3,600,000 shares of our common stock in this offering at the initial public offering price of $14.00 per share, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

The pro forma and pro forma as adjusted information below is illustrative only, and our capitalization following the completion of this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing. You should read this information in conjunction with our audited financial statements and the related notes included elsewhere in this prospectus and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section and other financial information contained in this prospectus.

	As of June 30, 2019		
	Actual	Pro Forma	Pro Forma As Adjusted
	(unaudited, in thousands, except share data)		
Cash and cash equivalents	$ 16,237	$ 27,237	$ 71,809
Redeemable convertible preferred stock warrant liabilities	$ 1,036	$ –	$ –
Borrowings, including current portion, net of discounts and debt issuance costs	25,331	25,331	25,331
Capital lease obligations, including current portion	602	602	602
Redeemable convertible preferred stock, $0.001 par value per share; 955,500,000 shares authorized; 681,534,421 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	121,026	–	–
Stockholders' equity (deficit):			
Preferred stock, $0.001 par value per share; no shares authorized, issued or outstanding, actual; 10,000,000 shares authorized and no shares issued or outstanding, pro forma and pro forma as adjusted	–	–	–
Common stock, $0.001 par value per share; 1,675,200,000 shares authorized; 63,055 shares issued and outstanding, actual; 200,000,000 shares authorized, pro forma and pro forma as adjusted; 7,894,770 shares issued and outstanding, pro forma; 11,494,770 shares issued and outstanding, pro forma as adjusted	–	8	11
Additional paid-in capital	36,319	169,223	213,792
Accumulated deficit	(158,053)	(157,903)	(157,903)
Total stockholders' equity (deficit)	(121,734)	11,328	55,900
Total capitalization	$ 26,261	$ 37,261	$ 81,833

The number of shares in the table above excludes:

- 662,987 shares of our common stock issuable upon exercise of stock options outstanding as of June 30, 2019, with a weighted-average exercise price of $1.24 per share;
- 812,745 shares of our common stock issuable upon the exercise of stock options to be granted under our 2019 Plan, which became effective in connection with the completion of this offering, with an exercise price that is equal to the initial public offering price;
- 1,013,107 shares of our common stock issuable upon the exercise of outstanding warrants (which number does not include the Net Exercise Warrants) as of June 30, 2019, with a weighted-average exercise price of $3.13 per share;
- 2,011,832 shares of our common stock reserved for future issuance under our 2019 Plan, which became effective in connection with the completion of this offering (which number includes the IPO grants, but does not include any potential annual evergreen increases pursuant to the terms of the 2019 Plan); and

- 120,000 shares of our common stock reserved for future issuance under our ESPP, which became effective on the day the ESPP was adopted by our board of directors (which number does not include any potential annual evergreen increases pursuant to the terms of the ESPP).

DILUTION

If you invest in our common stock in this offering, your ownership interest will be immediately diluted to the extent of the difference between the initial public offering price per share and the pro forma as adjusted net tangible book value per share of our common stock after this offering.

As of June 30, 2019, we had a historical net tangible book deficit of $(127.2) million, or $(2,017.92) per share of common stock based on 63,055 shares of common stock outstanding as of such date. Our historical net tangible book deficit per share represents total tangible assets less total liabilities and redeemable convertible preferred stock, divided by the number of shares of common stock outstanding at June 30, 2019.

On a pro forma basis after giving effect to (i) the issuance of 479,967,595 shares of our Series H redeemable convertible preferred stock in July 2019 and the receipt of $11.0 million in gross proceeds therefrom (including the conversion of 148,928,337 shares of our Series G redeemable convertible preferred stock into 246,521,076 shares of our Series H redeemable convertible preferred stock in July 2019), (ii) the automatic conversion of all outstanding shares of our redeemable convertible preferred stock into an aggregate of 7,816,643 shares of our common stock, (including the conversion of 479,967,595 shares of our Series H redeemable convertible preferred stock issued in July 2019 into 2,613,703 shares of our common stock), and the resultant reclassification of (A) the carrying value of the redeemable convertible preferred stock to permanent equity and (B) our Series F redeemable convertible preferred stock warrant liabilities to additional paid-in capital and Series D and Series E redeemable convertible preferred stock warrant liabilities to net loss, a component of accumulated deficit, in connection with such conversion, all of which will occur in connection with the completion of this offering, and (iii) the issuance of 15,072 shares of our common stock as a result of the expected net exercise of the Net Exercise Warrants in connection with the completion of this offering, based on the initial public offering price of $14.00 per share, which Net Exercise Warrants will terminate if not exercised prior to the completion of this offering, our pro forma net tangible book value as of June 30, 2019 would have been approximately $5.8 million, or approximately $0.74 per share of common stock.

After giving further effect to the issuance and sale of 3,600,000 shares of our common stock at the initial public offering price of $14.00 per share, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of June 30, 2019 would have been approximately $50.4 million, or approximately $4.38 per share. This amount represents an immediate increase in pro forma net tangible book value of approximately $3.64 per share to our existing stockholders and an immediate dilution in pro forma net tangible book value of approximately $9.62 per share to new investors purchasing shares of common stock in this offering.

Dilution per share to new investors is determined by subtracting pro forma as adjusted net tangible book value per share after this offering from the initial public offering price per share paid by new investors. The following table illustrates this dilution:

Initial public offering price per share		$14.00
Historical net tangible book deficit per share as of June 30, 2019	$(2,017.92)	
Pro forma increase in historical net tangible book value per share attributable to the pro forma transactions described above	2,018.66	
Pro forma net tangible book value per share as of June 30, 2019	0.74	
Increase in pro forma net tangible book value per share attributable to this offering	3.64	
Pro forma as adjusted net tangible book value per share after this offering		4.38
Dilution per share to new investors in this offering		$ 9.62

If the underwriters exercise their option to purchase additional shares in full in this offering, the pro forma as adjusted net tangible book value after the offering would be approximately $4.77 per share, the increase in pro forma net tangible book value per share to existing stockholders would be approximately $4.03 per share and the dilution per share to new investors would be approximately $9.23 per share, in each case based on the initial public offering price of $14.00 per share.

The following table summarizes on the pro forma as adjusted basis described above, as of June 30, 2019, the differences between the number of shares purchased from us, the total consideration paid to us in cash and the average price per share paid by existing stockholders for shares issued prior to this offering and the price to be paid by new investors in this offering. The calculations below are based on the initial public offering price of $14.00 per share, before deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders before this offering(1)	7,894,770	68.7%	$147,121,140	74.5%	$ 18.64
New investors participating in this offering	3,600,000	31.3	50,400,000	25.5	$ 14.00
Total	11,494,770	100%	$197,521,140	100%	

(1) Certain of our existing stockholders, including entities affiliated with certain of our directors, have indicated an interest in purchasing an aggregate of approximately $12.0 million in shares of our common stock in this offering at the initial public offering price per share and on the same terms as the other purchasers in this offering. However, because these indications of interest are not binding agreements or commitments to purchase, the underwriters may determine to sell more, less or no shares in this offering to any or all of these stockholders, or any or all of these stockholders may determine to purchase more, less or no shares in this offering. The presentation in this table regarding ownership by existing stockholders before this offering does not give effect to any potential purchases in this offering by such stockholders.

The foregoing tables and calculations (other than the historical net tangible book value calculation) are based on 7,894,770 shares of our common stock outstanding as of June 30, 2019, after giving effect to the automatic conversion of all outstanding shares of our redeemable convertible preferred stock into 7,816,643 shares of our common stock (including the conversion of 479,967,595 shares of our Series H redeemable convertible preferred stock issued in July 2019) and the issuance of 15,072 shares of our common stock as a result of the expected net exercise of the Net Exercise Warrants in connection with the completion of this offering, based on the initial public offering price of $14.00 per share, which Net Exercise Warrants will terminate if not exercised prior to the completion of this offering, and excludes:

- 662,987 shares of our common stock issuable upon exercise of stock options outstanding as of June 30, 2019, with a weighted-average exercise price of $1.24 per share;
- 812,745 shares of our common stock issuable upon the exercise of stock options to be granted under our 2019 Plan, which became effective in connection with the completion of this offering, with an exercise price that is equal to the initial public offering price;
- 1,013,107 shares of our common stock issuable upon the exercise of outstanding warrants (which number does not include the Net Exercise Warrants) as of June 30, 2019, with a weighted-average exercise price of $3.13 per share;
- 2,011,832 shares of our common stock reserved for future issuance under our 2019 Plan, which became effective in connection with the completion of this offering (which number includes the IPO grants, but does not include any potential annual evergreen increases pursuant to the terms of the 2019 Plan); and

- 120,000 shares of our common stock reserved for future issuance under our ESPP, which became effective on the day the ESPP was adopted by our board of directors (which number does not include any potential annual evergreen increases pursuant to the terms of the ESPP).

To the extent any options or warrants outstanding as of June 30, 2019 are exercised, there will be further dilution to new investors. If all of such outstanding options and warrants had been exercised as of June 30, 2019, the pro forma as adjusted net tangible book value per share after this offering would be $4.13, and total dilution per share to new investors would be $9.87.

If the underwriters exercise their option to purchase additional shares of our common stock in full:

- the percentage of shares of common stock held by existing stockholders will decrease to approximately 65.6% of the total number of shares of our common stock outstanding after this offering; and
- the number of shares held by new investors will increase to 4,140,000, or approximately 34.4% of the total number of shares of our common stock outstanding after this offering.

SELECTED FINANCIAL DATA

The following tables set forth our selected historical financial data as of, and for the periods ended on, the dates indicated. We have derived the selected statements of operations data for the years ended December 31, 2017 and 2018 and the balance sheet data as of December 31, 2017 and 2018 from our audited financial statements included elsewhere in this prospectus. The statements of operations data for the six months ended June 30, 2018 and 2019 and the balance sheet data as of June 30, 2019 have been derived from our unaudited financial statements included elsewhere in this prospectus. You should read this data together with our audited financial statements and the related notes included elsewhere in this prospectus and the section of this prospectus entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations." Our historical results for any prior period are not necessarily indicative of our future results.

	Years Ended December 31,		Six Months Ended June 30,	
	2017	2018[1][3]	2018[1]	2019
(in thousands, except share and per share data)		**(As Revised)**	**(Unaudited)**	
Statements of Operations Data:				
Revenue	$ 26,807	$ 32,440	$ 14,576	$ 19,734
Operating expenses:				
Costs of revenue (excluding amortization of purchased technology)	14,137	15,379	7,524	9,434
Selling, general and administrative expenses	18,820	19,675	9,487	13,481
Research and development expenses	1,551	2,125	1,067	1,103
Amortization of intangible assets	186	141	94	–
Change in fair value of acquisition-related liabilities	(51)	–	–	–
Total operating expenses	34,643	37,320	18,172	24,018
Loss from operations	(7,836)	(4,880)	(3,596)	(4,284)
Interest expense	(2,948)	(2,868)	(1,394)	(1,811)
Loss on extinguishment of share purchase rights and 2013 Term Loan	(6,050)	–	–	–
Change in fair value of financial instruments	(9,391)	(318)	–	467
Other income, net	45	112	51	139
Loss before income taxes	(26,180)	(7,954)	(4,939)	(5,489)
Income tax (benefit) expense	(549)	58	–	–
Net loss	(25,631)	(8,012)	(4,939)	(5,489)
Accretion of redeemable convertible preferred stock	(5,353)	(9,318)	(3,694)	(4,302)
Deemed dividend recorded in connection with financing transactions	(1,790)	(1,152)	(1,152)	–
Net loss attributable to common stockholders	$ (32,774)	$ (18,482)	$ (9,785)	$ (9,791)
Net loss per share attributable to common stockholders, basic and diluted[2]	$ (520.18)	$ (293.34)	$ (155.31)	$ (155.33)
Weighted-average number of shares used to compute net loss per share attributable to common stockholders, basic and diluted[2]	63,005	63,005	63,005	63,033
Pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)[2]		$ (1.46)		$ (1.02)
Pro forma weighted-average number of shares used to compute pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)[2]		5,277,265		5,831,017

(1) We adopted ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)*, as of January 1, 2018. See Note 3 to our audited financial statements included elsewhere in this prospectus for further discussion.

(2) See Note 2 to our audited financial statements included elsewhere in this prospectus for an explanation of the method used to calculate the historical net loss and the historical and pro forma net loss per share attributable to common stockholders, basic and diluted, and the number of shares used in the computation of these per share amounts.

(3) See Note 16 to our audited financial statements included elsewhere in this prospectus for a summary of the amounts and financial statement line items impacted by the revision.

(in thousands)	December 31, 2017	December 31, 2018(1)(3) (As Revised)	June 30, 2019 (Unaudited)
Balance Sheet Data:			
Cash and cash equivalents	$ 11,241	$ 13,164	$ 16,237
Working capital(2)	8,270	12,360	18,210
Total assets	20,390	28,887	33,088
Borrowings, non-current portion, net of discounts and debt issuance costs	18,809	24,617	25,331
Capital lease obligations, including current portion	108	360	602
Redeemable convertible preferred stock warrant liabilities	896	1,503	1,036
Redeemable convertible preferred stock	92,046	105,232	121,026
Total stockholders' deficit	(96,684)	(111,966)	(121,734)

(1) We adopted ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)*, as of January 1, 2018. See Note 3 to our audited financial statements included elsewhere in this prospectus for further discussion.

(2) We define working capital as current assets less current liabilities. See our audited financial statements and the related notes included elsewhere in this prospectus for further details regarding our current assets and current liabilities.

(3) See Note 16 to our audited financial statements included elsewhere in this prospectus for a summary of the amounts and financial statement line items impacted by the revision.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our audited financial statements and the related notes and other financial information included elsewhere in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business and future financial performance, includes forward-looking statements that are based on current beliefs, plans and expectations and involve risks, uncertainties and assumptions. You should review the "Risk Factors" section of this prospectus for a discussion of important factors that could cause our actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. Please also see the section of this prospectus entitled "Special Note Regarding Forward-Looking Statements."

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 SLE and 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 nine 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 82% of our revenue in the year ended December 31, 2018 and 83% of our revenue for the six months ended June 30, 2019. 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 Janssen agreement 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 expanded our salesforce from 31 representatives as of December 31, 2018 to 55 representatives in August 2019. We expect our SIMPONI® promotion efforts to contribute incremental revenue in 2019 with our quarterly tiered promotion fee based on the incremental increase in total prescribed units above a predetermined average baseline of approximately 29,000 prescribed units per quarter.

We also have additional agreements with other leading pharmaceutical companies, including GSK, Horizon Therapeutics and Corrona, 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 by CLIA and accredited by 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.

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 June 30, 2019 we had an accumulated deficit of $158.1 million. We incurred net losses of $25.6 million, $8.0 million (as revised) and $5.5 million in the years ended December 31, 2017 and 2018 and the six months ended June 30, 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. Since inception and through June 30, 2019, our operations have been financed primarily by net proceeds of approximately $161.1 million from sales of our common and redeemable convertible preferred stock and borrowings under various debt financings and revenue from the sales of our products. As of June 30, 2019 we had $16.2 million of cash and cash equivalents. In addition, in July 2019, we raised gross proceeds of approximately $11.0 million through the sale of our Series H redeemable convertible preferred stock.

Factors Affecting Our Performance

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 87%, with limited incremental investment in our commercial infrastructure. Approximately 83,000 AVISE® CTD tests were delivered in 2018, representing 18% growth over 2017, and the number of ordering physicians reached 1,298 in the fourth quarter of 2018, representing 18% growth over the same quarter in 2017. In the first half of 2019, 50,792 AVISE® CTD tests were delivered, representing approximately 30% growth over the same period in 2018, and the number of ordering physicians in the first half of 2019 reached 1,711. More than 326,000 AVISE® CTD tests have been delivered since launch, and in the first half of 2019, we achieved a record number of 766 adopting physicians (defined as those who had previously prescribed at least 11 tests in a quarter) compared to 635 in the same period in 2018. Revenue growth for our testing products will depend on our ability to continue to expand our base of ordering physicians and increase our penetration with existing physicians.
- ***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 only recently began promoting SIMPONI® in the United States under the Janssen agreement. We may encounter difficulties in successfully promoting SIMPONI® and generating significant revenue under the agreement. Our ability to effectively promote SIMPONI® will require us to be successful in a range of activities, including training and deploying additional sales representatives and creating demand for SIMPONI® through our own sales activities as well as those of Janssen. Based on our estimate of the total U.S. addressable market for SIMPONI®'s approved indications of $28 billion, each incremental 1% market share we are able to capture for SIMPONI® above the predetermined baseline under the Janssen Agreement could result in incremental revenue to us of $84 million. However, it may take longer to generate meaningful revenue than we currently expect 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 recently launched AVISE® Anti-CarP and AVISE® PC4d. 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 also expect an increase to our gross margins in January 2020 onwards upon 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 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***. Through December 31, 2017, we recognized revenue related to billings to payers on an accrual basis, net of contractual adjustments, only when we had established pricing with our payers as indicated by contractual pricing arrangements or when we had been able to demonstrate that a predictable pattern of payment for our services exists. For the year ended December 31, 2017, revenue was recognized on an accrual basis for one payer, Medicare, and totaled $8.2 million. In the absence of a predictable pattern of reimbursement or a contract with a payer, revenue was recognized upon cash receipt. Effective January 1, 2018, we began recognizing revenue in accordance with the provisions of Accounting Standards Codification, or 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. 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 a co-promotion agreement with Janssen, under which we are responsible for the costs associated with our sales force 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 ranging from $750 to $1,250 per prescription based on the incremental increase in total prescribed units of SIMPONI® for that quarter over a predetermined baseline. The predetermined average baseline for the initial term of 18 months is approximately 29,000 prescribed units per quarter, subject to adjustment under certain circumstances. The term of the agreement expires on June 30, 2020, unless extended by us for an additional 18 months upon 180 days written notice prior to the end of the initial term. Janssen can terminate the agreement at any time for any reason upon 30 days’ notice to us, and we can terminate the agreement for any reason at the end of any calendar quarter upon 30 days’ notice to Janssen. Either party may terminate the 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 co-promotional revenue of approximately $404,000 during the six months ended June 30, 2019 and expect to continue to recognize revenue as we perform co-promotional services based on the number of total prescribed units of SIMPONI® over the predetermined baseline.

Financial Overview

Basis of Presentation

Revision of Previously issued Financial Statements for Correction of Immaterial Errors

During 2019, we identified immaterial misstatements in the financial statements for the year ended December 31, 2018 related to the carrying value of redeemable convertible preferred stock warrant liabilities. These amounts have been adjusted in the accompanying financial statements. See Note 16

to our audited financial statements for a summary of the amounts and financial statement line items impacted by the revision. All amounts set forth in the discussion and year ended December 31, 2018 have been adjusted to reflect these revisions.

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.

Through December 31, 2017, we recognized revenue related to billings to payers on an accrual basis, net of contractual adjustments, only when we had established pricing with our payers as indicated by contractual pricing arrangements or when we had been able to demonstrate that a predictable pattern of payment for our services exists. For the year ended December 31, 2017, revenue was recognized on an accrual basis for one payer, Medicare, and totaled $8.2 million. In the absence of a predictable pattern of reimbursement or a contract with a payer, revenue was recognized upon cash receipt.

Effective January 1, 2018, we began recognizing 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®.

Operating Expenses

Costs of Revenue (Excluding Amortization of Purchased Technology)

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.

We expect that our costs of revenue will increase in absolute dollars as the number of tests we perform increases. However, we expect that the cost per test will decrease over time due to volume discounts on materials and shipping costs and other volume efficiencies we may gain as the number of tests we perform increases.

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 as we expand our sales and sales support functions, including expansion activities related to our promotion of SIMPONI®. We also expect our selling, general and administrative expenses will increase because of operating as a public company, including expenses related to compliance with the rules and regulations of the SEC and Nasdaq, 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 as we continue to invest in research and development activities related to our existing testing products and product candidates.

Amortization of Intangible Assets

Amortization of intangible assets represents the total amortization expense for our purchased technologies.

The intangible assets recorded as of December 31, 2017 became fully amortized in 2018; accordingly, we do not expect any future amortization expense related to these assets.

Change in Fair Value of Acquisition-Related Liabilities

In connection with the acquisition of the medical diagnostics division of Cypress Bioscience, Inc., or Cypress, in 2010, we were assigned certain agreements with Royalty Pharma. We initially agreed to pay an additional amount not to exceed $9.0 million in the event specified revenue, contractual and product launch milestones were achieved. In February 2017, we amended two of the remaining agreements for which a contingent payment amount had been originally agreed to.

We do not expect any further fair value adjustments for these acquisition-related liabilities as the one remaining milestone is not expected to be achieved.

Interest Expense

Interest expense consists of cash and non-cash interest expense associated with our financing arrangements, including the borrowings under our current loan agreement with Innovatus and our prior term loan agreement, or the 2013 Term Loan, with Capital Royalty Partners II, L.P. and its affiliates, collectively referred to as Capital Royalty, which was repaid in September 2017.

We expect interest expense to increase in 2019 due to the draws we made under our loan agreement and to decrease in years thereafter due to lower interest rates and lower outstanding principal balances.

Loss on Extinguishment of Share Purchase Rights and 2013 Term Loan

In 2016 and 2017, we entered into agreements with existing stockholders of our redeemable convertible preferred stock that contained future purchase obligations that were required to be accounted for as liabilities and remeasured to fair value at each reporting date, with any change in the

fair value reported as a component of other income (expense). In May 2017, we completed the first closing of the sale of our Series F redeemable convertible preferred stock which resulted in the conversion of all outstanding share purchase rights. We remeasured the share purchase right liabilities to fair value on the date of conversion and the difference between the fair value of the shares of Series F redeemable convertible preferred stock received and the sum of the cash proceeds received and the fair value of the outstanding share purchase and tranche participation rights resulted in the recognition of a loss on extinguishment of the outstanding share purchase rights.

In September 2017, we repaid our 2013 Term Loan with Capital Royalty and incurred a loss on the extinguishment of debt related to the unamortized portion of the of the placement fees and the capitalized value of the warrants associated with the notes.

We did not have any similar transactions in 2018 or the six months ended June 30, 2019 and accordingly, there were no similar charges in 2018 or the first half of 2019.

Change in Fair Value of Financial Instruments

As discussed above, we remeasured the share purchase right liabilities to fair value on the date of the conversion to shares of Series F redeemable convertible preferred stock and reclassified the liabilities to permanent equity.

In addition, we classify our outstanding warrants to purchase shares of our redeemable convertible preferred stock as liabilities on our balance sheets at their estimated fair value since the underlying redeemable convertible preferred stock was classified as temporary equity. At the end of each reporting period, changes in the estimated fair value during the period are recorded as a component of other income (expense).

The outstanding warrants to purchase shares of our Series D and E redeemable convertible preferred stock will terminate if not exercised prior to the completion of this offering and will no longer be subject to measurement once exercised or terminated. The outstanding warrants to purchase shares of our Series F redeemable convertible preferred stock will convert into warrants to purchase shares of our common stock in connection with the completion of this offering and will no longer be subject to measurement.

Other Income, Net

Other income, net, consists primarily of interest income earned on our cash and cash equivalents.

Income Tax (Benefit) Expense

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

Results of Operations

Comparison of the Six Months Ended June 30, 2018 and 2019:

	Six Months Ended June 30,		
	2018	2019	Change
	(unaudited, in thousands)		
Revenue	$ 14,576	$ 19,734	$5,158
Operating expenses:			
Costs of revenue (excluding amortization of purchased technology)	7,524	9,434	1,910
Selling, general and administrative expenses	9,487	13,481	3,994
Research and development expenses	1,067	1,103	36
Amortization of intangible assets	94	–	(94)
Total operating expenses	18,172	24,018	5,846
Loss from operations	(3,596)	(4,284)	(688)
Interest expense	(1,394)	(1,811)	(417)
Change in fair value of financial instruments	–	467	467
Other income, net	51	139	88
Loss before income taxes	(4,939)	(5,489)	(550)
Income tax expense	–	–	–
Net loss	$ (4,939)	$ (5,489)	$ (550)

Revenue

Revenue increased $5.2 million, or 35.4%, for the six months ended June 30, 2019 compared to the six months ended June 30, 2018, primarily due to an increase in the number of diagnostic tests delivered and an increase in the average reimbursement per test. The number of AVISE® CTD tests, which accounted for 83% and 86% of revenue in the six months ended June 30, 2019 and 2018, respectively, increased to 50,792 tests delivered in the six months ended June 30, 2019 compared to 39,134 tests delivered in the same 2018 period. The increase is primarily due to the increased adoption of the AVISE® CTD test by rheumatologists as the number of ordering physicians increased to 1,711 in the six months ended June 30, 2019 as compared to 1,454 physicians in the same 2018 period. In addition, our average reimbursement per AVISE® CTD test increased to approximately $325 per test delivered in the six months ended June 30, 2019 from approximately $308 per test delivered in the same 2018 period, an increase of approximately 6%.

In addition, we began co-promoting SIMPONI® in early 2019 and recognized approximately $404,000 of revenue during the six months ended June 30,2019.

Costs of Revenue (excluding amortization of purchased technology)

Costs of revenue increased $1.9 million, or 25.4%, for the six months ended June 30, 2019 compared to the six months ended June 30, 2018. This increase was primarily due to increased direct costs such as materials and supplies and royalties associated with the increase in test volume in 2019 compared to 2018.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased $4.0 million, or 42.1%, for the six months ended June 30, 2019 compared to the six months ended June 30, 2018. This increase was primarily due to increased employee related expenses as a result of increasing the size of our sales force from 29 at March 31, 2018 to 53 at June 30, 2019.

Research and Development Expenses

Research and development expenses remained relatively consistent for the six months ended June 30, 2019 compared to the six months ended June 30, 2018.

Amortization of Intangible Assets

Our purchased intangible assets were fully amortized at December 31, 2018, therefore there is no amortization expense recorded for the six months ended June 30, 2019.

Interest Expense

Interest expense increased $0.4 million, or 29.9%, for the six months ended June 30, 2019 compared to the six months ended June 30, 2018. This increase was primarily due to higher principal amounts outstanding at June 30, 2019 under our long-term borrowing arrangements.

Change in Fair Value of Financial Instruments

The change in the fair value of financial instruments was a benefit of $0.5 million for the six months ended June 30, 2019 and resulted from changes in the valuation of our redeemable convertible preferred stock warrant liabilities. There was no such change in valuation for the six months ended June 30, 2018.

Other Income, Net

Other income, net, remained relatively consistent for the six months ended June 30, 2019 compared to the six months ended June 30, 2018.

Comparison of the Years Ended December 31, 2017 and 2018:

	Year Ended December 31,		
	2017	2018	Change
		(in thousands) (As Revised)	
Revenue	$ 26,807	$ 32,440	$ 5,633
Operating expenses:			
Costs of revenue (excluding amortization of purchased technology)	14,137	15,379	1,242
Selling, general and administrative expenses	18,820	19,675	855
Research and development expenses	1,551	2,125	574
Amortization of intangible assets	186	141	(45)
Change in fair value of acquisitions-related liabilities	(51)	–	51
Total operating expenses	34,643	37,320	2,677
Loss from operations	(7,836)	(4,880)	2,956
Interest expense	(2,948)	(2,868)	80
Loss on extinguishment of share purchase rights and 2013 Term Loan	(6,050)	–	6,050
Change in fair value of financial instruments	(9,391)	(318)	9,073
Other income, net	45	112	67
Loss before income taxes	(26,180)	(7,954)	18,226
Income tax (benefit) expense	(549)	58	607
Net loss	$ (25,631)	$ (8,012)	$17,619

Revenue

Revenue increased $5.6 million, or 21.0%, for the year ended December 31, 2018 compared to the year ended December 31, 2017, primarily due to an increase in the number of diagnostic tests delivered and the adoption of ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)*, offset by a 5.7% decrease in the average reimbursement per test. The number of AVISE® CTD tests, which accounted for 82% and 89% of revenue in the year ended December 31, 2018 and 2017, respectively, increased to 82,657 tests delivered in the year ended December 31, 2018 compared to 70,138 tests delivered in the same 2017 period. The increase is primarily due to the increased adoption of our products by rheumatologists as the number of ordering physicians increased to 1,298 in the fourth quarter of 2018 as compared to 1,098 physicians in the same 2017 period.

The adoption of ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)*, represented an increase in revenue for the year ended December 31, 2018 of approximately $1.5 million as this adoption resulted in an acceleration of revenue recognition since we were required to estimate consideration to which we expect to be entitled rather than record revenue on the cash basis as we had previously done for all but one customer.

Costs of Revenue (excluding amortization of purchased technology)

Costs of revenue increased $1.2 million, or 8.8%, in the year ended December 31, 2018 compared to the year ended December 31, 2017. This increase was primarily due to increased direct costs such as materials and supplies and royalties associated with the increase in test volume in 2018 compared to 2017.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased $0.9 million, or 4.5%, in the year ended December 31, 2018 compared to the year ended December 31, 2017. This increase was primarily due to increased employee related expenses of $0.4 million, increased audit and legal fees of $0.4 million and increased facility related expenses of $0.1 million.

Research and Development Expenses

Research and development expenses increased $0.6 million, or 37.0%, in the year ended December 31, 2018 compared to the year ended December 31, 2017. This increase was primarily due to increased clinical trial expenses related to the initiation of our CARE for Lupus randomized multi-site study in 2018 of $0.4 million, increased employee related expenses of $0.1 million and increased professional service fees of $0.1 million.

Amortization of Intangible Assets

Amortization of intangible assets remained relatively consistent for the year ended December 31, 2018 compared to the year ended December 31, 2017.

Change in Fair Value of Acquisition-Related Liabilities

The change in fair value of acquisition-related liabilities remained relatively consistent for the year ended December 31, 2018 compared to the year ended December 31, 2017.

Interest Expense

Interest expense remained relatively consistent for the year ended December 31, 2018 compared to the year ended December 31, 2017.

Loss on Extinguishment of Share Purchase Rights and 2013 Term Loan

The loss on extinguishment of share purchase rights and 2013 Term Loan decreased $6.1 million, or 100%, in the year ended December 31, 2018 compared to the year ended December 31, 2017, as there were no similar charges in 2018.

Change in Fair Value of Financial Instruments

The change in fair value of financial instruments decreased $9.1 million, or 96.6%, in the year ended December 31, 2018 compared to the year ended December 31, 2017. This decrease was primarily due to the conversion of all outstanding share purchase rights in the year ended December 31, 2017 thereby eliminating these items from being remeasured in the year ended December 31, 2018.

Other Income, Net

Other income, net, remained relatively consistent for the year ended December 31, 2018 compared to the year ended December 31, 2017.

Income Tax (Benefit) Expense

Income tax expense increased $0.6 million in the year ended December 31, 2018 compared to the year ended December 31, 2017. The income tax benefit in the year ended December 31, 2017 resulted from the impacts of The Tax Cuts and Job Act enacted in December 2017 with no additional impact in the year ended December 31, 2018.

Liquidity and Capital Resources

We have incurred net losses since our inception. For the years ended December 31, 2017 and 2018 and the six months ended June 30, 2019, we incurred a net loss of $25.6 million, $8.0 million (as revised) and $5.5 million, respectively, and we expect to incur additional losses and increased operating expenses in future periods. As of June 30, 2019, we had an accumulated deficit of $158.1 million. To date, we have generated only limited revenue, and we may never achieve revenue sufficient to offset our expenses.

Since inception and through June 30, 2019, our operations have been financed primarily by net proceeds of approximately $161.1 million from sales of our equity and borrowings under various debt financings and revenue from the sales of our products. As of June 30, 2019, we had $16.2 million of cash and cash equivalents. In addition, in July 2019, we raised gross proceeds of approximately $11.0 million through the sale of our Series H redeemable convertible preferred stock. 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 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. The loan term is for five years with a final maturity date of September 2022. The loan accrues interest at an annual rate of 11%, of which 2.5%, during the first 24 months, will be treated as paid in kind interest. Paid in kind interest is added to the principal balance each period. After the initial 24 months of the loan, the entire 11% will be paid in cash at the end of each period. We may, at our option, prepay the term loan borrowings by paying the lender a prepayment premium, which expires in October 2020.

Our obligations under the loan agreement are secured by a security interest in substantially all of our assets, including our intellectual property. The loan agreement contains customary conditions to borrowing, events of default, and covenants, including covenants requiring us to maintain certain levels

of minimum liquidity (in specified instances, is either $2.0 million or the trailing four months of cash used to fund operating activities) and achieve certain minimum amounts of revenue and either gross margins or gross profits, 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.

In connection with the execution of the 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 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. These warrants will become exercisable for an aggregate of 104,722 shares of our common stock upon the completion of this offering at an exercise price of $14.32 per share.

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 sales force 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 expect that we will use a substantial portion of the net proceeds of this offering, in combination with our existing cash and cash equivalents, for these purposes and for the increased expenses associated with being a public company. 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 the estimated net proceeds from this offering, together with 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:

- 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;
- fluctuations in working capital;
- 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;
- the costs of developing our product pipeline, including the costs associated with conducting our ongoing and future validation studies;

- 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;
- the additional costs we may incur as a result of operating as a public company; 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:

	Years Ended December 31,		Six Months Ended June 30,	
	2017	2018	2018	2019
(in thousands)			(unaudited)	
Net cash provided by (used in):				
Operating activities	$ (10,968)	$ (9,301)	$ (5,408)	$ (4,118)
Investing activities	(510)	(199)	(2,068)	(75)
Financing activities	19,156	11,423	2,706	7,266
Increase (decrease) in cash, cash equivalents and restricted cash	$ 7,678	$ 1,923	$ (4,770)	$ 3,073

Cash Flows from Operating Activities

Net cash used in operating activities for the six months ended June 30, 2018 was $5.4 million and primarily resulted from our net loss of $4.9 million adjusted for non-cash charges of $1.0 million for depreciation, amortization, stock-based compensation and non-cash interest and changes in our net operating assets of $1.5 million related to net decreases in accounts payable and accrued liabilities. Net cash used in operating activities for the six months ended June 30, 2019 was $4.1 million and primarily resulted from our net loss of $5.5 million adjusted for net non-cash charges of $0.8 million related to depreciation, amortization, stock- based compensation, non-cash interest and the revaluation of our preferred stock liabilities, and changes in our net operating assets of $0.6 million related to net increases in accounts payable, and accrued liabilities.

Net cash used in operating activities for the year ended December 31, 2017 was $11.0 million and primarily resulted from our net loss of $25.6 million adjusted for non-cash charges of $9.4 million for

remeasurements of financial instruments, $6.1 million for losses on extinguishment of the 2013 Term Loan and share purchase rights, and $1.7 million for depreciation, amortization and non-cash interest, all partially offset by a cash payment of accrued paid in-kind, or PIK, interest of $2.3 million associated with the extinguishment of the 2013 Term Loan. Net cash used in operating activities for the year ended December 31, 2018 was $9.3 million and primarily resulted from our net loss of $8.0 million (as revised) adjusted for non-cash charges of $0.3 million (as revised) for remeasurements of financial instruments and $1.8 million for depreciation, amortization and non-cash interest, partially offset by changes in our net operating assets consisting of a $2.3 million increase in accounts receivable primarily due to the adoption of ASC 606 and $1.3 million related to net increases in prepaid expenses and other current assets, accounts payable, and accrued liabilities.

Cash Flows from Investing Activities

Net cash used in investing activities for the six months ended June 30, 2018 was $2.1 million and was due to purchases of short-term investments of $2.0 million and purchases of property and equipment of $0.1 million. Net cash used in investing activities for the six months ended June 30, 2019 was $0.1 million and was due to net purchases of property and equipment.

Net cash used in investing activities for the years ended December 31, 2017 and 2018 was $0.5 million and $0.2 million, respectively, and were primarily due to purchases of property and equipment in both periods.

Cash Flows from Financing Activities

Net cash provided by financing activities for the six months ended June 30, 2018 and 2019 was $2.7 million and $7.3 million, respectively, and primarily resulted from net proceeds received from the issuance of our redeemable convertible preferred stock.

Net cash provided by financing activities was $19.2 million for the year ended December 31, 2017 and primarily resulted from $14.6 million of net proceeds received from the issuance of our redeemable convertible preferred stock and stock purchase rights and net proceeds of $4.5 million from refinancing our long-term borrowing arrangement. Net cash provided by financing activities was $11.4 million for the year ended December 31, 2018 and primarily resulted from $6.5 million of net proceeds received from the issuance of our redeemable convertible preferred stock and net proceeds of $5.0 million under our long-term borrowing agreement with Innovatus.

Contractual Obligations and Other Commitments

The following table summarizes our contractual obligations as of December 31, 2018:

	Payments Due by Period				
	Less Than 1 Year	1 to 3 Years	3 to 5 Years	More Than 5 Years	Total
			(in thousands)		
Contractual obligations:					
Operating leases(1)	$ 399	$ 445	$ –	$ –	$ 844
Capital leases	92	184	112		388
2017 Term Loan(2)	2,372	21,062	11,250	–	34,684
Non-cancelable purchase obligations(3)	3,250	3,250	–	–	6,500
Total contractual obligations:	$6,113	$24,941	$ 11,362	$ –	$42,416

(1) We lease approximately 33,500 square feet of office and laboratory space in Vista, California, under leases that expire in 2021, with options to extend the leases for an additional 24-month or 36-month period.

(2) We will make principal and interest payments to Innovatus in accordance with the required payment schedule for the 2017 Term Loan.
(3) Represents the minimum annual purchase commitment for one supplier.

The contractual obligations table does not include any additional potential contingent payments upon the future achievement by us of specified sales-based and other milestones, or royalty payments we may be required to make under license agreements we have entered into pursuant to which we have in-licensed certain intellectual property, including our license agreements with the University of Pittsburgh, Prometheus and Dr. Dervieux. See the section entitled "Business—Intellectual Property Overview—License Agreements" and Note 8 to our audited financial statements included elsewhere in this prospectus for additional information. The timing of when these additional payments will actually be made is uncertain and the payments are contingent upon the completion of future activities.

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 audited financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of these audited 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 audited 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. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Revenue Recognition

To date, substantially all of our revenue has been derived from sales of our testing products. We primarily market our testing products to rheumatologists and their physician assistants in the United States. The healthcare professionals who order our services and to whom test results are reported are generally not responsible for payment for these services. The parties that pay for these services consist of healthcare insurers, government payers (primarily Medicare and Medicaid), client payers (i.e. hospitals, other laboratories, etc.) and patient self-pays. Through December 31, 2017, we recognized revenue when the following criteria was met (i) persuasive evidence of an arrangement exists; (ii) delivery occurred or services have been rendered; (iii) the fee is fixed and determinable; and (iv) collectability is reasonably assured.

Our service is completed upon the delivery of test results to the prescribing rheumatologist which triggers billing for the service. Prior to January 1, 2018, we recognized revenue related to billings to payers on an accrual basis, net of contractual adjustments, only when we had established pricing with our third-party payers as indicated by contractual pricing arrangements or predictable patterns of payment for our services. In the absence of a predictable pattern of reimbursement or a contract with a payer, revenue was recognized upon cash receipt. For the year ended December 31, 2017, revenue was recognized on an accrual basis for one payer, Medicare, and totaled $8.2 million.

On January 1, 2018, we early adopted ASC Topic 606, *Revenue from Contracts with Customers,* and began recognizing revenue in accordance with the provisions thereof. Our 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 our list price. Net revenues recognized consist of amounts billed net of allowances for differences between amounts billed and the estimated consideration we expect to receive from such payers. We follow 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. 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. Our 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 our 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.

The process for estimating revenues and the ultimate collection of accounts receivable involves significant judgment and estimation by management.

In December 2018, we entered into the Janssen agreement to co-promote SIMPONI® in the United States. We are responsible for the costs associated with our sales force 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 our sales and co-promotional services, we are entitled to a tiered promotion fee ranging from $750 to $1,250 per prescription based on the incremental increase in total prescribed units of SIMPONI® for that quarter over a predetermined baseline. The predetermined average baseline for the initial term of 18 months is approximately 29,000 prescribed units per quarter, subject to adjustment under certain circumstances.

Our obligations relating to sales and co-promotion services for SIMPONI® is a series of single performance obligations since Janssen simultaneously receives and consumes the benefits provided by our 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. As of December 31, 2018, there were no performance obligations under the agreement and no consideration had been received. We began co-promoting SIMPONI® in early 2019 and recognized revenue of approximately $404,000 during the six months ended June 30, 2019.

Long-lived Assets

Our long-lived assets are comprised principally of our property and equipment, finite lived intangible assets, and goodwill.

We amortize all finite lived intangible assets over their respective estimated useful lives. In considering whether intangible assets are impaired, we combine our intangible assets and other long-lived assets (excluding goodwill), into groupings, a determination which we principally make on the basis of whether the assets are specific to a particular test offered by us or technology we are developing. If we identify events or circumstances indicate that the associated carrying amount of assets within a group may not be recoverable, we will consider the assets in the group impaired if the carrying value of the group's assets and directly associated liabilities exceed the estimated cash flows expected to be generated over the estimated useful life of the assets in the group. Management's estimates of future cash flows are impacted by projected levels of tests and levels of reimbursement, as well as expectations related to the future cost structure of the entity.

Goodwill is not amortized but is tested for impairment at least annually or more frequently whenever a triggering event or change in circumstances occurs, at the reporting unit level. For our goodwill impairment analysis, we operate in a single reporting unit, and allocate all goodwill to this

reporting unit. We are required to recognize an impairment charge if the carrying amount of the reporting unit exceeds its fair value. Management first assesses qualitative factors to determine whether it is more likely than not that the fair value of the reporting unit is less than the carrying amount as a basis for determining whether it is necessary to perform a quantitative assessment. If a quantitative assessment is deemed necessary, management uses all available information to make this fair value determination, including the present values of expected future cash flows using discount rates commensurate with the risks involved in the assets and observed market multiples of operating cash flows.

The judgments and estimates involved in identifying and quantifying the impairment of long-lived assets or goodwill involve inherent uncertainties, and the measurement of the fair value is dependent on the accuracy of the assumptions used in making the estimates and how those estimates compare to our future operating performance. No goodwill impairments were recorded during the years ended December 31, 2017 and 2018 or the six months ended June 30, 2019.

Following the completion of this offering, our stock price and associated market capitalization will also be considered in the determination of reporting unit fair value. A prolonged or significant decline in our share price could provide evidence of a need to record a material impairment of goodwill.

Stock-Based Compensation

We recognize compensation expense related to stock-based awards to employees and directors based on the estimated fair value of the awards on the date of grant over the requisite service period of the awards (usually the vesting period) on a straight-line basis. The grant date fair value, and the resulting stock-based compensation expense, is estimated using the Black-Scholes option pricing model. The grant date fair value of stock-based awards is expensed on a straight-line basis over the vesting period of the respective award.

We recorded stock-based compensation expense of approximately $187,000, $114,000, $90,000 and $23,000 for the years ended December 31, 2017 and 2018 and the six months ended June 30, 2018 and 2019, respectively. We expect to continue to grant stock options and other equity-based awards in the future, and to the extent that we do, our stock-based compensation expense recognized in future periods will likely increase.

The Black-Scholes option pricing model requires the use of highly subjective and complex assumptions, which determine the fair value of stock-based awards. If we had made different assumptions, our stock-based compensation expense, net loss and net loss per share attributable to common stockholders could have been significantly different. See Notes 2 and 12 to our audited financial statements included elsewhere in this prospectus for information concerning certain of the specific assumptions we used in applying the Black-Scholes option pricing model to determine the estimated fair value of our stock options granted in the years ended December 31, 2017 and 2018 and the six months ended June 30, 2018 and 2019.

Significant Factors, Assumptions and Methodologies Used in Determining Fair Value of Our Common Stock

We are also required to estimate the fair value of the common stock underlying our stock-based awards when performing the fair value calculations. Our board of directors, with the assistance of management, determined the fair value of our common stock on each grant date. All options to purchase shares of our common stock are intended to be granted with an exercise price per share no less than the fair value per share of our common stock underlying those options on the date of grant, based on the information known to us on the date of grant.

Because there has been no public market for our common stock, the fair value of the common stock that underlies our stock options has historically been determined by our board of directors based upon information available to it at the time of grant, including the following:

- contemporaneous valuations performed by independent third-party firms;
- rights, preferences and privileges of our common stock compared to the rights, preferences and privileges of our other outstanding equity securities;
- our current and projected operating and financial performance, including our levels of available capital resources;
- trends and developments in our industry;
- the likelihood of achieving a liquidity event for the shares of common stock, such as an initial public offering or an acquisition of our company given prevailing market and sector conditions;
- the illiquidity of our securities by virtue of being a private company;
- the valuation of publicly traded companies in our sector, as well as recently completed initial public offerings and mergers and acquisitions of comparable companies;
- stage of development; and
- U.S. and global economic and capital market conditions.

The valuations of our common stock were prepared in accordance with the guidelines outlined in the American Institute of Certified Public Accountants Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation,* or the Practice Aid, which prescribes several valuation approaches for setting the value of an enterprise, such as the cost, income and market approaches, and various methodologies for allocating the value of an enterprise to its common stock. The cost approach establishes the value of an enterprise based on the cost of reproducing or replacing the property less depreciation and functional or economic obsolescence, if present. The income approach establishes the value of an enterprise based on the present value of future cash flows that are reasonably reflective of our company's future operations, discounting to the present value with an appropriate risk adjusted discount rate or capitalization rate. The market approach is based on the assumption that the value of an asset is equal to the value of a substitute asset with the same characteristics. Each valuation methodology was considered in our valuations. In determining a fair value for our common stock, we estimated the enterprise value of our business using either the market approach or income approach. In 2017 and 2018, we concluded that the market approach was the most appropriate. In accordance with the Practice Aid, we considered the various methods for allocating the enterprise value across our classes and series of capital stock to determine the fair value of our common stock at each valuation date. Until December 2018, we concluded that the Option Pricing Method, or OPM, was most appropriate for each of the valuations of our common stock performed by independent third-party valuation specialists. We believed the OPM was the most appropriate given the expectation of various potential liquidity outcomes and the difficulty of selecting and supporting appropriate enterprise values given our early stage of development. Under the OPM, shares are valued by creating a series of call options with exercise prices based on the liquidation preferences and conversion terms of each equity class. The values of the preferred and common stock are inferred by analyzing these options. In December 2018, we changed to a Probability-Weighted Expected Return Method, or PWERM, for estimating enterprise value given the increased probability of an initial public offering liquidity scenario. The PWERM is a scenario-based analysis that estimates the value per share based on the probability-weighted present value of expected future investment returns, considering each of the possible outcomes available to us, as well as the economic and control rights of each share class.

If we had made different assumptions than those used, the amount of our stock-based compensation expense, net loss and net loss per share attributable to common stockholders could have been significantly different. Following the completion of this offering, the fair value per share of

our common stock for purposes of determining stock-based compensation expense will be the closing price of our common stock as reported on the applicable grant date on the primary stock exchange on which our common stock is traded.

Based on the initial public offering price of $14.00 per share, the intrinsic value of stock options outstanding as of June 30, 2019 would be $8.8 million, of which approximately $18,000 and $8.8 million would have been related to stock options that were vested and unvested, respectively, at that date.

Estimated Fair Value of Share Purchase Rights, Redeemable Convertible Preferred Stock Warrants and Other Financial Instruments

From time to time, we enter into agreements with existing stockholders of our redeemable convertible preferred stock that contain future purchase obligations of redeemable convertible preferred stock at a fixed price. We evaluate these share purchase right agreements and assess whether they meet the definition of a freestanding instrument and, if so, determine the fair value of the share purchase right liability and record it on the balance sheet. The share purchase right liability is revalued at each reporting period with changes in the fair value of the liability recorded as a component of other income (expense) in the statement of operations. The share purchase right liability is revalued at settlement and the resultant fair value is then reclassified to redeemable convertible preferred stock at that time. The estimated fair value of the share purchase right liability is determined using valuation models that consider the probability of achieving the requisite milestones, our cost of capital, the estimated time period the preferred stock right would be outstanding, consideration received for the convertible preferred stock, the number of shares to be issued to satisfy the preferred stock purchase right and at what price, and probability of the consummation of an initial public offering, as applicable.

We account for our redeemable convertible preferred stock warrant liabilities as freestanding instruments for shares that are puttable or redeemable. These warrants are classified as liabilities on our balance sheet and are recorded at their estimated fair values. At the end of each reporting period, changes in estimated fair value during the period are recorded as a component of other income (expense), net in the accompanying statement of operations. We will continue to re-measure the fair value of the warrant liabilities until: (i) exercise; (ii) expiration of the related warrant; or (iii) conversion of the preferred stock underlying the security into common stock, which will occur in connection with the completion of this offering. We estimate the fair values of our warrant liabilities using an option pricing model based on inputs as of the valuation measurement dates, including the fair value of our redeemable convertible preferred stock, the estimated volatility of the price of our redeemable convertible preferred stock, the expected term of the warrants and the risk-free interest rates.

There are significant judgments and estimates inherent in the determination of the fair values of our preferred stock purchase right liabilities and redeemable convertible preferred stock warrant liabilities. If we had made different assumptions, the carrying value of these liabilities, net loss and net loss per share attributable to common stockholders could have been significantly different.

Acquisition-Related Liabilities

In connection with the acquisition of the medical diagnostics division of Cypress in 2010, we initially agreed to pay an additional amount not to exceed $9.0 million in the event specified revenue, contractual and product launch milestones are achieved. This contingent liability required the use of inputs which were not observable in the market to assess its fair value at the end of each reporting period. For this liability, fair value was determined based on probabilities assigned to the milestones being achieved, revenue projections, and interest rates. Changes in fair value were recorded in the statement of operations and comprehensive loss. In February 2017, we amended two of the remaining agreements for which a contingent payment amount had been originally agreed to. One contingent payment amount remains outstanding.

Income Taxes

We operate in, and are subject to tax authorities in, various tax jurisdictions in the United States. To date, we have not been audited by the Internal Revenue Service or any state income tax authority, however all tax years remain open for examination by federal tax authorities.

At December 31, 2018, our deferred tax assets are primarily comprised of federal and state tax net operating loss carryforwards. We have performed an analysis to determine whether an “ownership change” occurred from inception to December 31, 2013. Based on this analysis, we determined that we did experience a historical ownership change of greater than 50% in 2008. Therefore, our ability to utilize our net operating losses incurred prior to this date is limited.

We are required to reduce our deferred tax assets by a valuation allowance if it is more likely than not that some or all of our deferred tax assets will not be realized. We must use judgment in assessing the potential need for a valuation allowance, which requires an evaluation of both negative and positive evidence. The weight given to the potential effect of negative and positive evidence should be commensurate with the extent to which it can be objectively verified. In determining the need for and amount of our valuation allowance, if any, we assess the likelihood that we will be able to recover our deferred tax assets using historical levels of income, estimates of future income and tax planning strategies. As a result of historical cumulative losses and uncertainties surrounding our ability to generate future taxable income and, based on all available evidence, we believe it is more likely than not that our recorded net deferred tax assets will not be realized. Accordingly, we have recorded a valuation allowance against all of our net deferred tax assets at December 31, 2018. We will continue to maintain a full valuation allowance on our deferred tax assets until there is sufficient evidence to support the reversal of all or some portion of this allowance.

The above listing is not intended to be a comprehensive list of all of our accounting policies. In many cases, the accounting treatment of a particular transaction is specifically dictated by GAAP. There are also areas in which our management’s judgment in selecting any available alternative would not produce a materially different result. Please see our audited financial statements and notes thereto included elsewhere in this prospectus, which contain accounting policies and other disclosures required by GAAP.

Recently Adopted Accounting Standards

In May 2014, the FASB issued Accounting Standards Update, or ASU, 2014-09, *Revenue from Contracts with Customers*, which, along with subsequent amendments and addenda to this standard, provides a five-step analysis of transactions to determine when and how revenue is recognized. The core principle is that a company should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. We elected to early adopt this guidance on January 1, 2018 using a cumulative-effect adjustment to the opening balance of accumulated deficit and accounts receivable of $3.1 million. The cumulative-effect adjustment was the result of an acceleration of revenue recognition since we are required to estimate consideration to which we expect to be entitled rather than record revenue on a cash basis.

In November 2016, the FASB issued ASU 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash.* The amendments in this update require that a statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. As a result, companies will no longer present transfers between cash and cash equivalents and restricted cash and restricted cash equivalents in the statement of cash flows. We adopted this guidance for our fiscal year beginning January 1, 2018 and adjusted the presentation of our Statement of Cash Flows to include our restricted cash balance with

our non-restricted cash balances. Our restricted cash balance consists of a federally insured certificate of deposit held with an affiliate of a large publicly traded financial institution that secures our corporate credit card program. Due to the duration of this certificate of deposit, the amounts restricted as to use have been classified outside of cash and cash equivalents. The adoption of this guidance did not have a material impact on our financial statements.

In January 2017, the FASB issued ASU 2017-04, *Simplifying the Test for Goodwill Impairment*. This guidance is intended to simplify the accounting for goodwill impairment for all entities by requiring impairment charges to be based on the first step in today's two-step impairment test under the guidance contained in ASC 350. Specifically, this guidance eliminates the requirement to calculate the implied fair value of goodwill to measure a goodwill impairment charge. Instead, entities will record an impairment charge based on the excess of a reporting unit's carrying amount over its fair value. We adopted this guidance on January 1, 2018 and the adoption did not have a material impact on our financial statements since we completed a qualitative assessment as of December 31, 2018.

Recent Accounting Pronouncements Not Yet Adopted

In February 2016, the FASB issued 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 we will not restate comparative periods presented in our financial statements. The effective date of this guidance for public companies is for reporting periods beginning after December 15, 2018, and periods beginning after December 15, 2019 for private companies. ASU 2016-02 mandates a modified retrospective transition method. We intend to adopt this new standard using a cumulative effect adjustment to accumulated deficit and will elect the package of practical expedients, which among other things will allow us to carry forward our historical lease classification. We are currently evaluating the impact of ASU 2016-02 on our financial statements.

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. This update is effective for annual periods beginning after December 15, 2019, and interim periods within those periods, and early adoption is permitted. We are currently evaluating the impact of ASU 2018-13 on our financial statements.

Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements, as defined under the rules and regulations of the SEC.

Quantitative and Qualitative Disclosures about Market Risk

We are exposed to market risks in the ordinary course of our business. These risks primarily relate to interest rates. As of June 30, 2019, we had cash and cash equivalents of $16.2 million, which consist of bank deposits and money market funds. Such interest-bearing instruments carry a degree of

risk; however, we have not been exposed to, nor do we anticipate being exposed to, material risks due to changes in interest rates. A hypothetical 10% change in interest rates during any of the periods presented would not have had a material impact on our audited financial statements. Our long-term debt bears interest at a fixed rate.

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.

BUSINESS

Company Overview

Exagen 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. We have developed and are commercializing a portfolio of innovative testing products under our AVISE® brand, several of which are based on our proprietary Cell-Bound Complement Activation Products, or CB-CAPs, technology. CB-CAPs assess the activation of the complement system, a biological pathway that is widely implicated across many autoimmune and autoimmune-related diseases, including systemic lupus erythematosus, or SLE. 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 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.

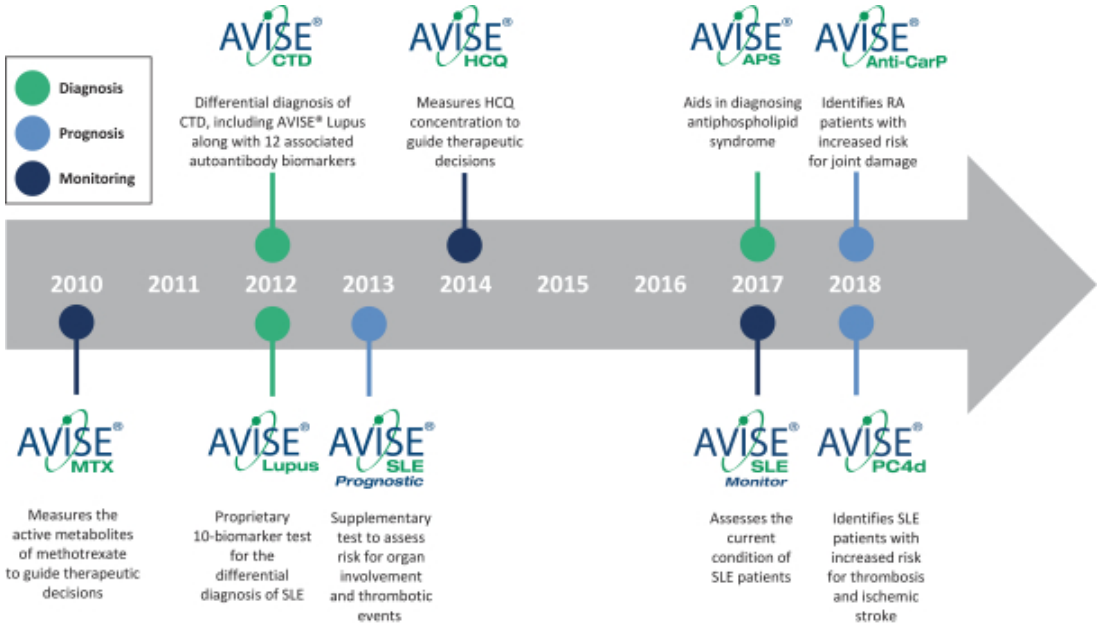
We currently market nine testing products under our AVISE® brand, which we are leveraging to establish partnerships with leading pharmaceutical companies. In December 2018, we entered into a co-promotion agreement with Janssen Biotech, Inc., or the Janssen agreement, to exclusively promote SIMPONI® (golimumab), a subcutaneous, once-per-month, anti-tumor necrosis factor, or anti-TNF, biologic prescribed in combination with methotrexate, in the United States for the treatment of adult patients with moderate to severe RA and for other indicated rheumatic diseases. Combined U.S. sales of SIMPONI® and SIMPONI ARIA®, an intravenous formulation, were approximately $1.0 billion in 2018, of which we estimate approximately 50% was from sales of SIMPONI®. We began direct promotion of SIMPONI® in January 2019 and expanded our salesforce from 31 representatives as of December 31, 2018 to 55 representatives in August 2019 to support these promotion efforts. 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. We therefore believe our strategy of integrating the promotion of testing products and therapeutics uniquely positions us to expand SIMPONI®'s U.S. market share. We expect our SIMPONI® promotion efforts to contribute incremental revenue in 2019 with our quarterly tiered promotion fee based on the incremental increase in total prescribed units above a predetermined average baseline of approximately 29,000 prescribed units per quarter.

We believe our strategy of integrating the promotion of testing products and therapeutics differentiates us from other diagnostic and pharmaceutical companies, and provides our specialized salesforce greater access to rheumatologists. Our integrated testing and therapeutics strategy results in a unique opportunity to promote targeted therapies in patient focused sales calls with rheumatologists, including those with whom we have a longstanding relationship and who have a history using our portfolio of testing products.

Our lead testing product, AVISE® CTD, enables differential diagnosis for patients presenting with symptoms indicative of a wide variety of connective tissue diseases, or CTDs, and other related diseases with overlapping symptoms. The comprehensive nature of AVISE® CTD allows for the testing of a number of relevant biomarkers in one convenient blood draw, as opposed to testing serially for individual biomarkers, which adds time and cost to the diagnostic process. We believe AVISE® CTD may provide clinical utility for over 23 million patients in the United States suffering from these diseases, which include SLE, RA, Sjögren's syndrome, antiphospholipid syndrome, or APS, other

autoimmune-related diseases such as autoimmune thyroid, and other disorders that mimic these diseases, such as fibromyalgia. 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.

We have demonstrated a strong track record of developing innovative testing products that meet the needs of diagnosing, prognosing and monitoring CTDs, as illustrated below:



AVISE® CTD leverages our proprietary CB-CAPs technology to enable the differential diagnosis SLE. AVISE® CTD provides rheumatologists and their patients with sensitive and specific results that allow for potentially faster and more accurate differential diagnosis of SLE as compared to other currently-marketed testing methods. Beyond SLE, AVISE® CTD allows rheumatologists to accurately diagnose other overlapping autoimmune and autoimmune-related diseases, including RA, with the same blood sample.

Our AVISE® SLE Monitor testing product also leverages our proprietary CB-CAPs technology by measuring two CB-CAPs biomarkers that offer insight into a patient's disease activity. This test is designed to enable rheumatologists to effectively assess and optimize therapeutic intervention in patients diagnosed with SLE. Depending on disease severity, AVISE® SLE Monitor may be utilized by patients multiple times a year throughout their lives.

Our RA-focused testing products include AVISE® MTX and AVISE® Anti-CarP. AVISE® MTX is a drug monitoring test designed to aid in the optimization of methotrexate therapy, the standard of care and first-line therapy for patients with RA. AVISE® MTX is based on our proprietary methotrexate polyglutamate, or MTXPG, technology that measures blood levels of MTXPGs, the active metabolite of methotrexate linked to disease control in RA patients. Measuring MTXPGs allows rheumatologists to identify patients presenting with inadequate exposure to methotrexate enabling them to optimize dosing and achieve therapeutic levels commensurate with adequate disease control. AVISE® Anti-CarP, which measures anti-carbamylated protein antibody, or anti-CarP, was developed by the Leiden

University Medical Center, and we recently introduced it as a biomarker-driven RA prognostic test through a distribution agreement with Inova Diagnostics, Inc. with the goal of identifying patients prone to more severe disease.

We market our AVISE® testing products using our specialized salesforce. Since the launch of AVISE® CTD in 2012 through December 31, 2018, we have delivered over 326,000 of these tests, representing a compound annual growth rate of 87%, with limited incremental investment in our commercial infrastructure. Approximately 83,000 AVISE® CTD tests were delivered in 2018, representing 18% growth over 2017, and the number of ordering physicians in the fourth quarter of 2018 reached 1,298, representing 18% growth over the same period in 2017. In the first half of 2019, 50,792 AVISE® CTD tests were delivered, representing approximately 30% growth over the same period in 2018, and the number of ordering physicians in the first half of 2019 reached 1,711. In the first half of 2019, we achieved a record number of 766 adopting physicians, which we classify as those who had previously prescribed at least 11 tests in a quarter, compared to 635 in the same period in 2018. Nearly 100% of adopting physicians continue to order tests in subsequent quarters. From launch of our direct promotion of SIMPONI® in January 2019 to the end of the second quarter of 2019, weekly ordering from healthcare providers increased by approximately 10% and total weekly prescriptions increased by approximately 17%.

In addition, we continue to populate a growing proprietary database of over 300,000 de-identified patient test results. We believe the insight emerging from these results has the potential to unlock value for pharmaceutical and biotechnology companies in the commercialization of therapeutics. We believe we also have the ability to further leverage our database to optimize patient selection in clinical trials for companies developing therapeutics for autoimmune and autoimmune-related diseases. We plan to collaborate with our existing and future pharmaceutical and biotechnology partners to help maximize the full value of our in-house database.

We believe our strategy of integrating the promotion of testing products and therapeutics differentiates us from other diagnostic and pharmaceutical companies, and provides our specialized salesforce greater access to rheumatologists. 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 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 who have a history using our portfolio of testing products.

We recently entered into the Janssen agreement for the promotion of SIMPONI® in order to advance our integrated testing and therapeutics strategy. To support the co-promotion of SIMPONI®, we expanded our salesforce from 31 representatives as of December 31, 2018 to 55 representatives in August 2019. This will enable us to conduct approximately 60,500 calls annually to rheumatologists, which we believe will enable us to achieve the optimal reach and frequency with rheumatologists. We also have agreements with other leading pharmaceutical companies, including GlaxoSmithKline LLC, or GSK, and Horizon Pharma USA, Inc., or Horizon Therapeutics, and Corrona, LLC, that leverage our testing products and the data generated from such tests. We provide GSK, a leader in lupus therapeutics, our test result data to provide market insight into and help increase awareness of the benefits of an early and accurate diagnosis of SLE. Our agreement with Horizon Therapeutics entails utilizing our AVISE® MTX test to report on levels of MTXPG in patients undergoing methotrexate therapy in combination with its anti-gout product KRYSTEXXA® in an ongoing Phase 4 clinical trial. We also provide Corrona, the operator of the largest real world observational database in RA containing data from over 40,000 patients, with testing services and support. We plan to pursue additional partnerships with a focus on integrating therapeutics that are synergistic with our evolving portfolio of testing products.

We are led by an experienced management team with unique capabilities to execute on our strategy of integrating the promotion of testing products and therapeutics. Our senior management has an average of over 20 years of experience in the healthcare industry and many were previously involved with successfully building Prometheus Laboratories Inc., or Prometheus, which was focused on integrating diagnostics and therapeutics, prior to its acquisition by Nestlé Health Science S.A. in 2011.

Our Strategy

We develop and commercialize next-generation testing products and promote synergistic therapeutics to ultimately improve the continuum of care for patients suffering from debilitating and chronic autoimmune diseases. The key tenets of our business strategy include:

- ***Drive additional market penetration for our testing products.*** Our portfolio of testing products enables the differential diagnosis, prognosis and monitoring of complex autoimmune and autoimmune-related diseases. We have demonstrated a strong track record of commercial growth from our testing products, leveraging our specialized salesforce and expansive network of relationships with rheumatologists across the United States. We believe we are uniquely positioned to continue expanding our commercial presence within the autoimmune disease market and plan to continue to invest in our salesforce in order to achieve the optimal reach and frequency with rheumatologists. This will support our strategy of integrating the promotion of testing products and therapeutics. In addition, we will continue to expand our efforts in the targeted promotion and education of rheumatologists and payers as to the clinical and cost benefits of our testing products. We believe these efforts will position us to capture additional market share for our portfolio of testing products.
- ***Integrate the promotion of testing products and therapeutics for autoimmune and autoimmune-related diseases.*** Our integrated testing and therapeutics strategy leverages our sales and marketing efforts, targeting rheumatologists for the commercialization of our testing products to promote therapeutics. This establishes a compelling synergy compared to traditional pharmaceutical sales resulting in greater access to rheumatologists and positions us to potentially create value for pharmaceutical partners. In January 2019, we began our exclusive promotion of SIMPONI® in the United States, leveraging our integrated testing and therapeutics strategy, for the treatment of adult patients with moderate to severe RA and for other indicated rheumatic diseases.
- ***Continue our track record of developing innovative testing products.*** Since inception, we have demonstrated a strong track record of developing testing products that address the challenges in the differential diagnosis, prognosis and monitoring of patients with autoimmune and autoimmune-related diseases. We are leveraging our proprietary CB-CAPs and MTXPG technologies to develop additional testing products designed to have superior clinical utility for CTDs. We believe our commitment to innovating our portfolio of testing products will further strengthen our relationships with rheumatologists and our value proposition to our existing and future pharmaceutical and biotechnology partners.
- ***Establish additional therapeutic partnerships.*** We believe our agreements with Janssen Biotech, Inc., or Janssen, and other leading pharmaceutical companies validate our unique value proposition to pharmaceutical companies seeking a competitive edge for commercializing therapeutics for autoimmune and autoimmune-related diseases. We intend to leverage our integrated testing and therapeutics strategy to establish additional partnerships with a focus on the commercialization of therapeutics that are synergistic with our testing products.
- ***Achieve meaningful margin expansion.*** We believe growth from the promotion of therapeutics will meaningfully improve our margin profile and further support our goal of achieving profitability. We also expect an increase to our gross margins in January 2020

onwards upon 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.

Autoimmune and Connective Tissue Diseases

Autoimmune diseases encompass a broad range of serious, chronic and debilitating conditions in which a person's immune system creates antibodies that mistakenly react against normal healthy tissues causing inflammation and irreversible tissue damage. These antibodies are called autoantibodies and their detection through blood tests can help diagnose, prognose and monitor the course of autoimmune diseases. However, knowing when and which autoantibody to test for is challenging due to the vagueness of symptoms, the unexplained flaring and remission of symptoms, and the many conditions which can mimic autoimmune disease. Early and accurate diagnosis of the conditions causing these overlapping symptoms is critical as an incorrect diagnosis can lead to toxicity from inappropriate medications, irreversible tissue damage and other comorbidities associated with uncontrolled disease. There is no known cause or cure for these chronic conditions and current treatment interventions are targeted at managing symptoms and limiting disease progression.

CTDs are a sub-category of autoimmune diseases involving inflammation of the joints, tissues and internal organs. Persons with CTDs often present to their rheumatologist with complaints of joint pain, fatigue, unexplained fever, inflammation, rash, stiffness and muscle aches. These symptoms overlap among numerous CTDs, including SLE, one of the most severe CTDs and historically difficult to rule out, as well as other autoimmune-related diseases and other disorders that mimic these diseases, such as fibromyalgia. Based on a study we commissioned in 2014, we estimate that there are approximately 23 million undiagnosed patients in the United States who are symptomatic of these conditions and who may benefit from the differential diagnosis of CTDs. Of these patients, we estimate approximately seven million are potentially referable to rheumatologists and would be candidates for an AVISE® CTD test, representing a total addressable market of approximately $3.7 billion, based on the current Medicare allowable reimbursement rate. We estimate the total addressable market for our AVISE® testing products to be approximately $5 billion, based on estimated patient populations, the current Medicare allowable reimbursement rate and testing frequencies.

Systemic Lupus Erythematosus

SLE, the most common and severe form of lupus, is a chronic, inflammatory disorder that can damage any part of the body, including the skin, joints and internal organs. The blood of a person afflicted with SLE contains autoantibodies, which are the cause of the inflammation and organ damage and are one indicator of immune system abnormalities. SLE is characterized by a rise in symptoms and/or abnormal laboratory test results. SLE varies in severity, from mild cases to those in which significant and potentially fatal damage occurs to vital organs such as the brain, heart, kidneys and lungs. Detection of these autoantibodies can assist rheumatologists in the diagnosis of SLE. Diagnosis of SLE allows rheumatologists to initiate the most appropriate therapy to minimize irreversible organ damage and reduce morbidity and mortality. Current treatment for SLE involves the use of antimalarials, corticosteroids, immunosuppressants and biologic agents to prevent or suppress active disease or flares.

Standard laboratory tests for diagnosing SLE include measuring immunological biomarkers, such as antinuclear antibodies, or ANA, anti-double stranded DNA, or anti-dsDNA, and other autoantibody tests. ANA are a group of autoantibodies produced by a person's immune system when it fails to

adequately distinguish between self and non-self. The ANA test detects these autoantibodies in the blood and is a useful screening tool for SLE and other autoimmune and autoimmune-related diseases. The vast majority of SLE patients test positive for ANA. However, the high sensitivity of ANA for SLE is counterbalanced by somewhat poor specificity. Sensitivity measures the proportion of patients who are correctly identified as having a particular condition, while specificity measures the proportion of patients who are correctly identified as not having a particular condition. Therefore, the majority of individuals who test positive for ANA do not have SLE. Only approximately 11-13% of individuals with a positive ANA test have SLE. This lack of specificity leads to many inappropriate non-autoimmune referrals to the rheumatologist from primary care physicians. For example, it has been reported that 30% of fibromyalgia patients may test positive for ANA, potentially generating as many as four million inappropriate rheumatology referrals. In addition, a study published in 2012 reported the estimated prevalence of a positive ANA test in the normal, healthy, U.S. population to be 13.8%, or 32 million people, indicating a significant need for a highly-specific test for this disease.

Anti-dsDNA are autoantibodies that target a person's double stranded DNA. The anti-dsDNA antibody test is a very specific test for SLE as anti-dsDNA antibodies are rarely found in autoimmune diseases other than SLE. A strongly positive anti-dsDNA antibody test makes it very likely that a person has SLE, although if the test is negative it does not necessarily rule out SLE. Approximately 30-70% of people with SLE have a negative anti-dsDNA antibody test, reaffirming the need for an effective testing product which adds clarity to the rheumatologist's clinical assessment.

Activation of the complement system is an integral part of the disease process of SLE. Thus, rheumatologists measure components of the complement system, including serum levels of C3 and C4, to help diagnose SLE and monitor SLE disease activity. In 2012, the Systemic Lupus Collaborating Clinics added low C3 and low C4 as immunologic criteria for classifying SLE. In active SLE, C3 and C4 complement proteins are consumed and broken down to fragments, known as complement activation products. Therefore, low levels of C3 and C4 suggest a diagnosis of SLE and that the disease is active. However, variability in the levels of C3 and C4 can occur due to factors unrelated to SLE disease presence or disease activity, making them less reliable as biomarkers for SLE. For example, C3 and C4 are acute phase reactants and produced during inflammation. As a result, many SLE patients have normal complement levels even when the disease is active. Although relatively specific for SLE, low complement levels can also be seen in certain chronic infections, including non-lupus related kidney inflammation, severe liver disease and other autoimmune diseases. CB-CAPs are formed when the fragments of complement activation products from C4 bind permanently to circulating cells such as red blood cells, b-cells and platelets. This binding lasts for the life of the cell and represents a more stable and reliable indicator of complement activation than measuring C3 and C4 alone.

In March 2011, the first new biologic drug targeting treatment of SLE in over 50 years, GSK's Benlysta®, was approved by the U.S. Food and Drug Administration, or the FDA. It is the only approved biologic for the treatment of SLE. Since its approval, there have been a number of drug development programs that have failed in SLE, which may suggest that guidelines for classifying SLE patients and the endpoints used to determine clinical effectiveness have not adequately addressed the complexity of the disease process and its heterogeneous population. We believe biopharmaceutical companies would benefit from the differential diagnosis enabled by our AVISE® testing products in order to better identify sub-populations of SLE patients for targeted therapies.

Rheumatoid Arthritis

RA is a chronic, systemic autoimmune disease in which the immune system attacks the joints and can also affect other organ systems. The annual incidence and prevalence of RA in the United States is estimated to be 75,000 and 1.75 million, respectively. Patients suffering from RA develop joint damage that is associated with painful inflammation which often progresses to irreversible damage of

cartilage and bone leading to significant disability and a reduction in quality of life and the ability to work. Early diagnosis and effective treatment of RA is critically important to prevent erosive bone or joint damage and disability. Rheumatologists are compelled to reach a definitive diagnosis quickly and administer effective treatment.

Diagnosis of RA involves performing a complete medical history with physical and/or radiographic examination of the number and distribution of swollen, tender and painful joints that have persisted for more than six weeks. Laboratory testing for rheumatoid factor, or RF, anti-cyclic citrullinated peptide, or CCP, antibodies, and testing for general, nonspecific inflammation with erythrocyte sedimentation rate, or the ESR, and C-reactive protein tests are used to assist in the diagnosis.

The standard of care for the treatment for RA involves the use of Disease Modifying Anti-Rheumatic Drugs, or DMARDs, which have shown, in clinical studies, the ability to slow or stop disease progression. Methotrexate remains the most commonly used DMARD, due to its low cost, effectiveness, and the extensive clinical experience with its use. It is estimated that approximately 74% of RA patients in the United States, or 1.3 million patients, are treated with methotrexate, either as a monotherapy or in combination with another DMARD.

Biologics DMARDs are proteins that have been genetically modified to target cellular components of the immune system that attack healthy tissues causing the symptoms of RA. They are a targeted form of therapy, which makes them different from traditional RA treatments, such as methotrexate. The first FDA approved biologics for RA were the anti-TNFs. ENBREL® was approved for RA in 1998 and the latest, SIMPONI®, was approved in 2009. The anti-TNFs dominate the therapy for RA and generally are the first biologics chosen to augment methotrexate when patients are not achieving a satisfactory response.

Our Solution

We currently market nine testing products under our AVISE® brand that allow for the differential diagnosis, prognosis and monitoring of complex autoimmune and autoimmune-related diseases, including SLE and RA. Our product portfolio integrates our proprietary CB-CAPs technology, which is a stable and reliable method for differentially diagnosing SLE. We focus on leveraging our portfolio of testing products to promote therapeutics through our sales channel targeting the approximately 5,000 rheumatologists across the United States. In December 2018, we entered into the Janssen agreement 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. In January 2019, we began direct promotion of SIMPONI® with our specialized salesforce.

Our Proprietary Technologies

We have two core proprietary technologies, CB-CAPs and MTXPGs, which form the backbone of several of our testing products.

CB-CAPs

Our proprietary CB-CAPs technology determines the blood levels of complement activation proteins permanently deposited on hematopoeitic cells. The determination of complement proteins in a patient's blood is a mainstay in clinical laboratory science, and state-of-the-art methods traditionally rely on measurement of serum or plasma levels of soluble complements. C3 and C4 are the most commonly determined complement proteins in the blood and the precursors to activation of complement proteins into biologically active breakdown products. However, there are limitations with measuring C3 and C4 blood levels as indicators of complement activation. For example, increased synthesis of C3 and C4 by the liver can offset increased C3 and C4 breakdown during activation of the complement cascade, resulting in no change in serum levels. While the limitations and drawbacks of

measuring standard components of the complement system, such as C3 and C4, are well recognized by the medical community, these laboratory biomarkers are part of international guidelines for the classification of SLE.

We believe the availability of novel complement biomarkers supporting or replacing standard C3 and C4 measures will be of great value for rheumatologists and ultimately their patients. Our CB-CAPs technology directly measures protein products of complement activation, such as C4d, the product of C4 activation. These complement activation products become stably attached to surfaces of circulating blood cells to become CB-CAPs. As such, the determination of CB-CAPs in the blood provides benefits when compared to the traditional complement measurement. These include the stable, accurate and unequivocal information of complement activation that enable consistent measurement and an improved ability to assess and monitor changes in biological activity related to activation of the complement system. In a head-to-head study published in 2014, CB-CAPs (EC4d or BC4d) showed 22% higher sensitivity (66%) than C3 and C4 (44%) in diagnosing SLE, with specificity fixed at 91%.

MTXPGs

Methotrexate is the standard of care and first-line treatment of many autoimmune diseases including RA and psoriatic arthritis. Our proprietary technology measures blood levels of MTXPGs, which are the active metabolite of methotrexate. The technology uses a dried capillary blood-based collection method coupled with liquid chromatographic tandem mass spectrometry and quantifies nanomolar concentrations of MTXPG using at least two orders of magnitude lower blood volume than venipuncture. MTXPG blood levels are actionable clinical utility checkpoints and can help clinicians identify causes for a lack of response to methotrexate, such as poor activation to active metabolites, underexposure secondary to poor absorption or poor compliance, all of which are limiting factors to the achievement of a robust clinical response with this first-line treatment. We believe we can leverage this technology to optimize anti-TNF treatment by reducing the formation of anti-drug antibodies that are known to impact the clinical efficacy of these drugs.

Testing Products

Since inception, we have been committed to developing and commercializing innovative testing products that address the challenges rheumatologists face in differentially diagnosing, prognosing and monitoring complex autoimmune and autoimmune-related diseases. We estimate the total addressable market for our AVISE® testing products to be approximately $5 billion, based on estimated patient populations, the current Medicare allowable reimbursement rate and testing frequencies.

Diagnosis

AVISE® CTD

Our lead testing product, AVISE® CTD, is a comprehensive test that aids in the differential diagnosis of SLE versus other common CTDs. The SLE portion of the test employs our proprietary CB-CAPs technology and specifically measures activation of the complement system by quantifying the level of two CB-CAPs biomarkers in the patient's blood, B-cell C4d, or BC4d, and erythrocyte bound C4d, or EC4d, which are higher in patients with SLE compared to patients with other CTDs. In addition, the comprehensive nature of AVISE® CTD enables testing for a series of 22 biomarkers in one convenient blood draw to further aid in the differential diagnosis of a wide variety of CTDs and other diseases which can be challenging to diagnose as a result of overlapping symptoms. These diseases include SLE, RA, Sjögren's syndrome, APS, other autoimmune-related diseases such as autoimmune thyroid, and other disorders that mimic these diseases, such as fibromyalgia. Our test's ability to allow rheumatologists to effectively rule out SLE and differentially diagnose other CTDs such as RA adds clarity to the rheumatologist's assessment, thereby making the evaluation process more efficient and accurate. The clinical performance of our proprietary biomarkers and the convenience of a single blood draw make AVISE® CTD an attractive choice among rheumatologists.

AVISE® Lupus

The AVISE® Lupus test employs our proprietary CB-CAPs technology and is the cornerstone of the SLE assessment within our more comprehensive AVISE® CTD testing product. AVISE® Lupus measures activation of the complement system by quantifying the level of BC4d and EC4d in the patient's blood. Rheumatologists choose to order the comprehensive AVISE® CTD test or the more focused AVISE® Lupus test based on medical necessity, which is determined by each patient's symptoms and medical history.

AVISE® APS

AVISE® APS consists of a specialized panel of eight autoantibody tests. This test aids in both the diagnosis and management of APS, a hyper-coagulation state leading to thrombosis, pregnancy complications, and even death. Rheumatologists would typically request the AVISE® APS test in patients who initially tested positive for one or more APS biomarkers contained in AVISE® CTD, or in the management of patients experiencing a high-risk pregnancy.

Prognosis

AVISE® SLE Prognostic

AVISE® SLE Prognostic is a ten-biomarker panel of autoantibodies that have established predictive value for assessing the potential for complications affecting the kidney, brain and cardiovascular system, including lupus nephritis and lupus psychosis. Rheumatologists rely on insights from the AVISE® SLE Prognostic test to help tailor their treatment approach.

AVISE® Anti-CarP

We were the first commercial laboratory to make testing for anti-CarP available in the United States with the introduction of AVISE® Anti-CarP in 2018. This test uniquely addresses two major challenges facing rheumatologists today – (1) patients presenting with RA symptoms but lacking the common confirmatory blood tests for anti-RF or anti-CCP, known as sero-negative patients, and (2) the lack of a serologic indicator, which indicates a poor prognosis and helps guide treatment decisions. Anti-CarP can be positive in up to 26% of RA patients who are negative for anti-CCP. Furthermore, RA patients positive for Anti-CarP have an increased risk for more severe RA disease, including permanent joint damage.

AVISE® PC4d

AVISE® PC4d is one of our newest offerings, which reflects over 10 years of research efforts and employs our proprietary CB-CAPs technology. This proprietary CB-CAP biomarker measures platelet- bound C4d, or PC4d, and has been shown in clinical studies to have significant association with thrombosis and ischemic stroke in SLE. These thrombotic events can be among the most damaging and deadly forms of lupus flares and often strike without warning. Because of its strong association with thrombosis, we believe AVISE® PC4d promises to be a valuable tool for SLE disease monitoring.

Monitoring

AVISE® SLE Monitor

AVISE® SLE Monitor is a six-biomarker blood test that employs our proprietary CB-CAPs technology and is intended to assess the condition of a patient that has been diagnosed with SLE. It offers a unique combination of biomarkers that measure for EC4d, which has shown greater accuracy in tracking disease activity than C3 and C4, and PC4d, which is associated with thrombosis risk in SLE. AVISE® SLE Monitor offers additional insight into a patient's disease activity as well as possible adverse events. Rheumatologists have limited methods for evaluating the extent of disease activity

taking place inside the body of an SLE patient. They rely on imperfect biomarkers, overt symptoms or flares, and patient reported history, all of which leave the rheumatologists looking for greater insights. In surveys conducted with SLE patients, it has been reported that patients tend to under report their symptoms and over 70% of physicians are unaware of this bias. AVISE® SLE Monitor demonstrates correlation to SLE disease activity and is therefore designed to enable rheumatologists to effectively assess and optimize therapeutic intervention in patients diagnosed with SLE. Depending on disease severity, our AVISE® SLE Monitor testing product may be utilized by patients multiple times a year and throughout their lives. We believe AVISE® SLE Monitor will play an increasingly important role in the management of SLE patients and further solidify the role and relationship of AVISE® testing products for these patients.

AVISE® MTX

AVISE® MTX is a patented and validated blood test that precisely measures levels of MTXPG, the active form of methotrexate, in the patient's blood. There is large variability in the way patients absorb and metabolize methotrexate, leaving rheumatologists unsure of what steps to take when a patient has an inadequate response. Methotrexate is the most widely prescribed drug by rheumatologists in the treatment of RA. When faced with a patient who is not responding to methotrexate therapy, the options include increasing the dose, switching to a parenteral delivery method and/or advancing to a more costly biologic therapy. AVISE® MTX provides crucial information as to whether a patient has achieved MTXPG blood levels consistent with an appropriate response to methotrexate, also known as the therapeutic level, or if the MTXPG blood levels are too low to produce adequate effects. The rheumatologists can then make informed therapeutic decisions to optimize methotrexate therapy and give patients their best chance at achieving an optimal response.

AVISE® MTX is compatible with AVISE® Touch, our low-volume test sample collection method that allows for a micro-volume blood sample to be collected anywhere from a simple fingerstick. AVISE® Touch has a number of advantages, including empowering rheumatologists to collect and submit samples without full phlebotomy services, convenience for patients who have trouble with venipuncture and potential patient self-collection.

AVISE® HCQ

AVISE® HCQ is a blood test designed to help rheumatologists objectively monitor levels of hydroxychloroquine, or HCQ, in whole blood as they treat patients with SLE and other CTDs, including RA. HCQ is typically prescribed to patients to control SLE disease activity and prevent flares. However, there is large variability in the response to HCQ therapy, the drug can sometimes take weeks or months to have a therapeutic effect and compliance has been documented to be an issue in CTD patients. We believe measuring HCQ makes the patient accountable, and also helps to determine whether HCQ blood levels are adequate and consistent with clinical efficacy. The addition of new and costly biologic therapies approved for the treatment of SLE may drive interest by all healthcare stakeholders, especially payers, to adopt an approach that optimizes a generic drug before advancing to a costlier alternative. AVISE® HCQ is also compatible with AVISE® Touch.

Test Reports

We provide the results of our AVISE® testing products in a comprehensive and easy-to-understand test report typically sent to rheumatologists within five business days following receipt of the blood specimen. As shown below, the result of the AVISE® Lupus portion of the AVISE® CTD report displays a gradient illustrating the likelihood of the presence of lupus, which facilitates interpretation and discussion of the result with the patient versus only reporting a numerical value.

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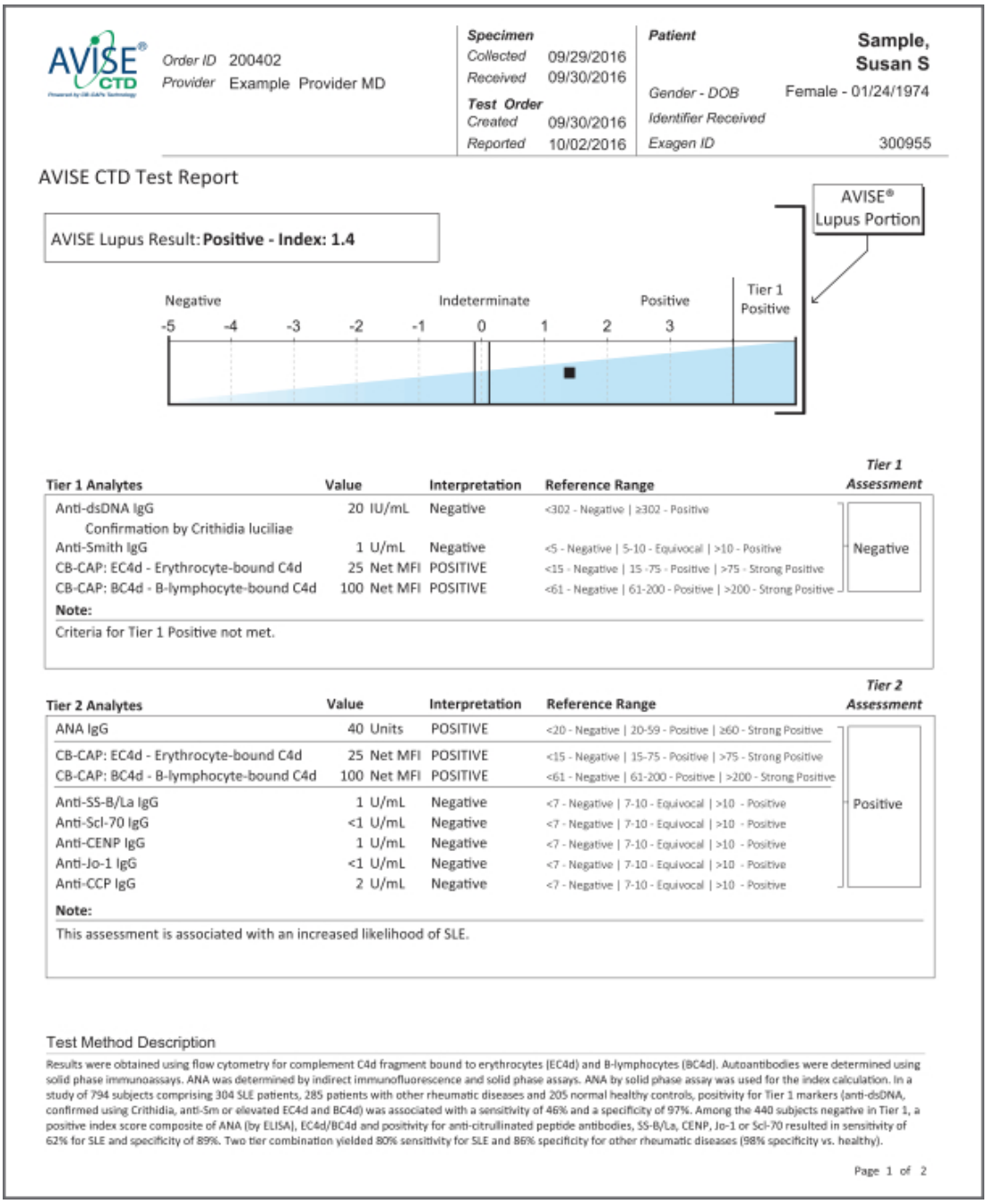
In addition, all biomarker results for AVISE® CTD are reported and organized by disease state, providing clarity and convenience for the rheumatologists. A sample of the full AVISE® CTD report is shown below:

AVISE® CTD Report



AVISE CTD

Order ID 200402
Provider Example Provider MD

Specimen
Collected 09/29/2016
Received 09/30/2016
Test Order
Created 09/30/2016
Reported 10/02/2016

Patient
Sample, Susan S
Gender - DOB Female - 01/24/1974
Identifier Received
Exagen ID 300955

AVISE CTD Test Report

AVISE Lupus Result: **Positive - Index: 1.4**

Tier 1 Analytes	Value	Interpretation	Reference Range	Tier 1 Assessment
Anti-dsDNA IgG	20 IU/mL	Negative	<302 - Negative | ≥302 - Positive	Negative
Confirmation by Crithidia luciliae				
Anti-Smith IgG	1 U/mL	Negative	<5 - Negative | 5-10 - Equivocal | >10 - Positive	
CB-CAP: EC4d - Erythrocyte-bound C4d	25 Net MFI	POSITIVE	<15 - Negative | 15-75 - Positive | >75 - Strong Positive	
CB-CAP: BC4d - B-lymphocyte-bound C4d	100 Net MFI	POSITIVE	<61 - Negative | 61-200 - Positive | >200 - Strong Positive	

Note:
Criteria for Tier 1 Positive not met.

Tier 2 Analytes	Value	Interpretation	Reference Range	Tier 2 Assessment
ANA IgG	40 Units	POSITIVE	<20 - Negative | 20-59 - Positive | ≥60 - Strong Positive	Positive
CB-CAP: EC4d - Erythrocyte-bound C4d	25 Net MFI	POSITIVE	<15 - Negative | 15-75 - Positive | >75 - Strong Positive	
CB-CAP: BC4d - B-lymphocyte-bound C4d	100 Net MFI	POSITIVE	<61 - Negative | 61-200 - Positive | >200 - Strong Positive	
Anti-SS-B/La IgG	1 U/mL	Negative	<7 - Negative | 7-10 - Equivocal | >10 - Positive	
Anti-Scl-70 IgG	<1 U/mL	Negative	<7 - Negative | 7-10 - Equivocal | >10 - Positive	
Anti-CENP IgG	1 U/mL	Negative	<7 - Negative | 7-10 - Equivocal | >10 - Positive	
Anti-Jo-1 IgG	<1 U/mL	Negative	<7 - Negative | 7-10 - Equivocal | >10 - Positive	
Anti-CCP IgG	2 U/mL	Negative	<7 - Negative | 7-10 - Equivocal | >10 - Positive	

Note:
This assessment is associated with an increased likelihood of SLE.

Test Method Description

Results were obtained using flow cytometry for complement C4d fragment bound to erythrocytes (EC4d) and B-lymphocytes (BC4d). Autoantibodies were determined using solid phase immunoassays. ANA was determined by indirect immunofluorescence and solid phase assays. ANA by solid phase assay was used for the index calculation. In a study of 794 subjects comprising 304 SLE patients, 285 patients with other rheumatic diseases and 205 normal healthy controls, positivity for Tier 1 markers (anti-dsDNA, confirmed using Crithidia, anti-Sm or elevated EC4d and BC4d) was associated with a sensitivity of 46% and a specificity of 97%. Among the 440 subjects negative in Tier 1, a positive index score composite of ANA (by ELISA), EC4d/BC4d and positivity for anti-citrullinated peptide antibodies, SS-B/La, CENP, Jo-1 or Scl-70 resulted in sensitivity of 62% for SLE and specificity of 89%. Two tier combination yielded 80% sensitivity for SLE and 86% specificity for other rheumatic diseases (98% specificity vs. healthy).

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AVISE® CTD

Order ID 200402
Provider Example Provider MD

Specimen
Collected 09/29/2016
Received 09/30/2016
Test Order
Created 09/30/2016
Reported 10/02/2016

Patient
Sample, Susan S
Gender - DOB Female - 01/24/1974
Identifier Received
Exagen ID 300955

SLE-Associated Analytes	Value		Interpretation	Reference Range
✦ ANA IgG	40	Units	POSITIVE	ELISA: <20 - Negative | 20-59 - Positive | ≥60 - Strong Positive
✦ HEp-2 cell fluorescence *Titer:*	1:320		POSITIVE	IFA: <1:80 - Negative | ≥1:80 - Positive
Nuclear Pattern: Speckled				
Cytoplasmic Pattern: Not Observed				
Anti-dsDNA IgG	20	IU/mL	Negative	ELISA: <302 - Negative | ≥302 - Positive
Anti-dsDNA - confirmatory	N/A			IFA - using Crithidia luciliae
Anti-Smith IgG	1	U/mL	Negative	ELISA: <5 - Negative | 5-10 - Equivocal | >10 - Positive
✦ CB-CAP: EC4d - Erythrocyte-bound C4d	25	Net MFI	POSITIVE	FACS: <15 - Negative | 15-75 - Positive | >75 - Strong Positive
✦ CB-CAP: BC4d - B-lymphocyte-bound C4d	100	Net MFI	POSITIVE	FACS: <61 - Negative | 61-200 - Positive | >200 - Strong Positive

Other Autoimmune Disease Auto-Antibodies	Value		Interpretation	Reference Range
✦ Anti-U1RNP IgG	20	U/mL	POSITIVE	ELISA: <7 - Negative | 7-10 - Equivocal | >10 - Positive
Anti-RNP70 IgG	3	U/mL	Negative	ELISA: <7 - Negative | 7-10 - Equivocal | >10 - Positive
Anti-SS-A/Ro IgG	2	U/mL	Negative	ELISA: <7 - Negative | 7-10 - Equivocal | >10 - Positive
Anti-SS-B/La IgG	1	U/mL	Negative	ELISA: <7 - Negative | 7-10 - Equivocal | >10 - Positive
Anti-Scl-70 IgG	<1	U/mL	Negative	ELISA: <7 - Negative | 7-10 - Equivocal | >10 - Positive
Anti-CENP IgG	1	U/mL	Negative	ELISA: <7 - Negative | 7-10 - Equivocal | >10 - Positive
Anti-Jo-1 IgG	<1	U/mL	Negative	ELISA: <7 - Negative | 7-10 - Equivocal | >10 - Positive

Rheumatoid Arthritis Auto-Antibodies	Value		Interpretation	Reference Range
Rheumatoid Factor IgM	2.0	U/mL	Negative	ELISA: <3.5 - Negative | 3.5-5 - Equivocal | >5 - Positive
Rheumatoid Factor IgA	1	U/mL	Negative	ELISA: <14 - Negative | 14-20 - Equivocal | >20 - Positive
Anti-CCP IgG	2	U/mL	Negative	ELISA: <7 - Negative | 7-10 - Equivocal | >10 - Positive
✦ Anti-Carbamylated Protein (CarP) IgG	22	U/mL	POSITIVE	ELISA: <20 - Negative | ≥20 - Positive

Antiphospholipid Syndrome Auto-Antibodies	Value		Interpretation	Reference Range
Anti-Cardiolipin IgM	2	CU	Negative	ELISA: <20 - Negative | ≥20 - Positive
Anti-Cardiolipin IgG	<6	CU	Negative	ELISA: <20 - Negative | ≥20 - Positive
Anti-β2 Glycoprotein 1 IgM	1	CU	Negative	ELISA: <21 - Negative | ≥21 - Positive
Anti-β2 Glycoprotein 1 IgG	<6	CU	Negative	ELISA: <21 - Negative | ≥21 - Positive

Thyroid Auto-Antibodies	Value		Interpretation	Reference Range
Anti-Thyroglobulin IgG	<12	IU/mL	Negative	ELISA: <40 - Negative | 40-60 - Equivocal | >60 - Positive
Anti-Thyroid Peroxidase IgG	<4	IU/mL	Negative	ELISA: <25 - Negative | 25-35 - Equivocal | >35 - Positive

Notes:

In the context of suspected RA, elevated anti-CarP antibodies are associated with more aggressive disease. The significance of a positive anti-CarP value in the absence of RA has not been established.

References

1. Thermo Fisher/Connective Tissue Markers references and results (Phadia product inserts).
2. Manzi S et al. Measurement of erythrocyte C4d and complement receptor 1 in systemic lupus erythematosus. Arthritis Rheum, 50(11):3596-604. 2004.
3. Kalunian et al. Measurement of cell-bound complement activation products enhances diagnostic performance in systemic lupus erythematosus. Arthritis Rheum. 2012 Dec;64(12):4040-7.
4. Putterman C et al. Cell-bound complement activation products in systemic lupus erythematosus: comparison with anti-double-stranded DNA and standard complement measurements. Lupus Science & Medicine 2014;1:e000056

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Therapeutics

In December 2018, we entered into the Janssen agreement 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. Combined U.S. sales of SIMPONI® and SIMPONI ARIA® were approximately $1.0 billion in 2018, of which we estimate approximately 50% was from sales of SIMPONI®.

We began direct promotion of SIMPONI® with our specialized salesforce in January 2019 and expanded our salesforce from 31 representatives as of December 31, 2018 to 55 representatives in August 2019. This will enable us to deliver approximately 60,500 calls annually to rheumatologists, which we believe will enable us to achieve the optimal reach and frequency, and support our strategy of integrating the promotion of testing products and therapeutics. We believe that educating providers regarding SIMPONI® has and will continue to facilitate greater acceptance of SIMPONI®. From the date we began our promotion of SIMPONI® through June 30, 2019, SIMPONI® unit prescriptions increased by approximately 17%.

Our AVISE® MTX test can identify methotrexate patients with inadequate methotrexate exposure who are potential candidates for SIMPONI® therapy. Our AVISE® Anti-CarP test can identify RA patients with more severe disease requiring more aggressive therapy, such as anti-TNF biologics like SIMPONI®. We believe our strategy of integrating the promotion of testing products and therapeutics, combined with our specialized salesforce, uniquely position us to expand SIMPONI®'s U.S. market share. We will receive a quarterly tiered promotion fee ranging from $750 to $1,250 per prescription based on incremental total prescribed units above a predetermined average baseline of approximately 29,000 prescribed units per quarter for an initial term of 18 months. We estimate the total U.S. addressable market for SIMPONI's ® approved indications, including RA, psoriatic arthritis and ankylosing spondylitis, to be approximately $28 billion. Based on this estimated market size, each incremental 1% market share we are able to capture for SIMPONI® above the predetermined baseline could result in incremental revenue to us of $84 million. For more information regarding the Janssen agreement, see "—Agreements with Pharmaceutical Companies."

In recent years, advancements in the understanding of the autoimmune and autoimmune-related disease process have led to a significant number of novel biologic drugs and drug development initiatives, especially in RA and SLE, and we intend to leverage our integrated testing and therapeutics strategy to establish additional partnerships with a focus on the commercialization of therapeutics that are synergistic with our testing products.

Our Pipeline and Growth Opportunities

We believe there is significant potential to capitalize on our proprietary CB-CAPs and MTXPG technologies by integrating those technologies with commercially validated biomarkers to develop testing products with superior clinical utility. The complement pathway is widely implicated in the pathogenesis of a variety of conditions, including autoimmune diseases and organ transplant rejection, and emerging data suggests its implication in cancer development. We believe that our proprietary CB-CAPs technology, owing to its stability and reliability, will allow us to produce meaningful and differentiated proprietary solutions for rheumatologists. For example, we are focused on leveraging our proprietary CB-CAPs technology by developing a thrombosis risk score with PC4d in prognosing cardiovascular events in SLE. We plan to initiate proof of concept studies to develop alternatives to biopsy in the monitoring of transplant rejection and the differential diagnosis of fibromyalgia in the primary care physician setting. In addition, we are developing a panel of antibody systems that we believe may have high prognostic value in patients with RA, Sjögren's, fibromyalgia and autoimmune thyroid, and we continue to evaluate the use of AVISE® Touch and microfluidics for our broader portfolio of testing products to increase convenience and cost-effectiveness.

Sales and Marketing

Our specialized salesforce is focused on targeting the approximately 5,000 rheumatologists across the United States. Our sales representatives generally have extensive experience in healthcare sales

with backgrounds in rheumatology, biologics, specialty therapeutics and/or testing. In addition, our sales representatives complete a comprehensive disease-level sales training program and are required to participate in regular, ongoing training activities and certifications.

Our sales model involves integrating the promotion of testing products and therapeutics in a unique approach that will enable our sales representatives to gain greater access and time with rheumatologists. The test information available to our sales representatives creates a different dynamic as compared to a traditional drug sales representative's product detail. It enables a timely, extended, patient-focused discussion that naturally transitions to a therapeutic discussion during the same sales call. Our goal is for our sales representative to be viewed as a collaborative consultant versus a traditional drug sales representative. We intend to capitalize on our established reputation, market presence and expertise to sell additional products and services into the autoimmune and autoimmune-related disease market. We believe that a collaborative relationship with rheumatologists helps build a lasting sales channel through which additional products and services can be introduced.

As of June 30, 2019, our overall sales team consisted of approximately 64 members, including 53 sales representatives, six regional sales directors, two vice presidents and three managed care professionals. In connection with the promotion of SIMPONI®, we expanded the number of sales representatives from 31 representatives as of December 31, 2018 to 55 representatives in August 2019, who will be managed by a team of six regional sales directors. Our increased salesforce will allow for expansion into markets not previously covered by us. In addition, this salesforce expansion is estimated to double the number of sales calls made per year, helping us to cultivate a strong collaborative relationship with rheumatologists through increased interactions. To further support our promotional efforts, we have a centralized, dedicated client services department with a high level of technical training that augments our specialized salesforce and marketing activities and enhances sales efficiency and customer satisfaction by providing personalized customer support.

Right Doctor, Right Message, Right Frequency

We believe our sales model of integrating the promotion of testing products and therapeutics will be complemented by our focused "high-touch" selling approach that emphasizes execution in three core areas: *targeting, messaging and call frequency*. We strategically *target* the highest-potential practices by utilizing various data sources (e.g., market analytics, demographic data, historical biologic and diagnostic product usage trends). Furthermore, we believe the increased access afforded by our testing products will allow for patient-focused *messaging,* including safety and efficacy data for SIMPONI® and the increased accuracy of our testing products over current standard of care diagnostic methodologies. Finally, we execute a high-*frequency* promotional strategy for our top targeted rheumatologists and their office personnel to build knowledge, understanding and retention of the benefits of SIMPONI® and our testing products.

We plan to leverage core channels for building awareness and adoption including our participation with multiple patient advocacy organizations, such as the Lupus Foundation of America, or LFA, and medical societies, such as the American College of Rheumatology, or ACR. We have also established strong relationships with multiple rheumatology care management organizations, or super groups, which can be key in influencing favorable reimbursement. Our AVISE® MTX testing product has been included in the clinical guidelines for two of these groups. We believe our experience with advancing a testing product from initial development through clinical adoption differentiates us and uniquely positions us to replicate success with our other testing products. Beyond working with these groups, we intend to continue to augment field selling activity with a balanced marketing mix including print and digital advertising, direct marketing, continuing medical education programs and working with key opinion leaders to support peer-to-peer educational events.

Reimbursement, Clinical Validation and Clinical Utility

Reimbursement

We seek reimbursement for our testing products from several sources, including commercial third-party payers, government payers and patients. Payment from commercial third-party payers differs depending on whether we have entered into a contract with the payer as a participating provider or do not have a contract and are considered to be an out-of-network provider. When we contract to serve as a participating provider, reimbursements are made pursuant to a percentage of our charges or a negotiated fee schedule amount. Currently, we are reimbursed on an out-of-network basis, at various rates that can be higher or lower than participating providers. Where we are not reimbursed in full, we may elect to appeal the insurer's underpayment or denial of payment or seek payment from the patient. We continue to focus on expanding coverage among existing contracted providers and achieving coverage with commercial payers, laboratory benefit managers and evidence review organizations. We employ a multi-pronged strategy designed to achieve broad coverage and reimbursement for our AVISE® testing products:

- *Meet the evidence standards necessary to be consistent with leading clinical guidelines.* We believe inclusion in leading clinical guidelines plays a critical role in payers' coverage decisions. In order to change clinical guidelines, tests must carry a high level of published evidence demonstrating analytical validity, clinical validity, clinical utility and cost effectiveness. When studies with such evidence are published in peer-reviewed journals, the authors of clinical guidelines may assess the level of evidence and determine whether modifying existing guidelines to include new technology is warranted. For example, we previously conducted peer-reviewed, published clinical studies for AVISE® MTX which helped us secure favorable coverage for that testing product from the MolDx Program, Noridian and various commercial Medicare Advantage plans. The two largest rheumatology super groups have included AVISE® MTX in their respective RA patient pathway guidelines for physician adoption of AVISE® MTX. In addition, UpToDate, a leading evidence-based clinical decision support resource for physicians and payers, recommends the measurement of polyglutamate levels as done by AVISE® MTX. We have conducted, and continue to conduct, clinical validation and clinical utility studies for AVISE® Lupus, which we believe will provide a basis for the ACR and/or UpToDate to consider inclusion of AVISE® Lupus in their respective guidelines. In the future, we also intend to conduct similar studies in order to develop similar supporting literature with respect to our other testing products.
- *Execute an internal managed care policy and claims adjudication function as part of our core business operations.* We employ a team of in-house claims processing and reimbursement specialists who work with patients and payers to obtain maximum reimbursement. In parallel, a managed care team collaborates with our reimbursement specialists to ensure our payer outreach strategy reacts and anticipates the changing needs of our customer base. Our customer service team is an integral part of our reimbursement strategy, working with patients and rheumatologists to navigate the claims process.
- *Cultivate a network of key opinion leaders.* Key opinion leaders are able to influence clinical practice by publishing research and determining whether new tests should be integrated into clinical guidelines. We collaborate with key opinion leaders early in the development process to ensure our clinical studies are designed and executed in a way that clearly demonstrates the benefits of our testing products to physicians and payers.

Clinical Validation

We demonstrated the clinical validity of AVISE® Lupus in a study of 794 patients conducted from 2010 to 2014 across multiple leading academic centers. The primary endpoint of the study was the specificity and sensitivity of AVISE® Lupus compared to common autoantibodies used to diagnose SLE

and other CTDs, such as ANA and anti-dsDNA. The final results of this study showed that AVISE® Lupus demonstrated 86% specificity and 80% sensitivity in distinguishing SLE from other CTDs and fibromyalgia, was 33% more specific than ANA (53% specificity/89% sensitivity) and was 48% more sensitive than anti-dsDNA (32% sensitivity/97% specificity).

Clinical Utility

We have collaborated with both academic and community clinicians to demonstrate the clinical utility of AVISE® Lupus versus standard diagnostic tests in physician diagnosis, impact on patient management decisions, patient reported outcomes and health economics.

We sponsored a longitudinal, case-control, retrospective review of medical charts in 2016 to assess the value and clinical utility of AVISE® Lupus to rheumatologists. The results of this study were published in the Open Rheumatology Journal in 2016 and suggested that a positive AVISE® Lupus test aids in the diagnosis of SLE versus standard diagnostic tests.

In early 2018, we initiated CARE for Lupus, a prospective, randomized, multi-site study to assess the performance of AVISE® Lupus versus a number of other standard diagnostic tests. We submitted the Care for Lupus manuscript for publication in July 2019, and it was accepted in August 2019. We also plan to initiate the CLEAR study in conjunction with CareFirst by late-2019 to further evaluate the clinical utility of AVISE® Lupus by collecting and analyzing applicable claims data. In addition, we collaborated with leading health economic experts and clinicians to conduct a health economics study. The results of that health economics study were presented at the ACR conference in 2018, demonstrated the cost savings to a payer associated with AVISE® Lupus over a one to four year time horizon and were submitted for publication in April 2019. The above referenced studies are included in the AVISE® Lupus Dossier, which was completed in May 2019. Formal coverage determinations meetings are expected to take place in the first half of 2020 following publications of studies.

We believe our reimbursement strategy, including establishing the clinical validation, clinical utility and health economics of our testing products will allow us to drive an expansion in reimbursement coverage for our testing products.

Laboratory Operations

We perform all of our AVISE® tests in our approximately 8,000 square foot clinical laboratory, which is certified by the Clinical Laboratory Improvement Amendments of 1988, or CLIA, and accredited by the College of American Pathologists, or CAP, and located in Vista, California. Our laboratory is certified for the performance of high-complexity testing by the Centers for Medicare and Medicaid Services, or 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. We believe that our existing laboratory facilities are adequate to meet our business needs for at least the next 12 months and that additional laboratory space will be available on commercially reasonable terms, if required.

Quality Assurance

Our quality assurance function oversees the quality of our laboratory as well as research and development, client services, billing, sales and marketing operations. We have established oversight for systems implementation and maintenance procedures, document control processes, supplier qualification, preventive or corrective actions, and employee training processes that we believe achieves excellence in operations. We continuously monitor and improve our processes and procedures and believe this high-quality service leads to customer satisfaction and retention.

Competition

Our principal competition for our AVISE® testing products is traditional methods used by healthcare providers to test patients with CTD disease-like symptoms. Such traditional methods include testing for a broad range of diagnostic, immunology and chemistry biomarkers, such as ANA and anti-dsDNA, and serum complement, such as C3 and C4. We also face competition from commercial laboratories, such as Laboratory Corporation of America Holdings, Quest Diagnostics Incorporated, ARUP Laboratories, Inc. and Mayo Clinic, all of which have existing infrastructures to support the commercialization of diagnostic services. Large, multispecialty group medical clinics, health systems and academic medical university-based clinics may provide in-house clinical laboratories offering autoimmune and autoimmune-related disease testing services. Additionally, we compete against regional clinical laboratories providing testing in the autoimmune and autoimmune-related disease field, including Rheumatology Diagnostics Laboratories, Inc. Other potential competitors include companies that might develop diagnostic or disease or drug monitoring products, such as Myriad Genetics, Inc., Progentec Diagnostics Inc., Kypha, LLC, Genalyte Inc., Protagen AG, DxTerity Diagnostics Inc., HealthTell, Inc. and Immunovia AB. In the future, we may also face competition from companies developing new products or technologies.

Direct competition for the promotion of SIMPONI® includes all other companies with anti-TNF biologics and the marketing companies supporting their distribution and promotion. These products include HUMIRA® and RINVOQ™ from Abbvie Inc., ENBREL® from Amgen Inc., CIMZIA® from UCB, INFLECTRA® from Pfizer Inc., or Pfizer, (biosimilar REMICADE®) and RENFLEXIS® from Merck & Co. (biosimilar REMICADE®). Additional competitors include companies with other biologic drugs indicated for RA that have significant sales or sales potential. Specifically, these include ORENCIA® from Bristol-Myers Squibb Company, ACTEMRA® from Roche Holding AG, or Roche, RITUXAN® from Roche, XELJANZ® from Pfizer, KEVZARA® from Sanofi S.A. and OLUMIANT® from Eli Lilly and Company. There are also several late-stage RA drug and biosimilar development programs and several additional RA products that have minimal sales to date or that are indicated for other rheumatic indications competitive to SIMPONI® such as psoriatic arthritis and ankylosing spondylitis.

We believe the principal competitive factors in our target market include: quality and strength of clinical and analytical validation data; confidence in diagnostic results; safety and efficacy with respect to promoted therapeutics; sales and marketing capabilities; the extent of reimbursement; inclusion in clinical guidelines; cost-effectiveness; and ease of use.

Many of our potential competitors have widespread brand recognition and substantially greater financial, technical and research and development resources and selling and marketing capabilities than we do. Others may develop products with prices lower than ours that could be viewed by rheumatologists and payers as functionally equivalent to our solution or offer solutions at prices designed to promote market penetration, which could force us to lower the list price of our products and affect our ability to achieve profitability. If we are unable to change clinical practice in a meaningful way or compete successfully against current and future competitors, we may be unable to increase market acceptance and sales of our products, which could prevent us from increasing our revenue or achieving profitability and could cause the market price of our common stock to decline.

Agreements with Pharmaceutical Companies

Janssen Agreement

In December 2018, we and Janssen entered into the Janssen agreement to co-promote SIMPONI® in the United States. We are responsible for the costs associated with our 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 our sales and co-promotional services,

we are entitled to a quarterly tiered promotion fee ranging from $750 to $1,250 per prescription based on the incremental increase in total prescribed units of SIMPONI® for that quarter over a predetermined baseline. The predetermined average baseline for the initial term of 18 months is approximately 29,000 prescribed units per quarter, subject to adjustment under certain circumstances.

The term of the Janssen agreement expires on June 30, 2020, unless extended by us for an additional 18 months upon 180 days' written notice prior to the end of the initial term. Janssen can terminate the agreement at any time for any reason upon 30 days' notice to us, and we can terminate the agreement for any reason at the end of any calendar quarter upon 30 days' notice to Janssen. Either party may terminate the 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.

Collaboration Agreement with GSK

In January 2018, we entered into a collaboration agreement with GSK, pursuant to which we provide GSK with our test result data to provide market insight into and help increase awareness on the benefits of an early and accurate diagnosis of SLE. The agreement was amended in November 2018 to, among other things, include data from our AVISE® Prognostic and AVISE® HCQ testing products and extend the term of the agreement through December 31, 2019.

Under the agreement, we are required to deliver weekly de-identified data files to GSK covering all data obtained from the performance of certain AVISE® testing products, subject to applicable requirements under the Federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, internal policy requirements and other applicable laws. During the term of the agreement, the data we provide to GSK may not be provided, directly or through a third party, to any other pharmaceutical company that is marketing or developing a product for the treatment of SLE. GSK made a single upfront payment in exchange for the right to receive the applicable data files. In addition, GSK has agreed to create a joint steering committee to cooperate with us in order to raise awareness and physician support for our AVISE® testing products, including through the development and delivery of approved promotional materials and the implementation of a related training plan for each party's sales personnel.

The joint committee will meet at least 120 days prior to the end of the term of the agreement in order to discuss renewal options. Either party may terminate the agreement for breach and, in certain cases, such breach must remain uncured for a certain period of time following receipt of written notice of such breach. In addition, GSK may terminate the agreement immediately if we become insolvent or for convenience upon 60 days' prior written notice.

Master Services Agreement with Horizon Therapeutics

In August 2018, we entered into a master services agreement with Horizon Therapeutics, pursuant to which Horizon Therapeutics utilizes our AVISE® MTX test to report on levels of MTXPG in patients undergoing methotrexate therapy in combination with its anti-gout product KRYSTEXXA® in an ongoing Phase 4 clinical trial. Under the agreement, Horizon Therapeutics paid an initial one time set-up cost and now pays an incremental fee for each specimen processed. We provide, among other things, specimen collection kits, customized test requisition, pre-paid shipping, specimen storage and individual reports for each study subject. Either party can terminate the agreement for convenience upon 30 days' prior written notice to the other party. Absent early termination, the agreement will run through August 2020.

Intellectual Property Overview

We strive to protect and enhance the proprietary technologies that we believe are important to our business and seek to obtain and maintain patents for any patentable aspects of our testing products

and services and any other inventions that are important to the development of our business. Our success will depend on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business, to defend and enforce our patents, to maintain our licenses to use intellectual property owned by third parties, to preserve the confidentiality of our trade secrets and to operate without infringing the valid and enforceable patents and other proprietary rights of third parties. We also rely on continuing technological innovation and in-licensing opportunities to develop, strengthen, and maintain our proprietary position in the fields targeted by our testing products and services.

We are the owner or licensee of a portfolio of patents and patent applications and possess substantial know-how and trade secrets which protect various aspects of our business. The patent families comprising our patent portfolio are primarily focused on our AVISE® testing products for the diagnosis, prognosis and monitoring of autoimmune and autoimmune-related diseases, and are generally directed to CB-CAPs, red blood cell MTXPG exposure assessments, and anti-MCV antibodies. We intend to leverage the intellectual property surrounding our AVISE® testing products as an important component of our business strategy.

Patent Protection for our AVISE® Testing Products

Our portfolio of patents and patent applications related to our AVISE® testing products generally relates to three aspects: CB-CAPs, red blood cell MTXPG exposure assessments, and anti-MCV antibodies. The patent families which we believe are important for the protection of AVISE® are summarized below in the section entitled "—License Agreements."

CB-CAPs.

We are the exclusive licensee of five patent families related to CB-CAPs technology from the University of Pittsburgh, or UPitt. We expect that these patent families (U.S. Patent Nos. 7,361,517; 7,390,631; 7,585,640; 7,588,905; 8,080,382; and 8,126,654) will expire in 2024 or 2025. A foreign patent corresponding to U.S. Patent No. 7,361,517 has issued in Europe (EP 1,756,571). Foreign patents corresponding to U.S. Patent No. 7,390,631 have issued in Japan (JP 4570872 and JP 4906898). Foreign patents corresponding to U.S. Patent No. 7,585,640 have issued in Australia (AU 2005242719) and Canada (CA 2,564,492). A foreign patent corresponding to U.S. Patent Nos. 7,588,905 and 8,126,654 has issued in Japan (JP 4550051). We also own one issued patent (US 10,132,813) and two pending patent application families that relate to our AVISE® Lupus products. Foreign patents corresponding to US 10,132,813 have issued in Europe (EP 2,673,644) and Japan (JP 5,990,542). In order to manage our foreign filing costs and focus on the U.S. market, we made the decision to cease the prosecution and maintenance of several of our foreign patents and patent applications related to our CB-CAPs technology, including EP 1,432,731; EP 1,618,379; EP 1,635,692; EP 1,745,287; EP 2,214,014; EP 2,216,650, and certain of their corresponding family members.

MTX Exposure Assessment Products and Services

We are the exclusive licensee of four patents that relate to our AVISE® MTX product and methods for monitoring methotrexate therapy using red blood cell MTXPG exposure assessments. These patents and patent applications are owned by Prometheus and are exclusively licensed to us for all uses except for use in gastrointestinal diseases. These patents include U.S. Patent Nos. 6,921,667; 7,563,590; 7,582,282 and 7,695,908, which are expected to expire between 2023 and 2027. We also are the exclusive licensee of two issued US patents (US 9,261,509 and US 9,822,391) that relate to our AVISE® MTX product.

Proprietary Rights and Processes

We may rely, in some circumstances, on proprietary technology and processes (including trade secrets) to protect our technology. However, these can be difficult to protect. We seek to protect our

proprietary technology and processes, in part, by entering into confidentiality agreements with those who have access to our confidential information, including our employees, consultants, scientific advisors and contractors. We also seek to preserve the integrity and confidentiality of our proprietary technology and processes by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any such breach. In addition, our proprietary technology and processes may otherwise become known or be independently discovered by competitors. To the extent that our employees, consultants, scientific advisors, contractors, or any future collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. For this and more comprehensive risks related to our proprietary technology and processes, please see “Risk Factors—Risks Related to our Intellectual Property.”

License Agreements

Amended and Restated Exclusive License Agreement with the University of Pittsburgh

In August 2011, we entered into an amended and restated exclusive license agreement with UPitt, to amend and restate the exclusive license agreement we obtained by our purchase of the medical diagnostics division of Cypress Bioscience, Inc., or Cypress, in 2010, or the Cypress Purchase, and to obtain an exclusive license to UPitt’s patent rights in certain inventions, or the UPitt Patent Rights, related to the use of CB-CAPs technology in the diagnosis, prognosis and monitoring of diseases, including certain patents related to our AVISE® testing products. The agreement was amended three times, once in May 2012 to, among other things, limit the territory of the license to the United States and exclude certain foreign patents and applications from the agreement, once in September 2013 to add (1) an additional U.S. patent to the UPitt Patent Rights licensed under the agreement and (2) the field of monitoring of organ transplantation and organ rejection to the scope of the license, and once in June 2016 to, among other things, clarify the definition of combination products for determining royalties due under the license.

Under the agreement, we are permitted to make, use and sell products and services utilizing the UPitt Patent Rights in the field of SLE and the field of monitoring of organ transplantation and organ rejection, and to sublicense such rights. UPitt retained the right to practice under the UPitt Patent Rights and to use such rights for non-commercial education and research purposes. In addition, this agreement is subject to the rights of the United States government, if any, as set forth in 35 U.S.C. §200, et seq. Pursuant to this law, the U.S. government may have acquired a nonexclusive, nontransferable, paid up license to practice or have practiced for or on behalf of the U.S. government the inventions described in the UPitt Patent Rights throughout the world.

In consideration for the rights granted to us under the agreement, we made certain upfront payments to UPitt on the first and second anniversaries of the agreement that increased on the third and subsequent anniversaries of the agreement until the first sale of products or services utilizing the UPitt Patent Rights. We are required to pay UPitt a low single-digit royalty on net sales of products or services utilizing the UPitt Patent Rights sold by us or our affiliates, subject to minimum annual royalty payments and other adjustment in certain circumstances. We also made a $0.2 million milestone payment to UPitt with the achievement of certain levels of net sales which we met in 2014. Our royalty obligations continue for each licensed product or service on a country-by-country basis until the expiration of the last licensed patent covering the applicable licensed product or service in such country.

In the event we sublicense any of the UPitt Patent Rights, we are obligated to pay UPitt a low single-digit percentage sublicense royalty on net sales of products or services sold by our sublicensees that utilize the sublicensed UPitt Patent Rights and a low double-digit percentage of all non-royalty sublicensing income received by us.

The agreement requires that we diligently develop and commercialize products that are covered by the UPitt Patent Rights, and we have agreed to meet certain development and commercial milestones. UPitt may terminate the agreement if we fail to meet such milestones. In addition, if we fail to meet a milestone relating to development of the UPitt Patent Rights in the monitoring of organ transplantation and organ rejection field, UPitt may remove that field from our licensed rights. We are currently in compliance with these milestone requirements.

We may terminate the agreement upon six months' written notice to UPitt. UPitt may terminate the agreement in the event of our nonperformance of any of our obligations under the agreement if such nonperformance remains uncured for a certain period of time following our receipt of written notice of such nonperformance or in the event of our insolvency. Absent early termination, the agreement will continue until the expiration date of the longest-lived patent right included in the UPitt Patent Rights.

Exclusive License Agreement with the University of Pittsburgh

We made an economic decision to cease the maintenance and licensing of UPitt Patent Rights outside the United States, which led to such rights returning to UPitt. We subsequently made the determination to re-license these foreign patent rights from UPitt, but at the time of re-licensing these patent rights, a number of the foreign patent rights had permanently lapsed. Accordingly, in September 2013, we entered into an exclusive license agreement with UPitt to obtain an exclusive license to UPitt's remaining ex-U.S. patent rights in certain inventions, or the ex-U.S. UPitt Patent Rights, related to the use of CB-CAPs technology in the diagnosis, prognosis and monitoring of diseases, including certain patents related to our AVISE® testing products.

Under the agreement, we are permitted to make, use and sell products and services utilizing the ex-U.S. UPitt Patent Rights in the field of SLE and the field of monitoring of organ transplantation and organ rejection outside of the United States, and to sublicense such rights. UPitt retained the right to practice under the ex-U.S. UPitt Patent Rights and to use such rights for non-commercial education and research purposes. In addition, this agreement is subject to the rights of the U.S. government, if any, as set forth in 35 U.S.C. §200, et seq.

In consideration for the rights granted to us under the agreement, we paid an initial license fee to UPitt. We are also required to pay UPitt a low single-digit royalty on net sales of products or services utilizing the ex-U.S. UPitt Patent Rights sold by us or our affiliates, subject to adjustment in certain circumstances. Our royalty obligations continue for each licensed product or service on a country-by-country basis until the expiration of the last licensed patent covering the applicable licensed product or service in such country.

In the event we sublicense any of the ex-U.S. UPitt Patent Rights, we are obligated to pay UPitt a low single-digit percentage sublicense royalty on net sales of products or services sold by our sublicensees that utilize the sublicensed ex-U.S. UPitt Patent Rights and a low double-digit percentage of all non-royalty sublicensing income received by us.

The agreement requires that we diligently develop and commercialize products that are covered by the ex-U.S. UPitt Patent Rights, and we have agreed to meet certain commercial milestones. UPitt may terminate the agreement if we fail to meet such milestones. We are currently in compliance with these milestone requirements.

We may terminate the agreement upon six months' written notice to UPitt. UPitt may terminate the agreement in the event of our nonperformance of any of our obligations under the agreement if such nonperformance remains uncured for a certain period of time following our receipt of written notice of such nonperformance or in the event of our insolvency. Absent early termination, the agreement will continue until the expiration date of the longest-lived patent right included in the UPitt Patent Rights.

License Agreement with Prometheus Laboratories, Inc.

In connection with the Cypress Purchase, we acquired a license agreement, dated September 2007, between Prometheus Laboratories, Inc., or Prometheus, and Proprius Pharmaceuticals, Inc., or Proprius, a company which had been previously acquired by Cypress. Pursuant to this agreement, we obtained an exclusive, worldwide license to Prometheus's patent rights in certain inventions, or the Prometheus Patent Rights, related to the diagnosis, prognosis and monitoring of diseases, including certain patents related to our AVISE® testing products and services. This agreement was subsequently amended in October 2013.

Under the agreement, we are permitted to research, develop, manufacture and commercialize products utilizing the Prometheus Patent Rights and to sublicense such rights; provided, however, that any such sublicenses may only be granted with Prometheus's consent. We are not permitted to develop or commercialize products utilizing the Prometheus Patent Rights for use in diagnosing or treating any gastrointestinal diseases or to promote any such products to gastroenterologists. Pursuant to the agreement, we are obligated to use reasonable commercial efforts to undertake certain development activities with respect to products utilizing the Prometheus Patent Rights, including the completion of certain clinical studies. In addition, in the event that we do not timely complete these studies or approved substitute studies, we will become obligated to pay to Prometheus a one-time payment of $50,000.

We are required to make a milestone payment of $2.0 million upon the achievement of certain net sales. In addition, we are required to pay Prometheus tiered royalties in the mid-single-digit range on sales of any products utilizing the Prometheus Patent Rights by us, our affiliates or our sublicensees. Our royalty obligations continue on a licensed-product-by-licensed-product and country-by-country basis until the expiration, lapse or invalidation of the last valid claim in a licensed patent covering the applicable licensed product in such country.

In the event we sublicense any of the Prometheus Patent Rights, we are obligated to pay to Prometheus a fee based on a percentage of sublicense fees received by us, which percentage is in the mid-twenties. In addition, we are also required to pay to Prometheus a percentage of the royalty payments we receive from our sublicensees, which may not be less than a certain low single-digit percentage of net sales of products or services sold by our sublicensees that utilize the sublicensed Prometheus Patent Rights, nor more than a certain mid-single digit percentage of such net sales.

We may unilaterally terminate the agreement for any reason upon 60-days' written notice to Prometheus. Either party may terminate the agreement in the event of the other party's material breach of the agreement if such breach remains uncured for a certain period of time following receipt of written notice of such breach or in the event of the other party's insolvency. Absent early termination, the agreement will continue until the expiration date of the longest-lived patent right included in the Prometheus Patent Rights.

Asset Purchase Agreement with Cypress (Royalty Pharma) and Proprius

In October 2010, we completed the Cypress Purchase pursuant to an asset purchase agreement with Cypress and its wholly-owned subsidiary, Proprius, under which we obtained certain assets related to our AVISE® testing products and services. The agreement was amended six times, once in March 2011 to change certain obligations relating to certain accounts receivable we acquired from Cypress, once in August 2012 to convert a one-time payment obligation to a payment plan over four years with interest, once in February 2013 to convert a one-time contingent milestone payment obligation concerning a CB-CAPs monitoring assay to a payment plan over two years with interest, once in October 2013 to, among other things, provide consent for Exagen to use its IP as collateral on a financing round, once in January 2016 to restate an annual sales milestone, and once in February 2017 to restate specifics of the monitoring assay royalty.

In 2011, Royalty Pharma Collection Trust, or Royalty Pharma, acquired Cypress and became its successor-in-interest under the agreement. In consideration for the acquisition, we made certain initial cash payments to Cypress and we are currently making payments to Royalty Pharma, as a successor-in-interest to Cypress, pursuant to the August 2012 amendment, which payments are subject to acceleration in certain circumstances. Under our agreements with Royalty Pharma, we are required to pay Royalty Pharma a low double-digit royalty on the world wide net sales of CB-CAPs products and a low double-digit royalty on the net sales of certain new products in each case, for a period of eight years.

In addition, we are required to make certain one-time contingent milestone payments for two third-party commercial programs, for the launch of a CB-CAPs monitoring assay, and for the achievement of an annual, worldwide net sales level for CB-CAPs products. Our agreement with Royalty Pharma requires that we use commercially reasonable efforts to cause each of the milestones to be achieved. In December 2015, we achieved the specified annual world-wide nets sales of CB-CAPs products which required us to make a $2.0 million milestone payment to Royalty Pharma. We paid the applicable $2.0 million milestone payment in 2016. In February 2017, we amended our agreements with Royalty Pharma relating to the launch of a monitoring product using CB-CAPs technology. As a result of this amendment, a prior obligation to make a one-time payment of $1.0 million upon the launch of a monitoring product incorporating CB-CAPs technology was replaced with an agreement to pay Royalty Pharma a one-time payment of $100,000 upon the launch of such a product, plus a 2.5% royalty based on future cash collections from sales of that product which incorporate the licensed technology. Future royalties under this arrangement are limited to the lesser of $1,200,000 (including the upfront payment of $100,000) or the total royalty earned through January 1, 2024.

Asset Purchase Agreement With Cellatope

In connection with the Cypress Purchase, we acquired an asset purchase agreement, dated February 2009 and amended December 2012 and again in January 2017, between Cypress and Cellatope Corporation, or Cellatope. Pursuant to the amended agreement, we obtained assets related to our AVISE® testing products. In connection with one launch of our AVISE® SLE Monitor testing product, we paid an upfront payment of $100,000 and we are required to pay Cellatope a low-single digit royalty on net sales up to a maximum of $3.0 million.

Dr. Thierry Dervieux and De Novo Diagnostics, Inc.

In September 2011, we entered into a license agreement with Dr. Thierry Dervieux, our Chief Scientific Officer, and his company De Novo Diagnostics, Inc., under which we obtained an exclusive, worldwide (except for Australia and New Zealand) license to Dr. Dervieux's patent rights and know-how in certain inventions, or the Dervieux Patent Rights, related to the diagnosis, prognosis and monitoring of diseases, including certain patents related to our AVISE® testing products and services.

Under the agreement, we are permitted to develop, manufacture and commercialize products utilizing the Dervieux Patent Rights in the human healthcare market, and to sublicense such rights.

In considerations for the rights granted to us under the agreement, we are required to make milestone payments, up to an aggregate of $600,000, upon achievement of certain sales milestones. In addition, we are required to pay Dr. Dervieux a mid-single-digit royalty on net sales by us or our affiliates of any products utilizing the Dervieux Patent Rights, subject to adjustment in certain circumstances. We are also obligated to pay Dr. Dervieux a percentage in the mid-twenties of sublicense fees and royalties received by us.

The agreement requires that we diligently develop and commercialize products that are covered by the Dervieux Patent Rights, and we have agreed to use commercially reasonable efforts to bring technology covered by the Dervieux Patent Rights to market as soon as practicable.

We may unilaterally terminate the agreement upon 12 months' written notice to Dr. Dervieux. Either party may terminate this agreement in the event of the other party's nonperformance of any of its obligations under the agreement if such nonperformance remains uncured for a specified period of time following receipt of written notice of such nonperformance or in the event of the other party's insolvency. Absent early termination, the agreement will continue until the expiration date of the longest-lived patent right included in the Dervieux Patent Rights.

Regulations

Clinical Laboratory Improvement Amendments of 1988

As a clinical reference laboratory, we are required to hold certain federal, state and local licenses, certifications and permits to conduct our business. Under CLIA, we are required to hold a certificate applicable to the type of laboratory tests we perform and to comply with standards applicable to our operations, including test processes, personnel, facilities administration, equipment maintenance, recordkeeping, quality systems and proficiency testing. We must maintain CLIA compliance and certification to be eligible to bill for diagnostic services provided to Medicare beneficiaries.

We have current certification under CLIA to perform testing at our Vista facility. To renew our CLIA certificate, we are subject to survey and inspection every two years to assess compliance with program standards. The regulatory and compliance standards applicable to the testing we perform may change over time, and any such changes could have a material effect on our business.

Penalties for non-compliance with CLIA requirements include suspension, limitation or revocation of the laboratory's CLIA certificate, as well as directed plan of correction, state on-site monitoring, civil money penalties, civil injunctive suit or criminal penalties.

State Laboratory Licensing

In addition to federal certification requirements of laboratories under CLIA, licensure is required and maintained for our Vista clinical reference laboratory under California law. Such laws establish standards for the day-to-day operation of a clinical reference laboratory, including the training and skills required of personnel and quality control. In addition, California laws mandate proficiency testing, which involves testing of specimens that have been specifically prepared for the laboratory.

Because we receive specimens from New York, our clinical reference laboratory is required to be licensed by New York, under New York laws and regulations, which establish standards for:

- day-to-day operation of a clinical laboratory, including training and skill levels required of laboratory personnel;
- physical requirements of a facility;
- equipment; and
- validation and quality control.

New York law also mandates proficiency testing for laboratories licensed under New York state law, regardless of whether such laboratories are located in New York. If a laboratory is out of compliance with New York statutory or regulatory standards, the New York Department of Health, or NYDOH, may suspend, limit, revoke or annul the laboratory's New York license, censure the holder of the license or assess civil money penalties. Statutory or regulatory noncompliance may result in a laboratory's operator being found guilty of a misdemeanor under New York law. NYDOH also must approve the LDT before the test is offered in New York. We have received written approval from NYDOH to offer our products in New York.

In addition to New York and California, other states, including Maryland, Pennsylvania and Rhode Island, require licensing of out-of-state laboratories under certain circumstances.

Federal Oversight of Laboratory Developed Tests

The laws and regulations governing the marketing of diagnostic products are evolving, extremely complex, and in many instances, there are no significant regulatory or judicial interpretations of these laws and regulations. Clinical laboratory tests like AVISE® CTD, AVISE® SLE Prognostic and AVISE® MTX are regulated under CLIA, as administered by CMS, as well as by applicable state laws. In addition, the Federal Food, Drug and Cosmetic Act, or FDCA, defines a medical device to include any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals. Our in vitro testing products are considered by the FDA to be subject to regulation as medical devices. Among other things, pursuant to the FDCA and its implementing regulations, the FDA regulates the research, testing, manufacturing, safety, labeling, storage, recordkeeping, pre-market clearance or approval, marketing and promotion, and sales and distribution of medical devices in the United States to ensure that medical products distributed domestically are safe and effective for their intended uses. In addition, the FDA regulates the export of medical devices manufactured in the United States to international markets.

Although the FDA has statutory authority to assure that medical devices are safe and effective for their intended uses, the FDA has generally exercised its enforcement discretion and not enforced applicable regulations with respect to in vitro diagnostics that are designed, manufactured, and used within a single laboratory for use only in that laboratory. These tests are referred to as laboratory developed tests, or LDTs. We believe that the AVISE® CTD and AVISE® MTX are LDTs, as are our near-term pipeline candidate tests. As a result, we believe many of our diagnostic services are currently subject to the FDA's enforcement discretion and are not subject to the FDA's oversight. However, reagents, instruments, software or components provided by third parties and used to perform LDTs may be subject to regulation.

In recent years, FDA has stated its intention to modify its enforcement discretion policy with respect to LDTs. For example, on July 31, 2014, the FDA notified Congress of its intent to modify, in a risk-based manner, its policy of enforcement discretion with respect to LDTs. On October 3, 2014, the FDA issued two draft guidance documents entitled "Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)," or the Framework Guidance, and "FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs)," or the Reporting Guidance. The Framework Guidance states that FDA intends to modify its policy of enforcement discretion with respect to LDTs in a risk-based manner consistent with the classification of medical devices generally in Classes I through III. The FDA further states its intention in the Framework Guidance to publish general LDT classification guidance within 18 months of date on which the Framework Guidance is finalized. The Reporting Guidance would further enable FDA to collect information regarding the LDTs currently being offered for clinical use through a notification process, as well as to enforce its regulations for reporting safety issues and collecting information on any known or suspected adverse events related to the use of an LDT.

Although the FDA halted finalization of the guidance in November 2016 to allow for further public discussion on an appropriate oversight approach to LDTs and to give congressional authorizing committees the opportunity to develop a legislative solution, the FDA could ultimately modify its current approach to LDTs in a way that would subject our products marketed as LDTs to the enforcement of regulatory requirements. Moreover, legislative measures have recently been proposed in Congress that, if ultimately enacted, could provide the FDA with additional authority to require premarket review of and regulate LDTs.

Medical Device Regulatory Framework

Although we currently market our proprietary testing products as LDTs, which are currently subject to enforcement discretion, we could be subject to more onerous FDA compliance obligations in the future. Specifically, if the FDA begins to actively regulate LDTs, then, unless an exemption applies, each new or significantly modified medical device we seek to commercially distribute in the U.S. will require either a premarket notification to the FDA requesting permission for commercial distribution under Section 510(k) of the FDCA, also referred to as a 510(k) clearance, or approval from the FDA of a premarket approval, or PMA, application. Both the 510(k) clearance and PMA processes can be resource intensive, expensive, and lengthy, and require payment of significant user fees.

Device Classification

Under the FDCA, medical devices are classified into one of three classes-Class I, Class II or Class III depending on the degree of risk associated with each medical device and the extent of control needed to provide reasonable assurances with respect to safety and effectiveness.

Class I includes devices with the lowest risk to the patient and are those for which safety and effectiveness can be reasonably assured by adherence to a set of FDA regulations, referred to as the General Controls for Medical Devices, which require compliance with the applicable portions of the FDA's quality system regulation, or QSR, facility registration and product listing, reporting of adverse events and malfunctions, and appropriate, truthful and non-misleading labeling and promotional materials. Some Class I devices also require premarket clearance by the FDA through the 510(k) premarket notification process described below. Most Class I products are exempt from the premarket notification requirements.

Class II devices are those that are subject to the General Controls, and special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. These special controls can include performance standards, patient registries, FDA guidance documents and post-market surveillance. Most Class II devices are subject to premarket review and clearance by the FDA. Premarket review and clearance by the FDA for Class II devices is accomplished through the 510(k) premarket notification process.

Class III devices include devices deemed by the FDA to pose the greatest risk such as life-supporting or life-sustaining devices, or implantable devices, in addition to those deemed novel and not substantially equivalent following the 510(k) process. The safety and effectiveness of Class III devices cannot be reasonably assured solely by the General Controls and Special Controls described above. Therefore, these devices are subject to the PMA application process, which is generally more costly and time-consuming than the 510(k) process. Through the PMA application process, the applicant must submit data and information demonstrating reasonable assurance of the safety and effectiveness of the device for its intended use to the FDA's satisfaction. Accordingly, a PMA typically includes, but is not limited to, extensive technical information regarding device design and development, pre-clinical and clinical trial data, manufacturing information, labeling and financial disclosure information for the clinical investigators in device studies. The PMA application must provide valid scientific evidence that demonstrates to the FDA's satisfaction a reasonable assurance of the safety and effectiveness of the device for its intended use.

The Investigational Device Process

In the U.S., absent certain limited exceptions, human clinical trials intended to support medical device clearance or approval require an IDE application. Some types of studies deemed to present "non-significant risk" are deemed to have an approved IDE once certain requirements are addressed and IRB approval is obtained. If the device presents a "significant risk" to human health, as defined by the FDA, the sponsor must submit an IDE application to the FDA and obtain IDE approval prior to

commencing the human clinical trials. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. Generally, clinical trials for a significant risk device may begin once the IDE application is approved by the FDA and the study protocol and informed consent are approved by appropriate IRBs at the clinical trial sites. Submission of an IDE will note necessarily result in the ability to commence clinical trials, and although the FDA's approval of an IDE allows clinical testing to go forward for a specified number of subjects, it does not bind the FDA to accept the results of the trial as sufficient to prove the product's safety and efficacy, even if the trial meets its intended success criteria.

All clinical trials must be conducted in accordance with the FDA's IDE regulations that govern investigational device labeling, prohibit promotion and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. Clinical trials must further comply with the FDA's good clinical practice regulations for IRB approval and for informed consent and other human subject protections. Required records and reports are subject to inspection by the FDA. The results of clinical testing may be unfavorable, or, even if the intended safety and efficacy success criteria are achieved, may not be considered sufficient for the FDA to grant marketing approval or clearance of a product. The commencement or completion of any clinical trial may be delayed or halted, or be inadequate to support approval of a PMA application, for numerous reasons, including, but not limited to, the following:

- the FDA or other regulatory authorities do not approve a clinical trial protocol or a clinical trial, or place a clinical trial on hold;
- patients do not enroll in clinical trials at the rate expected;
- patients do not comply with trial protocols;
- patient follow-up is not at the rate expected;
- patients experience adverse events;
- patients die during a clinical trial, even though their death may not be related to the products that are evaluated during the trial;
- device malfunctions occur with unexpected frequency or potential adverse consequences;
- side effects or device malfunctions of similar products already in the market that change the FDA's view toward approval of new or similar PMAs or result in the imposition of new requirements or testing;
- institutional review boards and third-party clinical investigators may delay or reject the trial protocol;
- third-party clinical investigators decline to participate in a trial or do not perform a trial on the anticipated schedule or consistent with the clinical trial protocol, investigator agreement, investigational plan, good clinical practices, the IDE regulations or other FDA or IRB requirements;
- third-party investigators are disqualified by the FDA;
- we or third-party organizations do not perform data collection, monitoring and analysis in a timely or accurate manner or consistent with the clinical trial protocol or investigational or statistical plans, or otherwise fail to comply with the IDE regulations governing responsibilities, records and reports of sponsors of clinical investigations;
- third-party clinical investigators have significant financial interests related to us or our study such that the FDA deems the study results unreliable, or we or investigators fail to disclose such interests;
- regulatory inspections of our clinical trials or manufacturing facilities, which may, among other things, require us to undertake corrective action or suspend or terminate our clinical trials;
- changes in government regulations or administrative actions;

- the interim or final results of the clinical trial are inconclusive or unfavorable as to safety or efficacy; or
- the FDA concludes that our trial designs are unreliable or inadequate to demonstrate safety and efficacy.

The 510(k) Clearance Process

Under the 510(k) clearance process, the manufacturer must submit to the FDA a premarket notification, demonstrating that the device is "substantially equivalent" to a legally marketed predicate device. A predicate device is a legally marketed device that is not subject to a PMA, i.e., a device that was legally marketed prior to May 28, 1976 (pre-amendments device) and for which a PMA is not required, a device that has been reclassified from Class III to Class II or I, or a device that was previously found substantially equivalent through the 510(k) process. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data is sometimes required to support substantial equivalence.

After a 510(k) premarket notification is submitted, the FDA determines whether to accept it for substantive review. If it lacks necessary information for substantive review, the FDA will refuse to accept the 510(k) notification. If it is accepted for filing, the FDA begins a substantive review. By statute, the FDA is required to complete its review of a 510(k) notification within 90 days of receiving the 510(k) notification. As a practical matter, clearance often takes longer, and clearance is never assured. Although many 510(k) premarket notifications are cleared without clinical data, the FDA may require further information, including clinical data, to make a determination regarding substantial equivalence, which may significantly prolong the review process. If the FDA agrees that the device is substantially equivalent, it will grant clearance to commercially market the device.

If the FDA determines that the device is not "substantially equivalent" to a predicate device, or if the device is automatically classified into Class III, the device sponsor must then fulfill the much more rigorous premarketing requirements of the PMA approval process, or seek reclassification of the device through the de novo process. The de novo classification process is an alternate pathway to classify medical devices that are automatically classified into Class III but which are low to moderate risk. A manufacturer can submit a petition for direct de novo review if the manufacturer is unable to identify an appropriate predicate device and the new device or new use of the device presents a moderate or low risk. De novo classification may also be available after receipt of a "not substantially equivalent" letter following submission of a 510(k) to FDA.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a new or major change in its intended use, will require a new 510(k) clearance or, depending on the modification, could require a PMA application. The FDA requires each manufacturer to determine whether the proposed change requires a new submission in the first instance, but the FDA can review any such decision and disagree with a manufacturer's determination. Many minor modifications are accomplished by a letter-to-file in which the manufacture documents the change in an internal letter-to-file. The letter-to-file is in lieu of submitting a new 510(k) to obtain clearance for such change. The FDA can always review these letters to file in an inspection. If the FDA disagrees with a manufacturer's determination regarding whether a new premarket submission is required for the modification of an existing 510(k)-cleared device, the FDA can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or approval of a PMA application is obtained. In addition, in these circumstances, the FDA can impose significant regulatory fines or penalties for failure to submit the requisite application(s).

The PMA Approval Process

Following receipt of a PMA application, the FDA conducts an administrative review to determine whether the application is sufficiently complete to permit a substantive review. If it is not, the agency will refuse to file the PMA. If it is, the FDA will accept the application for filing and begin the review. The FDA has 180 days to review a filed PMA application, although the review of an application more often occurs over a significantly longer period of time. During this review period, the FDA may request additional information or clarification of information already provided, and the FDA may issue a major deficiency letter to the applicant, requesting the applicant's response to deficiencies communicated by the FDA.

Before approving or denying a PMA, an FDA advisory committee may review the PMA at a public meeting and provide the FDA with the committee's recommendation on whether the FDA should approve the submission, approve it with specific conditions, or not approve it. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Prior to approval of a PMA, the FDA may conduct inspections of the clinical trial data and clinical trial sites, as well as inspections of the manufacturing facility and processes. Overall, the FDA review of a PMA application generally takes between one and three years, but may take significantly longer. The FDA can delay, limit or deny approval of a PMA application for many reasons, including:

- the device may not be shown safe or effective to the FDA's satisfaction;
- the data from pre-clinical studies and/or clinical trials may be found unreliable or insufficient to support approval;
- the manufacturing process or facilities may not meet applicable requirements; and
- changes in FDA approval policies or adoption of new regulations may require additional data.

If the FDA evaluation of a PMA is favorable, the FDA will issue either an approval letter, or an approvable letter, the latter of which usually contains a number of conditions that must be met in order to secure final approval of the PMA. When and if those conditions have been fulfilled to the satisfaction of the FDA, the agency will issue a PMA approval letter authorizing commercial marketing of the device, subject to the conditions of approval and the limitations established in the approval letter. If the FDA's evaluation of a PMA application or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. The FDA also may determine that additional tests or clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and data is submitted in an amendment to the PMA, or the PMA is withdrawn and resubmitted when the data are available. The PMA process can be expensive, uncertain and lengthy and a number of devices for which the FDA approval has been sought by other companies have never been approved by the FDA for marketing.

New PMA applications or PMA supplements are required for modification to the manufacturing process, equipment or facility, quality control procedures, sterilization, packaging, expiration date, labeling, device specifications, ingredients, materials or design of a device that has been approved through the PMA process. PMA supplements often require submission of the same type of information as an initial PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the approved PMA application and may or may not require as extensive technical or clinical data or the convening of an advisory panel, depending on the nature of the proposed change.

In approving a PMA application, as a condition of approval, the FDA may also require some form of post-approval study or post-market surveillance, whereby the applicant conducts a follow-up study or

follows certain patient groups for a number of years and makes periodic reports to the FDA on the clinical status of those patients when necessary to protect the public health or to provide additional or longer term safety and effectiveness data for the device. The FDA may also approve a PMA application with other post-approval conditions intended to ensure the safety and effectiveness of the device, such as, among other things, restrictions on labeling, promotion, sale, distribution and use. New PMA applications or PMA supplements may also be required for modifications to any approved diagnostic tests, including modifications to our manufacturing processes, device labeling and device design, based on the findings of post-approval studies.

Federal and State Physician Self-Referral Prohibitions

We are subject to the federal physician self-referral prohibitions, commonly known as the Stark Law, and to similar state law restrictions, such as California's Physician Ownership and Referral Act, or PORA, and other comparable state laws. Together these restrictions generally prohibit us from billing a patient or any governmental or private payer for certain designated health services, including clinical laboratory services, when the physician ordering the service, or any member of such physician's immediate family, has a financial interest, such as an ownership or investment interest in or compensation arrangement with us, unless the arrangement meets an exception to the prohibition.

Sanctions for a Stark Law violation include the following:

- denial of payment for the services provided in violation of the prohibition;
- refunds of amounts collected by an entity in violation of the Stark Law;
- a civil penalty of up to $24,748 for each bill or claim for a service arising out of the prohibited referral;
- the imposition of up to three times the amounts for each item or service wrongfully claimed;
- possible exclusion from federal healthcare programs, including Medicare and Medicaid; and
- a civil penalty of up to $164,992 for each arrangement or scheme that the parties know (or should know) has the principal purpose of circumventing the Stark Law's prohibition.

These prohibitions apply regardless of any intent by the parties to induce or reward referrals or the reasons for the financial relationship and the referral. In addition, knowing violations of the Stark Law may also serve as the basis for liability under the Federal False Claims Act, which can result in additional civil and criminal penalties.

Further, a violation of PORA is a misdemeanor and could result in civil penalties and criminal fines. Other states also have self-referral restrictions with which we have to comply, some of which differ from those imposed by the Stark Law or California law.

Federal and State Anti-Kickback Laws

The Federal Anti-kickback Statute makes it a felony for a person or entity, including a clinical laboratory, to knowingly and willfully offer, pay, solicit or receive any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in order to induce business that is reimbursable under any federal health care program. A violation of the Anti-kickback Statute may result in imprisonment for up to ten years and fines of up to $100,000 for each violation and administrative civil money penalties of $100,000 plus up to three times the amount of the remuneration paid. Convictions under the Anti-kickback Statute result in mandatory exclusion from federal health care programs for a minimum of five years. In addition, The U.S. Department of Health and Human Services, or HHS, has the authority to impose civil assessments and fines and to exclude health care providers and others engaged in prohibited activities from Medicare, Medicaid and other federal health care programs. In addition, the government may assert that a claim that includes items or services resulting from a violation of the

Anti-kickback Statute constitutes a false or fraudulent claim under the Federal False Claims Act, which is discussed in greater detail below. Additionally, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

Although the Anti-kickback Statute applies only to items and services reimbursable under any federal health care program, a number of states, including California, have passed statutes substantially similar to the Anti-kickback Statute that apply to all third-party payers, including commercial insurers, and in some states, to patients without insurance. The California Attorney General and courts have interpreted the California anti-kickback and fee-splitting laws in substantially the same way as HHS and the courts have interpreted the Anti-kickback Statute. Penalties of such state laws include imprisonment and significant monetary fines.

Federal and state law enforcement authorities scrutinize arrangements between health care providers and potential referral sources to ensure that the arrangements are not designed as a mechanism to induce patient care referrals or induce the purchase or prescribing of particular products or services. Generally, courts have taken a broad interpretation of the scope of the Anti-kickback Statute, holding that the statute may be violated if merely one purpose of a payment arrangement is to induce referrals or purchases.

In addition to statutory exceptions to the Anti-kickback Statute, regulations provide for a number of safe harbors. If an arrangement meets the provisions of a safe harbor, it is deemed not to violate the Anti-kickback Statute. An arrangement must fully comply with each element of an applicable safe harbor in order to qualify for protection.

Failure to meet the requirements of the safe harbor, however, does not render an arrangement illegal. Rather, the government may evaluate such arrangements on a case-by-case basis, taking into account all facts and circumstances. There are no regulatory safe harbors under California laws.

Other Federal and State Health Care Laws

In addition to the requirements discussed above, several other health care fraud and abuse laws could have an effect on our business. For example, provisions of the Social Security Act permit Medicare and Medicaid to exclude an entity that charges the federal health care programs substantially in excess of its usual charges for its services. The terms “usual charge” and “substantially in excess” are subject to varying interpretations.

The Federal False Claims Act prohibits, among other things, a person from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval and from, making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim in order to secure payment or retaining an overpayment by the federal government. In addition to actions initiated by the government itself, the statute authorizes actions to be brought on behalf of the federal government by a private party having knowledge of the alleged fraud. Because the complaint is initially filed under seal, the action may be pending for some time before the defendant is even aware of the action. If the government intervenes and is ultimately successful in obtaining redress in the matter or if the plaintiff succeeds in obtaining redress without the government’s involvement, then the plaintiff will receive a percentage of the recovery. Finally, the Social Security Act includes its own provisions that prohibit the filing of false claims or submitting false statements in order to obtain payment. Violation of these provisions may result in fines, imprisonment or both, and possible exclusion from Medicare or Medicaid programs. Several states, including California, have enacted comparable false claims laws which may be broader in scope and may apply regardless of payer.

The civil monetary penalties statute imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health

program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. A person who offers or provides to a Medicare or Medicaid beneficiary any remuneration, including waivers of co-payments and deductible amounts (or any part thereof), that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of Medicare or Medicaid payable items or services may be liable for civil monetary penalties of up to $20,000 for each wrongful act and up to three times the amount improperly claimed. Moreover, in certain cases, providers who routinely waive copayments and deductibles for Medicare and Medicaid beneficiaries can also be held liable under the Anti-Kickback Statute and False Claims Act. One of the statutory exceptions to the prohibition is non-routine, unadvertised waivers of copayments or deductible amounts based on individualized determinations of financial need or exhaustion of reasonable collection efforts. The Office of Inspector General of HHS, or OIG, emphasizes, however, that this exception should only be used occasionally to address special financial needs of a particular patient. Although this prohibition applies only to federal healthcare program beneficiaries, applicable state laws related to, among other things, unlawful schemes to defraud, excessive fees for services, tortious interference with patient contracts and statutory or common law fraud, may also be implicated for similar practices offered to patients covered by commercial payers.

HIPAA created new federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payers, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Like the Anti-kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

The Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, collectively the Affordable Care Act, or ACA, among other things, also imposed annual reporting requirements on manufacturers of certain devices, drugs and biologics for certain payments and transfers of value by them and in some cases their distributors to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Any failure to comply with these reporting requirements could result in significant fines and penalties. Because we manufacture our own LDTs solely for use by or within our own laboratory, we believe that we are exempt from these reporting requirements. We cannot assure you, however, that the government will agree with our determination, and a determination that we have violated these laws and regulations, or a public announcement that we are being investigated for possible violations, could adversely affect our business, prospects, results of operations or financial condition.

If our operations are found to be in violation of any of the fraud and abuse laws described above or any other laws that apply to us, we may be subject to penalties, including potentially significant criminal and civil and/or administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

International Regulations

Many countries in which we may offer any of our testing products in the future have anti-kickback regulations prohibiting providers from offering, paying, soliciting or receiving remuneration, directly or indirectly, in order to induce business that is reimbursable under any national health care program. In situations involving physicians employed by state-funded institutions or national health care agencies,

violation of the local anti-kickback law may also constitute a violation of the U.S. Foreign Corrupt Practices Act, or FCPA, and/or other applicable anti-corruption laws.

The FCPA prohibits any U.S. individual, business entity or employee of a U.S. business entity from offering or providing, directly or through a third party, including any potential distributors we may rely on in certain markets, anything of value to a foreign official with corrupt intent to influence an award or continuation of business or to gain an unfair advantage, whether or not such conduct violates local laws. In addition, it is illegal for a company that reports to the SEC to have false or inaccurate books or records or to fail to maintain a system of internal accounting controls. We will also be required to maintain accurate information and control over sales and distributors' activities that may fall within the purview of the FCPA, including its books and records provisions and its anti-bribery provisions.

The standard of intent and knowledge under the FCPA's anti-bribery provisions is minimal intent and knowledge are usually inferred from the fact that bribery took place. The FCPA's accounting provisions do not require intent. Violations of the FCPA's anti-bribery provisions for corporations and other business entities are subject to a fine of up to $2 million and officers, directors, stockholders, employees, and agents are subject to a fine of up to $100,000 and imprisonment for up to five years. Other countries, including the United Kingdom and other OECD Anti-Bribery Convention members, have similar anti-corruption regulations, such as the UK Bribery Act.

When marketing our testing products outside of the U.S., we may be subject to foreign regulatory requirements governing human clinical testing, prohibitions on the import of tissue necessary for us to perform our testing products or restrictions on the export of tissue imposed by countries outside of the U.S. or the import of tissue into the U.S., and marketing approval. These requirements vary by jurisdiction, differ from those in the U.S. and may in some cases require us to perform additional pre-clinical or clinical testing. In many countries outside of the U.S., coverage, pricing and reimbursement approvals are also required.

Privacy and Security Laws

Health Insurance Portability and Accountability Act; California Consumer Privacy Act of 2018, or the CCPA

Under the Federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH Act, HHS has issued regulations to protect the privacy and security of protected health information used or disclosed by certain entities including health care providers, such as us. HIPAA also regulates standardization of data content, codes and formats used in certain health care transactions and standardization of identifiers for health plans and providers. Penalties for violations of HIPAA and HITECH laws and regulations include civil and criminal penalties.

Three standards have been promulgated under HIPAA's and HITECH's regulations: the Standards for Privacy of Individually Identifiable Health Information, which restrict the use and disclosure of certain individually identifiable health information, the Standards for Electronic Transactions, which establish standards for common healthcare transactions, such as claims information, plan eligibility, payment information and the use of electronic signatures, and the Security Standards for the Protection of Electronic Protected Health Information, or Security Standards, which require covered entities and business associates to implement and maintain certain security measures to safeguard certain electronic health information, including the adoption of administrative, physical and technical safeguards to protect such information.

In 2009, Congress passed the American Recovery and Reinvestment Act of 2009, or ARRA, which included sweeping changes to HIPAA, including an expansion of HIPAA's privacy and security

standards. ARRA includes the HITECH Act, which, among other things, made HIPAA's security standards directly applicable to business associates of covered entities effective February 17, 2010. A business associate is a person or entity that performs certain functions or activities on behalf of a covered entity that involve the use or disclosure of protected health information for or on behalf of the covered entity. As a result, business associates are now subject to significant civil and criminal penalties for failure to comply with applicable standards. Moreover, HITECH creates a new requirement to report certain breaches of unsecured, individually identifiable health information and imposes penalties on entities that fail to do so. This requirement was modified and expanded by the final HIPAA Omnibus Rule of 2013. HITECH also increased the civil and criminal penalties that may be imposed against covered entities and business associates and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorney fees and costs associated with pursuing federal civil actions.

HIPAA also governs patient access to laboratory test reports. Effective October 6, 2014, individuals (or their personal representatives, as applicable) have the right to access test reports directly from laboratories and to direct that copies of those reports be transmitted to persons or entities designated by the individual.

In addition to HIPAA and HITECH, there are state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act and CCPA, that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our collaborators. The state of California, for example, recently adopted the California Consumer Privacy Act of 2018, or the CCPA, which will come into effect beginning in January 2020. The CCPA has been characterized as the first "GDPR-like" privacy statute to be enacted in the United States because it mirrors a number of the key provisions of the European Union General Data Protection Regulation , or the GDPR, (discussed below). The CCPA establishes a new privacy framework for covered businesses by creating an expanded definition of personal information, establishing new data privacy rights for consumers in the State of California, imposing special rules on the collection of consumer data from minors, and creating a new and potentially severe statutory damages framework for violations of the CCPA and for businesses that fail to implement reasonable security procedures and practices to prevent data breaches. Penalties for violations of the CCPA will include civil penalties.

GDPR and Foreign Laws

We are also subject to foreign privacy laws in the foreign jurisdictions in which we sell our testing products. The interpretation, application and interplay of consumer and health-related data protection laws in the U.S., Europe and elsewhere are often uncertain, contradictory and in flux. For example, the European Union enacted Regulation (EU) 2016/679 (General Data Protection Regulation, or GDPR), has been enacted in the European Union and went into full effect in May 2018. These texts introduce many changes to privacy and security in the European Union, including stricter rules on consent and security duties for critical industries, including for the health sector. The interpretation of some rules is still unclear, and some requirements will be completed by national legislation. More generally, foreign laws and interpretations governing data privacy and security are constantly evolving and it is possible that laws may be interpreted and applied in a manner that is inconsistent with current practices, subjecting entities to government-imposed fines or orders. These fines can be very high. For instance, the GDPR introduces fines of up to EUR 20 million or 4% of a group's worldwide annual turnover for certain infringements. In addition, privacy regulations differ widely from country to country.

Billing and Government Reimbursement for Clinical Laboratory Services

Medicare coverage is limited to items and services that are within the scope of a Medicare benefit category that are reasonable and necessary for the diagnosis or treatment of an illness or injury. With

respect to Medicare coverage, Palmetto GBA, the Medicare Administrative Contractor, or MAC, responsible for administering Medicare's molecular diagnostic services program, or MolDX Program, issued a local coverage determination, or LCD, that provides coverage for our AVISE® MTX test. The MAC responsible for administering Medicare claims submitted by our laboratory, Noridian Healthcare Solutions, has adopted Palmetto's positive coverage policy, along with a related local coverage article that identifies a unique billing identifier for this test.

Under Medicare, payment for our laboratory tests are generally made under the Clinical Laboratory Fee Schedule, or CLFS, with payment amounts assigned to specific procedure billing codes. In April 2014, Congress passed the Protecting Access to Medicare Act, or PAMA, which included substantial changes to the way in which clinical laboratory services will be paid under Medicare. Under PAMA, laboratories that receive the majority of their Medicare revenue from payments made under the CLFS or the Physician Fee Schedule are required to report to CMS, beginning in 2017 and every three years thereafter (or annually for "advanced diagnostic laboratory tests"), private payer payment rates and volumes for their tests. Laboratories that fail to report the required payment information may be subject to substantial civil monetary penalties. As required under PAMA, CMS uses the rates and volumes reported by laboratories to develop Medicare payment rates for laboratory tests equal to the volume-weighted median of the private payer payment rates for the tests.

On June 23, 2016, CMS published the final rule implementing the reporting and rate-setting requirements under PAMA. For tests furnished on or after January 1, 2018, Medicare payments for clinical diagnostic laboratory tests are based upon these reported private payer rates. For clinical diagnostic laboratory tests that are assigned a new or substantially revised CPT code, initial payment rates will be assigned by the gap-fill methodology, as under prior law. Initial payment rates for new advanced diagnostic laboratory tests will be based on the actual list charge for the laboratory test. Any reductions to payment rates resulting from the new methodology are limited to 10% per test per year in each of the years 2018 through 2020 and to 15% per test per year in each of the years 2021 through 2023. PAMA's impact on Medicare reimbursement for AVISE® CTD in 2018 was -3.2% and is expected to be -10.1%, in 2019.

PAMA also authorizes the adoption of new, temporary billing codes and unique test identifiers for FDA-cleared or approved tests, as well as advanced diagnostic laboratory tests. The AMA's CPT Editorial Panel has approved a proposal to create a new section of billing codes to facilitate implementation of this section of PAMA. These proprietary laboratory analyses codes, or PLA codes, may be requested by a clinical laboratory or manufacturer to specifically identify their test. If approved, the codes are issued by the AMA on a quarterly basis. While our testing products are not presently identified by any PLA codes, we may seek a specific PLA code or codes to describe some of our testing products in the future.

Billing for diagnostic testing can be complicated. Depending on the billing arrangement and applicable law, we must bill various payers, such as insurance companies, Medicare, Medicaid, physicians, hospitals, employer groups and patients, all of which have different billing requirements. Additionally, compliance with applicable laws and regulations as well as internal compliance policies and procedures adds further complexity to the billing process. Changes in laws and regulations could negatively impact our ability to bill our clients or increase our costs. CMS also establishes new procedures and continuously evaluates and implements changes to the reimbursement process for billing government programs. Missing or incorrect information on test requisitions adds complexity to and slows the billing process, creates backlogs of unbilled tests, and generally increases the aging of accounts receivable and bad debt expense. Failure to timely or correctly bill may lead to our not being reimbursed for our services or an increase in the aging of our accounts receivable, which could

adversely affect our results of operations and cash flows. Failure to comply with applicable laws relating to billing federal healthcare programs could also lead to various penalties, including:

- overpayments and recoupments of reimbursement received;
- exclusion from participation in Medicare/Medicaid programs;
- asset forfeitures;
- civil and criminal fines and penalties; and
- the loss of various licenses, certificates and authorizations necessary to operate our business.

Any of these penalties or sanctions could have a material adverse effect on our results of operations or cash flows.

Healthcare Reform

In March 2010, the ACA was enacted in the U.S. The ACA made a number of substantial changes to the way healthcare is financed by governmental and private insurers. For example, the ACA requires each medical device manufacturer to pay a sales tax equal to 2.3% of the price for which such manufacturer sells its medical devices. The medical device tax has been suspended until December 31, 2019, but is scheduled to return beginning in 2020. It is unclear at this time when, or if, the provision of our LDTs will trigger the medical device tax if the FDA ends its policy of general enforcement discretion and regulates certain LDTs as medical devices, and it is possible that this tax will apply to some or all of our existing testing products or testing products we may develop in the future. The ACA also contains a number of other provisions, including provisions governing enrollment in federal and state healthcare programs, reimbursement matters and fraud and abuse, which we expect will impact our industry and our operations in ways that we cannot currently predict. Additionally, on December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, or Texas District Court Judge, ruled that the entire ACA is invalid based primarily on the fact that the Tax Cuts and Jobs Act of 2017 repealed the tax-based shared responsibility payment imposed by the ACA, on certain individuals who fail to maintain qualifying health coverage for all or part of a year, which is commonly referred to as the “individual mandate”. While the Texas District Court Judge, as well as the current presidential administration and CMS, have stated that this ruling will have no immediate effect, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA.

Additional state and federal health care reform measures may be adopted in the future, any of which could have a material adverse effect on the clinical laboratory industry.

Employees

As of June 30, 2019, we had 144 employees, all but two of whom were full time, 26 of whom work in laboratory operations, six in research and development, 68 in sales and marketing and 44 in general and administrative functions. None of our employees is represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

Suppliers

We rely on sole suppliers for the critical supply of reagents, equipment and other materials that we use to perform the tests that comprise our AVISE® testing products. We also purchase components used in our AVISE® testing product transportation kits from sole-source suppliers. Some of these items are unique to these suppliers and vendors.

Facilities

We lease approximately 14,000 square feet of office and laboratory space in Vista, California, under a lease that expires in 2021, with options to extend the lease for an additional 36-month period.

We also lease an additional approximately 19,500 square feet of office space in Vista, California, under a lease that is co-terminus with our other lease expiring in 2021. We believe that our existing facilities and arrangements are adequate to meet our business needs for at least the next 12 months and that additional space will be available on commercially reasonable terms, if required.

Environmental Matters

Our operations require the use of hazardous materials (including biological and chemical materials) which subject us to a variety of federal, state and local environmental and safety laws and regulations. We could be held liable for damages and fines as a result of our business operations. We cannot predict how changes in laws or regulations will affect our business, operations or the cost of compliance. We mitigate this risk by being in compliance with these laws and the CAP checklists. We have established Universal Precautions, as mandated by the Occupational Safety & Health Administration, to be practiced to prevent employee exposure to blood and other potentially infectious materials. Engineering and work practice controls are used to eliminate or minimize employee exposure. Personal protective equipment is used when occupational exposure may occur even though the engineering and work practice controls are in place. This Injury and Illness Prevention Program, or IIPP, is designed to furnish employees with a safe and healthy place of employment. This IIPP describes specific requirements for program responsibility, compliance, communication, hazard assessment, accident/exposure investigations, hazard correction, training and recordkeeping. In addition, appropriate biohazardous, chemical and sharps waste disposal are in place.

Legal Proceedings

We are not currently a party to any material legal proceedings, and we are not aware of any pending or threatened legal proceeding against us that we believe are likely to have a material adverse effect on our business, operating results or financial condition. 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.

MANAGEMENT

Executive Officers and Directors

The following table sets forth the name, age and position of each of our executive officers, key employees and directors as of August 31, 2019.

Name	Age	Position
Executive Officers		
Fortunato Ron Rocca	58	President, Chief Executive Officer and Director
Kamal Adawi	40	Chief Financial Officer and Corporate Secretary
Thierry Dervieux, Ph.D.	51	Chief Scientific Officer
Non-Employee Directors		
Brian Birk(3)	59	Chairman of the Board of Directors
Chet Burrell(1)	72	Director
Jeff Elliott(1)	41	Director
Tina S. Nova, Ph.D.(1)(2)	66	Director
Ebetuel Pallares, Ph.D.(3)	46	Director
Bruce C. Robertson, Ph.D.(2)(3)	56	Director
James L.L. Tullis(2)	72	Director

(1) Member of the audit committee

(2) Member of the compensation committee

(3) Member of the nominating and corporate governance committee

Executive Officers

Fortunato Ron Rocca has served as our President and Chief Executive Officer and as a member of our board of directors since December 2011. From 2005 to October 2011, Mr. Rocca served as Vice President, Sales and Marketing, and as General Manager, at Prometheus, a specialty pharmaceutical and diagnostic company which was acquired by Nestlé SA in 2011, where he was responsible for leading the commercial organization, strategic planning and implementation of projects designed to maximize brand sales. Prior to joining Prometheus, Mr. Rocca served as the General Manager of Alpharma Inc., a specialty pharmaceutical company. Earlier in his career, Mr. Rocca served in senior sales and marketing management positions for Elan Pharmaceuticals, Inc., a neuroscience-focused biotechnology company and Janssen Pharmaceuticals, Inc., a pharmaceutical subsidiary of Johnson & Johnson. Mr. Rocca received a B.S. in Marketing and Personnel Management from Towson State University. Mr. Rocca's extensive knowledge of our business, as well as his over 25 years of experience in the diagnostic and pharmaceutical industries, contributed to our board of directors' conclusion that he should serve as a director of our company.

Kamal Adawi has served as our Chief Financial Officer since June 2017 and as our Corporate Secretary since September 2017. From 2014 to 2017, Mr. Adawi served as the Chief Financial Officer, Corporate Secretary and Treasurer at Pathway Genomics Corporation, or Pathway Genomics, a global genetic testing company. Prior to joining Pathway Genomics, from March 2014 to December 2014, Mr. Adawi served as our Director of Financial Planning and Analysis. Earlier in his career, Mr. Adawi managed the finance departments for GenMark Diagnostics, Inc., serving as its Manager of Financial Planning and Analysis, and Digirad Corporation, serving as its Manager of Financial Planning and Analysis, both publicly traded diagnostic companies. Mr. Adawi also served in various capacities in the finance and accounting departments at Becton, Dickinson and Company, a global medical technology company. Mr. Adawi received a B.A. in Finance from Michigan State University, an M.B.A. from Oakland University with a focus on management, and a M.S. in Finance from San Diego State University.

Thierry Dervieux, Ph.D. has served as our Chief Scientific Officer and Medical Laboratory Director since October 2010. Prior to joining Exagen, from 2008 to October 2010, Dr. Dervieux served as Vice President of Research and Development with Cypress, a pharmaceutical company with a focus on drugs to treat central nervous system disorders, where he developed our current portfolio in the rheumatology space. Dr. Dervieux previously served as Senior Director Research and Development of Proprius Pharmaceuticals, Inc., a specialty pharmaceutical and personalized medicine company focused in rheumatology and pain management, until its acquisition by Cypress. Earlier in his career, Dr. Dervieux served as Principal Scientist and Director of Research and Development of Prometheus. Dr. Dervieux has nearly 20 years of experience with the development of drug monitoring and molecular diagnostic assays in partnership with academia and diagnostic industry. Dr. Dervieux is board certified by the American Board of Clinical Chemistry and holds certificates of qualification as medical laboratory director in the categories of cellular immunology, clinical chemistry, drug monitoring and diagnostic immunology. Dr. Dervieux holds Pharm.D. and Ph.D. degrees from Claude Bernard University in Lyon, France, an inter-university diploma in biostatistics from the University of Pierre et Marie Curie in Paris, France, and trained at St. Jude Children's Research Hospital in Memphis, Tennessee.

Non-Employee Directors

Brian Birk has served as a member of our board of directors since June 2008. In 2006, Mr. Birk co-founded Sun Mountain Capital, a boutique private equity firm focused on the southwest and Rocky Mountain regions which currently manages direct investment funds and funds of funds vehicles and where he serves as Managing Partner. Prior to forming Sun Mountain Capital, Mr. Birk served as a Vice President and Director of Private Equity at Fort Washington Capital Partners, a professional investment management services company. Mr. Birk also served as the Vice President of Technology Commercialization at Applied Minds, LLC, a technology consulting company, and the President of a division at BiosGroup Inc., a company which commercialized complex science software. Earlier in his career, Mr. Birk held a senior manager position at the Boston Consulting Group, Inc., a global management consulting firm, and finance manager positions at General Electric Company, an American multinational conglomerate, and GE Capital Corporation, its financial services unit. Mr. Birk is currently a member of the board of directors of several private companies, including Agilvax, Inc., Aspen Avionics, Inc., Avisa Pharma, Inc., Green Theme Technologies, Inc. and Respira Therapeutics, Inc. Mr. Birk received a B.A. in Economics from Carleton College and an M.B.A. from Northwestern University's Kellogg School of Management. Mr. Birk's experience as a venture capitalist and prior executive experience contributed to our board of directors' conclusion that he should serve as a director of our company.

Chet Burrell has served as a member of our board of directors since July 2019. In mid-2018, Mr. Burrell founded Silavon Healthcare Holdings, LLC, an entity he established in to pursue investments in the healthcare field and where he serves as Managing Member. Prior to forming Silavon Healthcare Holdings, from December 2007 to June 2018, Mr. Burrell served as President and Chief Executive Officer of CareFirst BlueCross BlueShield, a health insurer and health benefit services company. Prior to his role at CareFirst BlueCross BlueShield, Mr. Burrell served as Chairman and Chief Executive Officer of RealMed Corporation, a provider of online claims processing services for the health care industry, and as Founder, Chairman and Chief Executive Officer of Novalis Corporation, a managed care technology and consulting company. Mr. Burrell also served as an executive officer of numerous other U.S. healthcare companies in both the public and private sectors. Mr. Burrell currently serves as a member of the board of directors of several private companies and organizations in the healthcare field, including the Committee on Affordable and Quality Healthcare, America's Health Insurance Plans, and the National Blue Cross and Blue Shield Association. Mr. Burrell received a B.A. in Sociology and Political Science from Allegheny College and a M.P.A. from the State University of New York at Albany. Mr. Burrell's extensive chief executive and leadership experience in the healthcare field and his service as a leader and director of numerous healthcare companies and

organizations contributed to our board of directors' conclusion that he should serve as a director of our company.

Jeff Elliott has served as a member of our board of directors since March 2019. Mr. Elliott has served as Chief Financial Officer of Exact Sciences Corporation, a molecular diagnostics company, since November 2016. Prior to his appointment as Chief Financial Officer, Mr. Elliott served as the Vice President, Business Development and Strategy of Exact Sciences from June 2016 to November 2016. From 2007 to 2016, Mr. Elliott was with Robert W. Baird & Co., where from June 2012 to June 2016 he was a senior research analyst who covered diagnostics and life science tools companies. Earlier in his career, Mr. Elliott worked in a supply chain role for Walgreens and as a consultant at Cap Gemini Ernst & Young. Mr. Elliott earned a B.S. in business administration from the University of Illinois at Urbana-Champaign and an M.B.A. from the University of Chicago Booth School of Business. Mr. Elliott is a CFA charterholder. Mr. Elliott's executive experience and experience in the diagnostics and life sciences industries contributed to our board of directors' conclusion that he should serve as a director of our company.

Tina S. Nova, Ph.D., has served as a member of our board of directors since July 2019. Dr. Nova has served as President and Chief Executive Officer of Decipher Biosciences, Inc. (formerly GenomeDx, Inc.), a molecular diagnostics company, since September 2018. Dr. Nova served as President and Chief Executive of Molecular Stethoscope, Inc., a diagnostics company from September 2015 to August 2018. Dr. Nova served as Senior Vice President and General Manager of Illumina Inc.'s oncology business unit from July 2014 to August 2015. Dr. Nova was a co-founder of Genoptix, Inc., a medical laboratory diagnostics company, and served as its President from 2000 to April 2014. Dr. Nova also served as the Chief Executive Officer of Genoptix and as a member of its board of directors from 2000 until Novartis AG acquired Genoptix in March 2011. Dr. Nova was a co-founder of Nanogen, Inc., a provider of molecular diagnostic tests, and she served as its Chief Operating Officer and President from 1994 to 2000. Dr. Nova served as Chief Operating Officer of Selective Genetics, a biotechnology company, from 1992 to 1994, and in various director-level positions with Ligand Pharmaceuticals Incorporated, a drug discovery and development company, from 1988 to 1992, most recently as Executive Director of New Leads Discovery. Dr. Nova has also held various research and management positions with Hybritech, Inc., a former subsidiary of Eli Lilly & Company, a pharmaceutical company. Dr. Nova serves as a member of the board of directors of Arena Pharmaceuticals, Inc., a biopharmaceutical company, Veracyte, Inc., a diagnostics company, and OpGen, Inc., an infection prevention and treatment company. Within the past five years, Dr. Nova also served as a member of the board of directors of Adamis Pharmaceuticals Corporation, a biopharmaceutical company, NanoString Technologies, Inc., a provider of life science tools, and Cypress Biosciences, Inc., a pharmaceutical company. Dr. Nova holds a B.S. in Biological Sciences from the University of California, Irvine and a Ph.D. in Biochemistry from the University of California, Riverside. Dr. Nova's extensive leadership, business and scientific expertise in the biopharmaceutical and diagnostics industries, and her experience in successfully developing, launching and commercializing medical products contributed to our board of directors' conclusion that she should serve as a director of our company.

Ebetuel Pallares, Ph.D. has served as a member of our board of directors since October 2012. In December 2014, Dr. Pallares founded Proficio Capital Management (PCM), LLC, a seed and early-stage venture fund headquartered in El Paso, TX, and he has served as its General Partner since that time. Through PCM, Dr. Pallares manages several investments, including PCM/Exagen L.P. In June 2009, he co-founded Cottonwood Capital Partners, the general partner of Cottonwood Technology Fund, a seed and early-stage venture fund with headquarters in El Paso, Texas, and he served as its Managing Partner until December 2014. In 2006, Dr. Pallares founded Joseph Advisory Services, LLC, a strategic consulting firm, and has served as its Manager since that time. He also currently manages investments on behalf of a family office, managing fund commitments and direct investments into

private operating companies. His investment sectors span healthcare, medical diagnostics, therapeutics, IT, materials sciences and nanotechnology, education technology, AR/VR and financial technology companies. Dr. Pallares also serves on several corporate and non-profit boards, as an advisor to the UT Horizon Fund, the venture capital investment fund of the University of Texas system, as an Investor in Residence for New Mexico State University's Arrowhead Center and on the limited partnership advisory committee for several venture funds. He received a B.A. in economics from Brandeis University, an M.B.A. from The University of Texas at El Paso, or UTEP, and a Ph.D. in International Business from UTEP. Dr. Pallares's extensive venture capital experience and his service as a director for numerous companies contributed to our board of directors' conclusion that he should serve as a director of our company.

Bruce C. Robertson, Ph.D., has served as a member of our board of directors since July 2019. Since 2005, Dr. Robertson has served as Managing Director of H.I.G. Capital, LLC, a global private equity and investment firm. Dr. Robertson previously served as a Managing Director at Toucan Capital, an early-stage venture capital firm. Dr. Robertson serves as a member of the board of directors of Apollo Endosurgery, Inc., a medical device company. Dr. Robertson holds a B.S.E. in Chemical Engineering and B.A. in Mathematics from the University of Pennsylvania, an M.B.A. from Harvard Business School, and a Ph.D. in Chemical Engineering from the University of Delaware. Dr. Robertson's medical and research background and his extensive experience as an investor in the medical technologies industry contributed to our board of directors' conclusion that he should serve as a director of our company.

James L.L. Tullis has served as a member of our board of directors since May 2015. In 1986, Mr. Tullis founded Tullis Health Investors, a venture capital firm specializing in investments in the healthcare industry and served as its Chief Executive Officer from its inception until December 2018. Since January 2019, Mr. Tullis has served as its Chairman. Earlier in his career, Mr. Tullis was a Senior Vice President at E.F. Hutton & Co., a stock brokerage firm, and a principal at Morgan Stanley & Co., where he worked with the healthcare investment research and banking teams. Since 2006, Mr. Tullis has served as a member of the board of directors and since January 2017 as chair of the board of directors of Lord Abbett & Co. Mutual Funds, an investment management firm. Since 1998, he has served as a member of the board of directors of Crane Co., an industrial products manufacturing company, where he also serves as Chair of the Management Organization and Compensation Committee. Mr. Tullis also currently serves as a member of the board of directors of Alphatec Spine, Inc., a medical technology company, electroCore Inc., a bioelectronic medicine company, and a private company, SupplyPro, Inc., an inventory management solutions company. Mr. Tullis holds a B.A. from Stanford University and an M.B.A. from Harvard Business School. Mr. Tullis's extensive experience serving as a venture capitalist and board member for numerous companies in the health care industry contributed to our board of directors' conclusion that Mr. Tullis should serve as a director of our company.

Board Composition and Election of Directors

Director Independence

Our board of directors currently consists of eight members. Our board of directors has determined that all of our directors, other than Mr. Rocca, are independent directors in accordance with the listing requirements of Nasdaq. The Nasdaq independence definition includes a series of objective tests, including that the director is not, and has not been for at least three years, one of our employees and that neither the director nor any of his family members has engaged in various types of business dealings with us. In addition, as required by Nasdaq rules, our board of directors has made a subjective determination as to each independent director that no relationships exist, which, in the opinion of our board of directors, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In making these determinations, our board of directors reviewed

and discussed information provided by the directors and us with regard to each director's business and personal activities and relationships as they may relate to us and our management. There are no family relationships among any of our directors or executive officers.

Classified Board of Directors

In accordance with the terms of our amended and restated certificate of incorporation that will go into effect immediately prior to the completion of this offering, our board of directors will be divided into three classes with staggered, three-year terms. At each annual meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. Effective upon the completion of this offering, our directors will be divided among the three classes as follows:

- the Class I directors will be Mr. Birk, Dr. Nova and Dr. Pallares, and their terms will expire at our first annual meeting of stockholders following this offering;
- the Class II directors will be Mr. Burnell, Mr. Elliott and Mr. Tullis, and their terms will expire at our second annual meeting of stockholders following this offering; and
- the Class III directors will be Mr. Rocca and Dr. Robertson, and their terms will expire at our third annual meeting of stockholders following this offering.

Our amended and restated certificate of incorporation that will go into effect immediately prior to the completion of this offering will provide that the authorized number of directors may be changed only by resolution of the board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change in control of our company. Our directors may be removed only for cause by the affirmative vote of the holders of at least two thirds of our outstanding voting stock then entitled to vote in the election of directors.

Board Leadership Structure

Our board of directors is currently led by its chairman, Brian Birk. Our board of directors recognizes that it is important to determine an optimal board leadership structure to ensure the independent oversight of management as we continue to grow. We separate the roles of chief executive officer and chairman of the board in recognition of the differences between the two roles. The chief executive officer is responsible for setting the strategic direction for our company and the day-to-day leadership and performance of our company, while the chairman of the board of directors provides guidance to the chief executive officer and presides over meetings of the full board of directors. We believe that this separation of responsibilities provides a balanced approach to managing the board of directors and overseeing our company.

Our board of directors has concluded that our current leadership structure is appropriate at this time. However, our board of directors will continue to periodically review our leadership structure and may make such changes in the future as it deems appropriate.

Role of Board in Risk Oversight Process

Our board of directors has responsibility for the oversight of our risk management processes and, either as a whole or through its committees, regularly discusses with management our major risk exposures, their potential impact on our business and the steps we take to manage them. The risk oversight process includes receiving regular reports from board committees and members of senior management to enable our board to understand our risk identification, risk management and risk mitigation strategies with respect to areas of potential material risk, including operations, finance, legal, regulatory, strategic and reputational risk.

The audit committee reviews information regarding liquidity and operations, and oversees our management of financial risks. Periodically, the audit committee reviews our policies with respect to risk assessment, risk management, loss prevention and regulatory compliance. Oversight by the audit committee includes direct communication with our external auditors, and discussions with management regarding significant risk exposures and the actions management has taken to limit, monitor or control such exposures. The compensation committee is responsible for assessing whether any of our compensation policies or programs has the potential to encourage excessive risk-taking. The nominating and corporate governance committee manages risks associated with the independence of the board, corporate disclosure practices, and potential conflicts of interest. While each committee is responsible for evaluating certain risks and overseeing the management of such risks, the entire board is regularly informed through committee reports about such risks. Matters of significant strategic risk are considered by our board as a whole.

Board Committees and Independence

Our board of directors has established three standing committees—audit, compensation and nominating and corporate governance—each of which operates under a charter that has been approved by our board.

Audit Committee

The audit committee's main function is to oversee our accounting and financial reporting processes and the audits of our financial statements. This committee's responsibilities include, among other things:

- appointing our independent registered public accounting firm;
- evaluating the qualifications, independence and performance of our independent registered public accounting firm;
- approving the audit and non-audit services to be performed by our independent registered public accounting firm;
- reviewing the design, implementation, adequacy and effectiveness of our internal accounting controls and our critical accounting policies;
- discussing with management and the independent registered public accounting firm the results of our annual audit and the review of our quarterly unaudited financial statements;
- reviewing, overseeing and monitoring the integrity of our financial statements and our compliance with legal and regulatory requirements as they relate to financial statements or accounting matters;
- reviewing on a periodic basis, or as appropriate, any investment policy and recommending to our board any changes to such investment policy;
- reviewing with management and our auditors any earnings announcements and other public announcements regarding our results of operations;
- preparing the report that the SEC requires in our annual proxy statement;
- reviewing and approving any related party transactions and reviewing and monitoring compliance with our code of conduct and ethics; and
- reviewing and evaluating, at least annually, the performance of the audit committee and its members including compliance of the audit committee with its charter.

The members of our audit committee are Mr. Elliott, Mr. Burrell and Dr. Nova. Mr. Elliott serves as the chairperson of the committee. All members of our audit committee meet the requirements for financial literacy under the applicable rules and regulations of the SEC and Nasdaq. Our board of directors has determined that Mr. Elliott is an "audit committee financial expert" as defined by applicable SEC rules and has the requisite financial sophistication as defined under the applicable

Nasdaq rules and regulations. Our board of directors has determined each of Mr. Elliott, Mr. Burrell and Dr. Nova are independent under the applicable rules of the SEC and Nasdaq. Under the applicable Nasdaq rules, we are permitted to phase in our compliance with the independent audit committee requirements of Nasdaq on the same schedule as we are permitted to phase in our compliance with the independent audit committee requirements pursuant to Rule 10A-3 under the Exchange Act, which require: (i) one independent member at the time of listing, (ii) a majority of independent members within 90 days of listing and (iii) all independent members within one year of listing. We will comply with the phase-in requirements of the Nasdaq rules, and within one year of our listing on Nasdaq, all members of our audit committee will be independent under Nasdaq rules and Rule 10A-3. Upon the listing of our common stock on Nasdaq, the audit committee will operate under a written charter that satisfies the applicable standards of the SEC and Nasdaq.

Compensation Committee

Our compensation committee approves policies relating to compensation and benefits of our officers and employees. The compensation committee approves corporate goals and objectives relevant to the compensation of our chief executive officer and other executive officers, evaluates the performance of these officers in light of those goals and objectives and approves the compensation of these officers based on such evaluations. The compensation committee also approves the issuance of stock options and other awards under our equity plan. The compensation committee will review and evaluate, at least annually, the performance of the compensation committee and its members, including compliance by the compensation committee with its charter.

The members of our compensation committee are Dr. Robertson, Dr. Nova and Mr. Tullis. Dr. Robertson serves as the chairperson of the committee. Our Board has determined that each member of this committee is independent under the applicable rules and regulations of Nasdaq and is a “non-employee director” as defined in Rule 16b-3 promulgated under the Exchange Act. Upon the listing of our common stock on Nasdaq, the compensation committee will operate under a written charter, which the compensation committee will review and evaluate at least annually.

Nominating and Corporate Governance Committee

The nominating and corporate governance committee is responsible for assisting our board of directors in discharging the board’s responsibilities regarding the identification of qualified candidates to become board members, the selection of nominees for election as directors at our annual meetings of stockholders (or special meetings of stockholders at which directors are to be elected), and the selection of candidates to fill any vacancies on our board of directors and any committees thereof. In addition, the nominating and corporate governance committee is responsible for overseeing our corporate governance policies, reporting and making recommendations to our board of directors concerning governance matters and oversight of the evaluation of our board of directors. The members of our nominating and corporate governance committee are Mr. Birk, Dr. Pallares and Dr. Robertson. Mr. Birk serves as the chairman of the committee. Our board has determined that each member of this committee is independent under the applicable rules and regulations of Nasdaq relating to nominating and corporate governance committee independence. Upon the listing of our common stock on Nasdaq, the nominating and corporate governance committee will operate under a written charter, which the nominating and corporate governance committee will review and evaluate at least annually.

Compensation Committee Interlocks and Insider Participation

None of the members of our compensation committee has ever been one of our officers or employees. None of our executive officers currently serves, or has served, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving as a member of our board of directors or compensation committee.

Board Diversity

Upon the completion of this offering, our nominating and corporate governance committee will be responsible for reviewing with the board of directors, on an annual basis, the appropriate characteristics, skills and experience required for the board of directors as a whole and its individual members. In evaluating the suitability of individual candidates (both new candidates and current members) for election or appointment, the nominating and corporate governance committee, in recommending candidates for election, and the board of directors will take into account many factors, including the following:

- personal and professional integrity, ethics and values;
- experience in corporate management, such as serving as an officer or former officer of a publicly-held company;
- experience as a board member or executive officer of another publicly-held company;
- strong finance experience;
- diversity of expertise and experience in substantive matters pertaining to our business relative to other board members;
- diversity of background and perspective, including, but not limited to, with respect to age, gender, race, place of residence and specialized experience;
- experience relevant to our business industry and with relevant social policy concerns; and
- relevant academic expertise or other proficiency in an area of our business operations.

Currently, our board of directors evaluates, and following the completion of this offering will evaluate, each individual in the context of the board of directors as a whole, with the objective of assembling a group that can best maximize the success of the business and represent stockholder interests through the exercise of sound judgment using its diversity of experience in these various areas.

Code of Business Conduct and Ethics

We adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, which will be effective upon the completion of this offering. Upon the completion of this offering, our code of business conduct and ethics will be available under the Corporate Governance section of our website at www.exagen.com. In addition, we intend to post on our website all disclosures that are required by law or the listing standards of Nasdaq concerning any amendments to, or waivers from, any provision of the code. The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website, and you should not consider it to be a part of this prospectus.

EXECUTIVE AND DIRECTOR COMPENSATION

Executive Compensation

This section discusses the material components of the executive compensation program for our executive officers who are named in the "2018 Summary Compensation Table" below. In 2018, our chief executive officer and our two other highest-paid executive officers, or our named executive officers, were as follows:

- Fortunato Ron Rocca, President and Chief Executive Officer;
- Kamal Adawi, Chief Financial Officer and Corporate Secretary; and
- Thierry Dervieux, Ph.D., Chief Scientific Officer.

This discussion may contain forward-looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs. Actual compensation programs that we adopt following the completion of this offering may differ materially from the currently planned programs summarized in this discussion.

2018 Summary Compensation Table

The following table sets forth information concerning the compensation of our named executive officers during the fiscal year ended December 31, 2018:

Name and Principal Position:	Year	Salary($)	Bonus ($)	Option Awards($)(1)	All Other Compensation ($)(2)	Total($)
Fortunato Ron Rocca *President and Chief Executive Officer*	2018	348,113	157,357	53,499	8,250	567,219
Kamal Adawi *Chief Financial Officer and Corporate Secretary*	2018	271,039	61,088	13,910	8,250	354,287
Thierry Dervieux, Ph.D. *Chief Scientific Officer*	2018	278,391	62,920	16,050	8,250	365,611

(1) With respect to Mr. Adawi, amounts reflect the aggregate grant date fair value of stock options granted in 2018 and with respect to Mr. Rocca and Dr. Dervieux, amounts reflect the incremental fair value of stock options granted pursuant to our one-time stock option exchange in October 2018, as explained further below, each as computed in accordance with ASC Topic 718, *Compensation-Stock Compensation*. These amounts do not reflect the actual economic value that will be realized by the named executive officer upon the vesting of the stock options, the exercise of the stock options, or the sale of the common stock underlying such stock options. The assumptions that we used to calculate these amounts are discussed in Note 12 to our audited financial statements appearing elsewhere in this prospectus.

(2) Represents employer matching contributions under our 401(k) plan on behalf of each named executive officer.

Narrative Disclosure to Summary Compensation Table

2018 Salaries

The named executive officers receive a base salary to compensate them for services rendered to our company. The base salary payable to each named executive officer is intended to provide a fixed component of compensation reflecting the executive's skill set, experience, role and responsibilities.

The 2018 base salaries for Messrs. Rocca and Adawi and Dr. Dervieux were $348,113, $271,039, and $278,391, respectively.

2018 Bonuses

Our named executive officers were eligible to earn cash bonuses based on Company performance during the year ended December 31, 2018, as determined by our board of directors in its sole discretion. For 2018, Mr. Rocca was eligible to receive a target bonus of up to 50% of his base salary and Mr. Adawi and Dr. Dervieux were eligible to receive a target bonus of up to 25% of their respective base salaries, each pursuant to the terms of his employment agreement described below under "—Agreements with our Named Executive Officers." Our board of directors will generally consider each named executive officer's individual contributions towards reaching our annual corporate goals but does not typically establish specific individual goals for our named executive officers. There is no minimum bonus percentage or amount established for the named executive officers and, as a result, the bonus amounts vary from year to year based on corporate and individual performance. The 2018 bonuses for Messrs. Rocca and Adawi and Dr. Dervieux were $157,357, $61,088, and $62,920, respectively.

Equity Compensation

We typically grant equity awards to key new hires upon their commencing employment with us. We historically have used stock options as the primary incentive for long-term compensation to our named executive officers because they are able to profit from stock options only if our stock price increases relative to the stock option's exercise price, which generally is set at the fair market value of our common stock as of the applicable grant date. Generally, the stock options we grant vest as to 25% of the total number of option shares on the first anniversary of the date of grant and in equal monthly installments over the ensuing 36 months, subject to the employee's continued service with us on the vesting date.

In 2018 we awarded a stock option to Mr. Adawi covering 84,162 shares. Mr. Adawi's stock option vests in accordance with our typical vesting schedule described above. In addition, the stock option will become exercisable subject to Mr. Adawi's continuous service with respect to (i) 75% of the underlying shares upon the later to occur of (A) the applicable vesting date and (B) the closing of an initial public offering, and (ii) the remaining 25% of the underlying shares upon the later to occur of (A) the applicable vesting date and (B) the one-year anniversary of an initial public offering.

2018 Stock Option Exchange

In October 2018 we approved a one-time stock option exchange whereby certain underwater stock options, including those held by our named executive officers, were exchanged for replacement stock options to purchase shares of common stock having a lower exercise price.

Each replacement stock option was granted with an exercise price of $0.2571 per share, which our board of directors determined was the fair market value of our common stock on the grant date of the replacement option. In addition, each replacement option vests with respect to 25% of the shares underlying the option on the first anniversary of the grant date and with respect to the remaining shares, on each monthly anniversary thereafter, subject to the option holder's continued service. Further, Mr. Rocca's replacement option will also vest in full upon a termination of service due to a termination by us without cause or for good reason, or due to Mr. Rocca's death or disability, in each case, on or within 12 months following an initial public offering. For purposes of Mr. Rocca's replacement option, "cause" means: (i) a conviction for, or guilty plea to, a felony involving moral turpitude; (ii) an uncured willful refusal to comply with our lawful and reasonable instructions, or to otherwise perform duties as we lawfully and reasonably determine; (iii) any willful act of dishonesty intended to result in material gain or personal enrichment at the expense of us or any of our customers, partners, affiliates or employees; or (iv) any uncured willful act of gross misconduct that is injurious to us. "Good reason" means, without consent, and in the absence of cause, (i) any material reduction of base compensation; or (ii) any material reduction in title, authority or duties.

The following table shows the number of options exchanged for and received by our named executive officers as part of this option exchange. Mr. Adawi did not participate in the stock option exchange.

Named Executive Officer	Stock Options Exchanged	Stock Options Received
Fortunato Ron Rocca	34,739	323,702
Thierry Dervieux, Ph.D.	6,983	97,110

The replacement options held by our named executive officers will become exercisable subject to the executive's continuous service with respect to (i) 75% of the underlying shares upon the later to occur of (A) the applicable vesting date and (B) the closing of an initial public offering, and (ii) the remaining 25% of the underlying shares upon the later to occur of (A) the applicable vesting date and (B) the one-year anniversary of an initial public offering.

Other than the stock option granted to Mr. Adawi and the awards granted as part of our one-time option exchange, none of our named executive officers received a stock option, or other equity award, in 2018.

Stock options granted to our named executive officers may be subject to accelerated vesting in certain circumstances. For additional discussion, please see "—Offer Letters with Our Named Executive Officers" and "—Other Elements of Compensation—Severance and Change in Control Benefits" below.

IPO-Related Equity Grants

Our board of directors approved a grant of stock options pursuant to the 2019 Plan (as defined and further described below) to certain of our directors and employees, including our named executive officers, in connection with this offering, effective as of immediately following the determination of the initial public offering price per share of our common stock. These stock options cover an aggregate of 812,745 shares of our common stock. Of these, the stock options granted to our named executive officers, Messrs. Rocca and Adawi and Dr. Dervieux, cover 138,659, 21,635 and 10,891 shares of our common stock, respectively.

These stock option grants became effective immediately following the determination of the initial public offering price per share of our common stock. The stock options granted to our named executive officers will vest as to 1/4th of the shares underlying the option on the one-year anniversary of the grant date and as to 1/48th of the shares underlying the option on each monthly anniversary of the grant date thereafter, subject to the executive's continued service through the applicable vesting date.

Equity Compensation Plans

2013 Stock Option Plan

We currently maintain the 2013 Stock Option Plan, as amended from time to time, or the 2013 Plan, in order to provide additional incentives for our employees, directors and consultants, and to provide incentives to attract, retain and motivate eligible persons whose present and potential contributions are important to our success. We offer stock options to our employees, including our named executive officers, as the long-term incentive component of our compensation program.

For additional information about the 2013 Plan, please see the section titled "2013 Stock Option Plan" below. As mentioned below, in connection with the completion of this offering, no further awards will be granted under the 2013 Plan.

2002 Stock Option Plan

We also currently have awards outstanding under our 2002 Stock Option Plan, or the 2002 Plan. Generally, the stock options granted under the 2002 Plan vested as to 25% of the total number of option shares on the first anniversary of the date of grant and in equal monthly installments over the ensuing 36 months, subject to the employee's continued service with us on the vesting date. The 2002 Plan expired in accordance with its terms in December 2012 and no additional awards have been granted under the 2002 Plan since its expiration. For additional information about the 2002 Plan, please see the section titled "2002 Stock Option Plan" below.

2019 Incentive Award Plan

In connection with this offering, we have adopted, and our stockholders have approved, a 2019 Incentive Award Plan, referred to in this prospectus as the 2019 Plan, in order to facilitate the grant of cash and equity incentives to directors, employees (including our named executive officers) and consultants of our company and certain of our affiliates and to enable our company and certain of our affiliates to obtain and retain services of these individuals, which is essential to our long-term success. Upon the effectiveness of the 2019 Plan, no further grants will be made under the 2013 Plan. However, the 2013 Plan will continue to govern the terms and conditions of the outstanding awards granted under it. In addition, shares of our common stock subject to awards granted under the 2013 Plan that expire, lapse or are terminated, exchanged for or settled in cash, surrendered, repurchased, canceled without having been fully exercised or forfeited following the effective date of the 2019 Plan will become available for issuance under the 2019 Plan in accordance with its terms. For additional information about the 2019 Plan, please see the section titled "2019 Incentive Award Plan" below.

Other Elements of Compensation

Retirement Plans

We currently maintain a 401(k) retirement savings plan that allows eligible employees to defer a portion of their compensation, within limits prescribed by the Code, on a pre-tax basis through contributions to the plan. Our named executive officers are eligible to participate in the 401(k) plan on the same terms as other full-time employees generally. Currently, we make employer matching contributions under the 401(k) plan up to a specified percentage, and these matching contributions are fully vested as of the date on which the contribution is made. We believe that providing a vehicle for tax-deferred retirement savings though our 401(k) plan, and making matching contributions, adds to the overall desirability of our executive compensation package and further incentivizes our employees, including our named executive officers, in accordance with our compensation policies.

Employee Benefits and Perquisites

Our named executive officers are eligible to participate in our health and welfare plans to the same extent as all full-time employees generally, including:

- medical, dental and vision benefits;
- medical and dependent care flexible spending accounts;
- short-term and long-term disability insurance; and
- life insurance and accidental death and dismemberment insurance.

We do not provide our named executive officers with any other perquisites or other personal benefits.

No Tax Gross-Ups

We generally have not made gross-up payments to cover our named executive officers' personal income taxes that may pertain to any of the compensation paid or provided by our company.

Severance and Change in Control Benefits

Our named executive officers may become entitled to certain benefits or enhanced benefits upon a qualifying termination of employment pursuant to their offer letters, as explained in further detail below. In addition, stock options granted to our employees, including our named executive officers, may be subject to acceleration in connection with a change in control under our equity plans, and for Mr. Rocca, subject to acceleration upon a qualifying termination in connection with an initial public offering. For additional discussion, please see "—Equity Compensation" above and "—Offer Letters with our Named Executive Officers." and "—Equity Incentive Award Plans" below. Other than the benefits described above, none of our named executive officers are entitled to any severance or change in control benefits.

Offer Letters with our Named Executive Officers

Offer Letter with Fortunato Ron Rocca

In October 2011, we entered into an offer letter with Mr. Rocca, which was amended in September 2019.

Mr. Rocca's offer letter provides for at-will employment, and an annual base salary and bonus. Pursuant to Mr. Rocca's offer letter, if we terminate Mr. Rocca's employment without cause, Mr. Rocca will be entitled to a lump sum cash payment in an amount equal to nine months of his annual base salary as in effect immediately prior to the date of termination, subject to his delivery and non-revocation of a general release of claims in favor of our company.

Offer Letter with Kamal Adawi

In May 2017, we entered into an offer letter with Mr. Adawi, which was amended in September 2019.

Mr. Adawi's offer letter provides for at-will employment, and an annual base salary and bonus. Pursuant to Mr. Adawi's offer letter, if we terminate Mr. Adawi's employment without cause, Mr. Adawi will be entitled to a lump sum cash payment in an amount equal to six months of his annual base salary as in effect immediately prior to the date of termination, subject to his delivery and non-revocation of a general release of claims in favor of our company.

Offer Letter with Thierry Dervieux, Ph.D.

In October 2010, we entered into an offer letter with Dr. Dervieux, which was amended in September 2011 and September 2019.

Dr. Dervieux's offer letter provides for at-will employment, an annual base salary and eligibility to participate in our management bonus plan, with the goals and payments under the management bonus plan to be defined and approved by our board of directors. Pursuant to the offer letter, Dr. Dervieux received options to purchase 544 shares of our common stock in connection with the commencement of his employment. Such options were exchanged for replacement stock options to purchase shares of common stock having a lower exercise price as part of our one-time stock option exchange in October 2018.

Pursuant to Dr. Dervieux's offer letter, if we terminate Dr. Dervieux's employment without cause or Dr. Dervieux resigns for good reason, Dr. Dervieux will be entitled to a lump sum cash payment in an amount equal to his annual base salary as in effect immediately prior to the date of termination.

Outstanding Equity Awards at 2018 Fiscal Year-End

The following table presents the outstanding equity incentive plan awards held by each named executive officer as of December 31, 2018. Unless otherwise indicated, each option listed in the following table was granted under the 2013 Plan.

		Option Awards			
Name:	Grant Date	Number of Securities Underlying Unexercised Options (#) Exercisable[1]	Number of Securities Underlying Unexercised Options (#) Unexercisable[1]	Option Price($)	Option Expiration Date
Fortunato Ron Rocca	10/5/2018	–	323,702[2][3]	0.2571	10/5/2028
Kamal Adawi	10/5/2018	–	84,162[2]	0.2571	10/5/2028
Thierry Dervieux, Ph.D	10/5/2018	–	97,110[2]	0.2571	10/5/2028

(1) The option vests with respect to 25% of the shares underlying the option on the first anniversary of the grant date and with respect to the remaining shares, on each monthly anniversary over the three-year period thereafter, subject to the grantee's continued service.

(2) The option will become exercisable subject to the grantee's continuous service with respect to (i) 75% of the underlying shares upon the later to occur of (A) the applicable vesting date and (B) the closing of an initial public offering, and (ii) the remaining 25% of the underlying shares upon the later to occur of (A) the applicable vesting date and (B) the one-year anniversary of an initial public offering.

(3) Mr. Rocca's option will also vest in full upon a termination of service due to a termination by us without cause or by Mr. Rocca for good reason, or due to Mr. Rocca's death or disability, in each case, on or within 12 months following an initial public offering.

Director Compensation

2018 Director Compensation Table

The following table sets forth information for the year ended December 31, 2018 regarding the compensation awarded to, earned by or paid to our non-employee directors who served on our board of directors during 2018. Mr. Rocca, who served as our President and Chief Executive Officer during the year ended December 31, 2018, and continues to serve in that capacity, does not receive additional compensation for his service as a director, and therefore is not included in the Director Compensation table below. All compensation paid to Mr. Rocca is reported above in the "2018 Summary Compensation Table".

Name:	Fees Earned or Paid in Cash ($)	Option Awards ($)[1]	All Other Compensation ($)	Total ($)
Brian Birk	–	3,210	–	3,210
Dan Burrell[2]	–	2,140	–	2,140
Ebetuel Pallares, Ph.D.	–	2,140	–	2,140
James L.L. Tullis	–	2,140	–	2,140
Arthur Weinstein, M.D.[2]	–	2,140	126,769[3]	128,909

(1) Amounts reflect the aggregate grant date fair value of stock options granted in 2018, computed in accordance with the provisions of ASC Topic 718, Compensation-Stock Compensation. These amounts do not reflect the actual economic value that will be realized by the director upon the vesting of the stock options, the exercise of the stock options, or the sale of the common stock underlying such stock options. The assumptions that we used to calculate these amounts are discussed in Note 12 to our audited financial statements elsewhere in this prospectus. As of December 31, 2018, the following outstanding option awards were held by members of our Board: Mr. Birk, 19,422 shares, Mr. Burrell, 12,948 shares, Dr. Pallares, 12,948 shares, Mr. Tullis, 12,948 shares and Dr. Weinstein, 14,172 shares.

(2) Messrs. Burrell and Weinstein resigned from our board of directors on July 12, 2019.

(3) Amount paid to Dr. Weinstein reflects payments for his services as a consultant.

In November 2013, we entered into a director and consulting services agreement with Dr. Weinstein, pursuant to which he receives $18,000 per year, payable monthly, for his service as a member of our board of directors. In addition, in September 2017, we entered into a consulting services agreement with Dr. Weinstein, as amended in May 2018, that supplanted the prior director and consulting services agreement and pursuant to which he receives a bi-weekly fee for his services as our Chief Medical Officer for 20 hours per week. In 2018 this bi-weekly fee was $4,615.39 and was increased effective June 4, 2018 to $5,000. Dr. Weinstein's consulting services agreement provides for a stock option grant upon approval by our board of directors, as well as hotel reimbursement and a Company-provided cell phone. Mr. Weinstein resigned from our board of directors in July 2019, but continues to provide services under this consulting services agreement.

In May 2019, we appointed Jeff Elliott as a member of our board of directors. In connection with his appointment, we entered into an offer letter with Mr. Elliott pursuant to which he will receive $40,000 per year for his services, payable quarterly, which will be paid no later than the fifteenth day following the end of each calendar quarter. The compensation Mr. Elliott is eligible to receive under his offer letter will be superseded by our new non-employee director compensation program, as described below.

In July 2019, we appointed Tina Nova as a member of our board of directors. In connection with her appointment, we entered into an offer letter with Ms. Nova pursuant to which she will receive $50,000 per year for her services, and an additional $7,500 per year for each committee on which she serves, payable quarterly, which will be paid no later than the fifteenth day following the end of each calendar quarter. The compensation Ms. Nova is eligible to receive under her offer letter will be superseded by our new non-employee director compensation program, as described below.

Director IPO Grants

Our board of directors approved a grant of stock options covering 13,613 shares of our common stock to each of Ms. Nova and Messrs. Elliot and Burrell in connection with this offering, which became effective immediately following the determination of the initial public offering price per share of our common stock.

Each award will vest as to 1/36th of the shares underlying the option on each monthly anniversary of the grant date, subject to such director's continued service through the applicable vesting date. In accordance with our Director Compensation Program, as defined and further described below, each such award will vest in full upon a change in control of our company (as defined in the 2019 Plan).

Post-IPO Director Compensation Program

In connection with this offering, we intend to adopt a non-employee director compensation program (the "Director Compensation Program"), which provides for annual retainer fees and long-term equity awards for our non-employee directors (each, an "Eligible Director"). The material terms of the Director Compensation Program are summarized below.

The Director Compensation Program to consists of the following components:

Cash Compensation

- Annual Retainer: $50,000
- Annual Committee Chair Retainer:
  - Audit: $12,000
  - Compensation: $10,000
  - Nominating and Corporate Governance: $9,000
- Annual Committee Member (Non-Chair) Retainer:
  - Audit: $7,500
  - Compensation: $7,500

- Nominating and Corporate Governance: $7,500
- Annual Chairman of the Board Retainer: $20,000

The annual cash retainer will be paid in quarterly installments in arrears. Annual cash retainers will be pro-rated for any partial calendar quarter of service. All cash compensation payable to the directors designated by or affiliated with Sun Mountain Capital, H.I.G. Capital, LLC or Tullis-Dickerson Capital Focus III, L.P. is paid to Sun Mountain Capital, H.I.G. Capital, LLC or Tullis-Dickerson Capital Focus III, L.P., as applicable.

Equity Compensation

- *Initial Grant*: Each Eligible Director who is initially elected or appointed to serve on the Board after the effective date of this offering automatically shall be granted an option to purchase 15,000 shares of our common stock on the date on which such Eligible Director is appointed or elected to serve on the Board, and shall vest as to 1/36th of the shares underlying the option on each monthly anniversary of the grant date, subject to such Eligible Director's continued service through the applicable vesting date.
- *Annual Grant*: An Eligible Director who is serving on the Board as of the date of the annual meeting of the Company's stockholders each calendar year beginning with calendar year 2020 shall be granted, on such annual meeting date, an option to purchase 9,000 shares of our common stock, which shall vest in full on the earlier to occur of (i) the one-year anniversary of the applicable grant date and (ii) the date of the next annual meeting following the grant date, subject to continued service through the applicable vesting date.

In addition, each such award which vests and becomes exercisable will remain exercisable until the earlier of the maximum term of the option and the one-year anniversary of the Eligible Director's termination of service, other than for cause. Further, each such award will vest in full upon a change in control of our Company (as defined in the 2019 Plan).

Compensation under our non-employee director compensation policy will be subject to the annual limits on non-employee director compensation set forth in the 2019 Plan, as described below.

Equity Incentive Award Plans

The following summarizes the material terms of the 2002 Plan and 2013 Plan, under which we have previously made periodic grants of equity and equity-based awards to our named executive officers and other key employees, and the 2019 Plan.

2002 Stock Option Plan

On January 29, 2002, our board of directors and our stockholders approved the 2002 Plan.

The 2002 Plan expired in accordance with its terms in December 2012 and no additional awards have been granted under the 2002 Plan since its expiration. As of June 30, 2019, 4,694 shares of our common stock were subject to outstanding option awards under the 2002 Plan.

Administration. The board of directors administers the 2002 Plan. Subject to the terms and conditions of the 2002 Plan, the administrator has the authority to select the persons to whom awards are to be made, to determine the type or types of awards to be granted to each person, determine the number of awards to grant, determine the number of shares to be subject to such awards, and the terms and conditions of such awards, and make all other determinations and decisions and to take all other actions necessary or advisable for the administration of the 2002 Plan. The plan administrator is also authorized to establish, adopt, amend or revise rules relating to administration of the 2002 Plan, subject to certain restrictions.

Eligibility. Options were able to be granted to individuals who are then our employees, consultants and members of our board of directors. Only employees may be granted ISOs.

Awards. The 2002 Plan permitted the award of stock options. Only stock options were granted under the 2002 Plan. Each award is set forth in a separate agreement with the person receiving the award and indicates the type, terms and conditions of the award.

Corporate Transactions. In the event of a corporate transaction where the acquirer does not assume awards granted under the 2002 Plan, awards issued under the 2002 Plan will terminate as of a date to be fixed by our board of directors.

2013 Plan

Our board of directors and certain of our stockholders approved the 2013 Plan, which became effective in December 2012.

The 2013 Plan was amended in October 2018 to increase the share reserve to 669,806. As of June 30, 2019, 658,293 shares of our common stock were subject to outstanding option awards and 10,999 shares of our common stock remained available for future issuance. The 2013 Plan will expire in December 2022 unless earlier terminated by our board of directors. Following the effectiveness of the 2019 Plan, the 2013 Plan will terminate and we will not make any further awards under the 2013 Plan. However, any outstanding awards granted under the 2013 Plan will remain outstanding, subject to the terms of the 2013 Plan and applicable award agreement. Shares of our common stock subject to awards granted under the 2013 Plan that expire, lapse or are terminated, exchanged for or settled in cash, surrendered, repurchased, canceled without having been fully exercised or forfeited following the effective date of the 2019 Plan will become available for issuance under the 2019 Plan in accordance with its terms.

Administration. The board of directors administers the 2013 Plan. Subject to the terms and conditions of the 2013 Plan, the administrator has the authority to select the persons to whom option awards are to be made, determine the number of option awards to grant, determine the number of shares to be subject to such option awards, and the terms, the exercise price of such option awards, subject to the limits established in the 2013 Plan, conditions and restrictions of such awards, and make all other determinations and decisions and to take all other actions necessary or advisable for the administration of the 2013 Plan. The plan administrator is also authorized to establish, adopt, amend or revise rules relating to administration of the 2013 Plan, subject to certain restrictions.

Eligibility. Options may be granted to individuals who are then our employees, consultants and members of our board of directors. Only employees (including directors who are also employees) may be granted ISOs.

Awards. The 2013 Plan permits the award of stock options. Only stock options have been granted under the 2013 Plan to date. Each award is set forth in a separate agreement with the person receiving the award and indicates the type, terms and conditions of the award.

- Nonqualified stock options. Nonqualified stock options, or NSOs, provide for the right to purchase shares of our common stock at a specified price which may not be less than the fair market value of a share of stock on the date of grant, and usually will become exercisable (at the discretion of our board of directors) in one or more installments after the grant date, subject to the participant's continued employment or service with us and/or subject to the satisfaction of performance targets established by our compensation committee (or the board of directors, in the case of awards to non-employee directors). NSOs may be granted for any term specified by our compensation committee (or the board of directors, in the case of awards to non-employee directors), but the term may not exceed ten years.

- Incentive Stock Options. Incentive Stock Options, or ISOs, are designed to comply with the provisions of the Code and are subject to specified restrictions contained in the Code applicable to ISOs. Among such restrictions, ISOs must have an exercise price of not less than the fair market value of a share of common stock on the date of grant, may only be granted to employees, must expire within a specified period of time following the optionee's termination of employment, and must be exercised within the ten years after the date of grant. In the case of an ISO granted to an individual who owns (or is deemed to own) more than 10% of the total combined voting power of all classes of our capital stock on the date of grant, the 2013 Plan provides that the exercise price must be at least 110% of the fair market value of a share of common stock on the date of grant and the ISO must expire on the fifth anniversary of the date of its grant.

Corporate Transactions. In the event of a corporate transaction, all outstanding stock options will become fully vested and exercisable for the 30-day period immediately preceding the closing of such transaction (provided that the exercise of any stock option that would have been unvested but for the consummation of the change in control is contingent upon and will be subject to the closing of the transaction). In addition, in the event of a corporate transaction, the board of directors may provide for the termination of all outstanding stock options in exchange for a cash payment in an amount equal to the fair market value of the shares of our common stock subject to the stock option immediately prior to the consummation of such transaction less the exercise price of such option. Any options that are outstanding as of the consummation of a corporate transaction will expire automatically unless the acquirer assumes such awards or are otherwise continued in effect pursuant to the terms of the transaction.

Amendment or Termination of the 2013 Plan. Our board of directors may terminate, amend or modify the 2013 Plan, provided that any termination of the plan must be upon 30 days' written notice to participants. However, stockholder approval of any amendment to the 2013 Plan must be obtained to reduce the option price per share after the option has been granted or the extent necessary and desirable to comply with any applicable law, regulation or stock exchange rule. As described above, the 2013 Plan will terminate as of the effective date of the 2019 Plan.

2019 Incentive Award Plan

We have adopted, and our stockholders have approved, the 2019 Incentive Award Plan, or the 2019 Plan under which we may grant cash and equity incentive awards to eligible service providers in order to attract, motivate and retain the talent for which we compete. The material terms of the 2019 Plan are summarized below.

Eligibility and Administration. Our employees, consultants and directors, and employees, consultants and directors of our subsidiaries will be eligible to receive awards under the 2019 Plan. Following our initial public offering, the 2019 Plan will be administered by our board of directors with respect to awards to non-employee directors and by our compensation committee with respect to other participants, each of which may delegate its duties and responsibilities to committees of our directors and/or officers (referred to collectively as the plan administrator below), subject to certain limitations that may be imposed under the 2019 Plan, Section 16 of the Exchange Act, and/or stock exchange rules, as applicable. The plan administrator will have the authority to make all determinations and interpretations under, prescribe all forms for use with, and adopt rules for the administration of, the 2019 Plan, subject to its express terms and conditions. The plan administrator will also set the terms and conditions of all awards under the 2019 Plan, including any vesting and vesting acceleration conditions.

Shares Available. An aggregate of 2,011,832 shares of our common stock will be available for issuance under awards granted pursuant to the 2019 Plan, which shares may be authorized but

unissued shares, or shares purchased in the open market. Notwithstanding anything to the contrary in the 2019 Plan, no more than 25,000,000 shares of our common stock may be issued pursuant to the exercise of ISOs under the 2019 Plan.

The number of shares available for issuance will be increased by (i) the number of shares represented by awards outstanding under our 2013 Plan that expire, lapse or are terminated, exchanged for or settled in cash, surrendered, repurchased, cancelled without having been fully experienced or forfeited following the effective date of the 2019 Plan, with the maximum number of shares to be added to the 2019 Plan equal to 663,000 shares, and (ii) an annual increase on the first day of each calendar year beginning January 1, 2020 and ending on and including January 1, 2029, equal to the lessor of (A) 4% of the aggregate number of shares of common stock outstanding on the final day of the immediately preceding calendar year and (B) such smaller number of shares as is determined by our board of directors.

If an award under the 2019 Plan expires, lapses or is terminated, exchanged for or settled for cash, surrendered, repurchased, cancelled without having been fully exercised or forfeited any shares subject to such award may, to the extent of such forfeiture, expiration or cash settlement, be used again for new grants under the 2019 Plan. Further, shares delivered to us to satisfy the applicable exercise or purchase price of an award under the 2019 Plan or the 2013 Plan and/or to satisfy any applicable tax withholding obligations (including shares retained by us from the award under the 2019 Plan or the 2013 Plan being exercised or purchased and/or creating the tax obligation) will become or again be available for award grants under the 2019 Plan. The payment of dividend equivalents in cash in conjunction with any awards under the 2019 Plan will not reduce the shares available for grant under the 2019 Plan. However, the following shares may not be used again for grant under the 2019 Plan: (i) shares subject to stock appreciation rights, or SARs, that are not issued in connection with the stock settlement of the SAR on exercise, and (ii) shares purchased on the open market with the cash proceeds from the exercise of options.

Awards granted under the 2019 Plan upon the assumption of, or in substitution for, awards authorized or outstanding under a qualifying equity plan maintained by an entity with which we enter into a merger or similar corporate transaction will not reduce the shares available for grant under the 2019 Plan but will count against the maximum number of shares that may be issued upon the exercise of ISOs.

The 2019 Plan provides that the sum of any cash compensation and the aggregate grant date fair value (determined as of the date of the grant under ASC Topic 718, or any successor thereto) of all awards granted to a non-employee director as compensation for services as a non-employee director during any calendar year may not exceed the amount equal to $750,000, increased to $1,000,000, in the fiscal year of a non-employee director's initial service as a non-employee director.

Awards. The 2019 Plan provides for the grant of stock options, including ISOs and NSOs, SARs, restricted stock, dividend equivalents, restricted stock units, or RSUs, and other stock or cash based awards. Certain awards under the 2019 Plan may constitute or provide for a deferral of compensation, subject to Section 409A of the Code, which may impose additional requirements on the terms and conditions of such awards. All awards under the 2019 Plan will be evidenced by award agreements, which will detail all terms and conditions of the awards, including any applicable vesting and payment terms and post-termination exercise limitations. Awards other than cash awards generally will be settled in shares of our common stock, but the plan administrator may provide for cash settlement of any award. A brief description of each award type follows.

- *Stock Options and SARs*. Stock options provide for the purchase of shares of our common stock in the future at an exercise price set on the grant date. ISOs, in contrast to NSOs, may

provide tax deferral beyond exercise and favorable capital gains tax treatment to their holders if certain holding period and other requirements of the Code are satisfied. SARs entitle their holder, upon exercise, to receive from us an amount equal to the appreciation of the shares subject to the award between the grant date and the exercise date. The exercise price of a stock option or SAR may not be less than 100% of the fair market value of the underlying share on the grant date (or 110% in the case of ISOs granted to certain significant stockholders), except with respect to certain substitute awards granted in connection with a corporate transaction. The term of a stock option or SAR may not be longer than ten years (or five years in the case of ISOs granted to certain significant stockholders).

- *Restricted Stock*. Restricted stock is an award of nontransferable shares of our common stock that are subject to certain vesting conditions and other restrictions.
- *RSUs*. RSUs are contractual promises to deliver shares of our common stock in the future, which may also remain forfeitable unless and until specified conditions are met and may be accompanied by the right to receive the equivalent value of dividends paid on shares of common stock prior to the delivery of the underlying shares (i.e., dividend equivalent rights). The plan administrator may provide that the delivery of the shares underlying RSUs will be deferred on a mandatory basis or at the election of the participant. The terms and conditions applicable to RSUs will be determined by the plan administrator, subject to the conditions and limitations contained in the 2019 Plan.
- *Other Stock or Cash Based Awards*. Other stock or cash based awards are awards of cash, fully vested shares of our common stock and other awards valued wholly or partially by referring to, or otherwise based on, shares of our common stock. Other stock or cash based awards may be granted to participants and may also be available as a payment form in the settlement of other awards, as standalone payments and as payment in lieu of compensation to which a participant is otherwise entitled.
- *Dividend Equivalents*. Dividend equivalents represent the right to receive the equivalent value of dividends paid on shares of our common stock and may be granted alone or in tandem with awards other than stock options or SARs. Dividend equivalents are credited as of the dividend record dates during the period between the date an award is granted and the date such award vests, is exercised, is distributed or expires, as determined by the plan administrator.

Certain Transactions. The plan administrator has broad discretion to take action under the 2019 Plan, as well as make adjustments to the terms and conditions of existing and future awards, to prevent the dilution or enlargement of intended benefits and facilitate necessary or desirable changes in the event of certain transactions and events affecting our common stock, such as stock dividends, stock splits, mergers, acquisitions, consolidations and other corporate transactions. In addition, in the event of certain non-reciprocal transactions with our stockholders known as “equity restructurings,” the plan administrator will make equitable adjustments to the 2019 Plan and outstanding awards. In the event of a change in control of our company (as defined in the 2019 Plan), to the extent that the surviving entity declines to continue, convert, assume or replace outstanding awards, then all such awards will become fully vested and exercisable in connection with the transaction. Awards under the 2019 Plan are generally non-transferrable, except by will or the laws of descent and distribution, or, subject to the plan administrator’s consent, pursuant to a domestic relations order, and are generally exercisable only by the participant.

Foreign Participants, Claw-Back Provisions, Transferability, and Participant Payments. The plan administrator may modify award terms, establish subplans and/or adjust other terms and conditions of awards, subject to the share limits described above, in order to facilitate grants of awards subject to the laws and/or stock exchange rules of countries outside of the United States. All awards will be subject to the provisions of any claw-back policy implemented by our company to the extent set forth in such claw-back policy and/or in the applicable award agreement. With regard to tax withholding, exercise

price and purchase price obligations arising in connection with awards under the 2019 Plan, the plan administrator may, in its discretion, accept cash or check, shares of our common stock that meet specified conditions, a "market sell order" or such other consideration as it deems suitable.

Plan Amendment and Termination. Our board of directors may amend or terminate the 2019 Plan at any time; however, no amendment, other than an amendment that increases the number of shares available under the 2019 Plan, may materially and adversely affect an award outstanding under the 2019 Plan without the consent of the affected participant, and stockholder approval will be obtained for any amendment to the extent necessary to comply with applicable laws or to increase the director limit. The plan administrator will have the authority, without the approval of our stockholders, to "reprice" any stock option or SAR, or cancel any stock option or SAR in exchange for cash or another award when the option or SAR price per share exceeds the fair market value of the underlying shares. The 2019 Plan will remain in effect until the tenth anniversary of the date the board of directors adopted the 2019 Plan, unless earlier terminated.

2019 Employee Stock Purchase Plan

In connection with this offering, we adopted, and our stockholders approved, the ESPP, which became effective on the day the ESPP was adopted by our board of directors. The material terms of the ESPP are summarized below.

Shares Available; Administration. A total of 120,000 shares of our common stock is initially reserved for issuance under our ESPP. In addition, the number of shares available for issuance under the ESPP will be annually increased on January 1 of each calendar year beginning in 2020 and ending in 2029, by an amount equal to the lesser of: (i) 1% of the aggregate number of shares of common stock outstanding on the final day of the immediately preceding calendar year and (ii) such smaller number of shares as is determined by our board of directors. In no event will more than 5,000,000 shares of our common stock be available for issuance under the ESPP.

Our board of directors or a committee designated by our board of directors will have authority to interpret the terms of the ESPP and determine eligibility of participants. The compensation committee will be the administrator of the ESPP.

Eligibility. The plan administrator may designate certain of our subsidiaries as participating "designated subsidiaries" in the ESPP and may change these designations from time to time. Employees of our company and our designated subsidiaries are eligible to participate in the ESPP if they meet the eligibility requirements under the ESPP established from time to time by the plan administrator. However, an employee may not be granted rights to purchase stock under the ESPP if such employee, immediately after the grant, would own (directly or through attribution) stock possessing 5% or more of the total combined voting power or value of all classes of our common or other class of stock.

If the grant of a purchase right under the ESPP to any eligible employee who is a citizen or resident of a foreign jurisdiction would be prohibited under the laws of such foreign jurisdiction or the grant of a purchase right to such employee in compliance with the laws of such foreign jurisdiction would cause the ESPP to violate the requirements of Section 423 of the Code, as determined by the plan administrator in its sole discretion, such employee will not be permitted to participate in the ESPP.

Eligible employees become participants in the ESPP by enrolling and authorizing payroll deductions by the deadline established by the plan administrator prior to the relevant offering date. Directors who are not employees, as well as consultants, are not eligible to participate. Employees who choose not to participate, or are not eligible to participate at the start of an offering period but who become eligible thereafter, may enroll in any subsequent offering period.

Participation in an Offering. We intend for the ESPP to qualify under Section 423 of the Code and stock will be offered under the ESPP during offering periods. The length of offering periods under the ESPP will be determined by the plan administrator and may be up to 27 months long. Employee payroll deductions will be used to purchase shares on each purchase date during an offering period. The number of purchase periods within, and purchase dates during, each offering period will be established by the plan administrator. Offering periods under the ESPP will commence when determined by the plan administrator. The plan administrator may, in its discretion, modify the terms of future offering periods.

The ESPP will permit participants to purchase our common stock through payroll deductions of up to 20% of their eligible compensation, which will include a participant's gross base compensation for services to us, including overtime payments and excluding sales commissions, incentive compensation, bonuses, expense reimbursements, fringe benefits and other special payments. The plan administrator will establish a maximum number of shares that may be purchased by a participant during any offering period or purchase period, which, in the absence of a contrary designation, will be 100,000 shares. In addition, no employee will be permitted to accrue the right to purchase stock under the ESPP at a rate in excess of $25,000 worth of shares during any calendar year during which such a purchase right is outstanding (based on the fair market value per share of our common stock as of the first day of the offering period).

On the first trading day of each offering period, each participant automatically will be granted an option to purchase shares of our common stock. The option will be exercised on the applicable purchase date(s) during the offering period, to the extent of the payroll deductions accumulated during the applicable purchase period. We expect that the purchase price of the shares, in the absence of a contrary determination by the plan administrator, will be 85% of the lower of the fair market value of our common stock on the first trading day of the offering period or on the applicable purchase date, which will be the final trading day of the applicable purchase period.

Participants may voluntarily end their participation in the ESPP at any time at least one week prior to the end of the applicable offering period (or such longer or shorter period specified by the plan administrator), and will be paid their accrued payroll deductions that have not yet been used to purchase shares of common stock. Participation ends automatically upon a participant's termination of employment.

Transferability. A participant may not transfer rights granted under the ESPP other than by will, the laws of descent and distribution or as otherwise provided in the ESPP.

Certain Transactions. In the event of certain transactions or events affecting our common stock, such as any stock dividend or other distribution, change in control, reorganization, merger, consolidation or other corporate transaction, the plan administrator will make equitable adjustments to the ESPP and outstanding rights. In addition, in the event of the foregoing transactions or events or certain significant transactions, including a change in control, the plan administrator may provide for (i) either the replacement of outstanding rights with other rights or property or termination of outstanding rights in exchange for cash, (ii) the assumption or substitution of outstanding rights by the successor or survivor corporation or parent or subsidiary thereof, (iii) the adjustment in the number and type of shares of stock subject to outstanding rights, (iv) the use of participants' accumulated payroll deductions to purchase stock on a new purchase date prior to the next scheduled purchase date and termination of any rights under ongoing offering periods or (v) the termination of all outstanding rights. Under the ESPP, a change in control has the same definition as given to such term in the 2019 Plan.

Plan Amendment; Termination. The plan administrator may amend, suspend or terminate the ESPP at any time. However, stockholder approval of any amendment to the ESPP must be obtained

for any amendment which increases the aggregate number or changes the type of shares that may be sold pursuant to rights under the ESPP, changes the corporations or classes of corporations whose employees are eligible to participate in the ESPP, or changes the ESPP in any manner that would cause the ESPP to no longer be an employee stock purchase plan within the meaning of Section 423(b) of the Code. The ESPP will terminate on the tenth anniversary of the date it is initially approved by our board of directors.

Limitations of Liability and Indemnification Matters

Our amended and restated certificate of incorporation and our amended and restated bylaws provide that we will indemnify our directors and officers to the fullest extent permitted by the Delaware General Corporation Law, which prohibits our amended and restated certificate of incorporation from limiting the liability of our directors for the following:

- any breach of the director's duty of loyalty to us or our stockholders;
- acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- unlawful payment of dividends or unlawful stock repurchases or redemptions; or
- any transaction from which the director derived an improper personal benefit.

Our amended and restated certificate of incorporation and our amended and restated bylaws also provide that if Delaware law is amended to authorize corporate action further eliminating or limiting the personal liability of a director, then the liability of our directors will be eliminated or limited to the fullest extent permitted by Delaware law, as so amended. This limitation of liability does not apply to liabilities arising under the federal securities laws and does not affect the availability of equitable remedies such as injunctive relief or rescission.

Our amended and restated certificate of incorporation and our amended and restated bylaws also provide that we shall have the power to indemnify our employees and agents to the fullest extent permitted by law. Our amended and restated bylaws also permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in this capacity, regardless of whether our amended and restated bylaws would permit indemnification. We have obtained directors' and officers' liability insurance.

We have entered into separate indemnification agreements with our directors and executive officers, in addition to indemnification provided for in our amended and restated certificate of incorporation and amended and restated bylaws. These agreements, among other things, provide for indemnification of our directors and executive officers for expenses, judgments, fines and settlement amounts incurred by this person in any action or proceeding arising out of this person's services as a director or executive officer or at our request. We believe that these provisions in our amended and restated certificate of incorporation and amended and restated bylaws and indemnification agreements are necessary to attract and retain qualified persons as directors and executive officers.

The above description of the indemnification provisions of our amended and restated certificate of incorporation, our amended and restated bylaws and our indemnification agreements is not complete and is qualified in its entirety by reference to these documents, each of which is filed as an exhibit to the registration statement of which this prospectus is a part.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might benefit us and our

stockholders. A stockholder's investment may be harmed to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions. Insofar as indemnification for liabilities under the Securities Act may be permitted to directors, officers or persons controlling us pursuant to the foregoing provisions, we have been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable. There is no pending litigation or proceeding naming any of our directors or officers as to which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any director or officer.

CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS

The following includes a summary of transactions since January 1, 2016 to which we have been a party in which the amount involved exceeded or will exceed $120,000 (or, if less, 1% of the average of our total assets amounts as of December 31, 2016, 2017 and 2018), and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described under “Executive and Director Compensation.” We also describe below certain other transactions with our directors, executive officers and stockholders.

Redeemable Convertible Preferred Stock, Convertible Promissory Notes and Warrant Financings

Series E Redeemable Convertible Preferred Stock and Warrant Financing.

In January 2016, we entered into an agreement to issue shares of Series E redeemable convertible preferred stock, pursuant to which we sold to investors in an initial closing and subsequent closing in January 2016 and March 2016, respectively, in private placements an aggregate of 83,406,724 shares of Series E redeemable convertible preferred stock at a purchase price of $0.25 per share, for an aggregate purchase price of $16.9 million, including the conversion of previously outstanding convertible promissory notes and accrued interest thereon of approximately $11.6 million. Pursuant to the purchase agreement, we also issued to the investors warrants, or the 2016 Warrants, exercisable for up to an aggregate of 908,385 shares of our common stock. The 2016 Warrants are immediately exercisable at an exercise price of $1.84 per share, and expire in 2026.

In conjunction with the issuance of the Series E redeemable convertible preferred stock pursuant to the purchase agreement, existing investors exchanged an aggregate of 105,610, 41,509,393, 7,112,819, and 34,415,512, of previously outstanding shares of Series A-3, Series B-3, Series C, and Series D redeemable convertible preferred stock, respectively, for an aggregate of 83,143,334 shares of Series E redeemable convertible preferred stock.

As a result of the Series E financing, outstanding warrants issued in October 2015, or the 2015 Warrants, became exercisable for 2,688,181 shares of our Series E redeemable convertible preferred stock. The 2015 Warrants are immediately exercisable at an exercise price of $0.25 per share, and expire in October 2020.

2016 and 2017 Convertible Promissory Note Financings.

In June 2016, we entered into a note purchase agreement with certain existing holders of our redeemable convertible preferred stock pursuant to which we sold, in a private placement, an aggregate of $2.1 million of convertible promissory notes, or the June 2016 Notes. The June 2016 Notes accrued interest at a rate of 8% per annum and were due six months from the date of issuance, subject to their earlier conversion in the event we completed a qualified equity financing or a qualified initial public offering, or at the option of the investor at any time prior to the maturity date or upon the occurrence of a liquidation (as defined in our sixteenth amended and restated certificate of incorporation). In December 2016, we entered into an amendment to the convertible promissory notes issued in June 2016 to extend the maturity date to June 12, 2017.

In August 2016, we entered into a note purchase agreement with certain existing holders of our redeemable convertible preferred stock pursuant to which we sold, in a private placement, an aggregate of $1.0 million of convertible promissory notes, or the August 2016 Notes. The August 2016 Notes accrued interest at a rate of 8% per annum and were due six months from the date of issuance,

subject to their earlier conversion in the event we completed a qualified equity financing or a qualified initial public offering, or at the option of the investor at any time prior to the maturity date or upon the occurrence of a liquidation (as defined in our sixteenth amended and restated certificate of incorporation). In March 2017, we entered into an amendment to the convertible promissory notes issued in August 2016 to extend the maturity date to December 31, 2017.

In October 2016, we entered into a note purchase agreement with certain existing holders of our redeemable convertible preferred stock pursuant to which we sold, in a private placement, an aggregate of $1.0 million of convertible promissory notes. The October 2016 Notes accrued interest at a rate of 8% per annum and were due six months from the date of issuance, subject to their earlier conversion in the event we completed a qualified equity financing or a qualified initial public offering, or at the option of the investor at any time prior to the maturity date or upon the occurrence of a liquidation (as defined in our sixteenth amended and restated certificate of incorporation). In March 2017, we entered into an amendment to the convertible promissory notes issued in October 2016 to extend the maturity date to December 31, 2017.

In November 2016, we entered into a note purchase agreement with certain existing holders of our redeemable convertible preferred stock pursuant to which we sold, in a private placement, an aggregate of $1.0 million of convertible promissory notes. The November 2016 Notes accrued interest at a rate of 8% per annum and were due six months from the date of issuance, subject to their earlier conversion in the event we completed a qualified equity financing or a qualified initial public offering, or at the option of the investor at any time prior to the maturity date or upon the occurrence of a liquidation (as defined in our sixteenth amended and restated certificate of incorporation).

In December 2016, we entered into a note purchase agreement with certain existing holders of our redeemable convertible preferred stock pursuant to which we sold, in a private placement, an aggregate of $1.0 million of convertible promissory notes. The December 2016 Notes accrued interest at a rate of 8% per annum and were due six months from the date of issuance, subject to their earlier conversion in the event we completed a qualified equity financing or a qualified initial public offering, or at the option of the investor at any time prior to the maturity date or upon the occurrence of a liquidation (as defined in our sixteenth amended and restated certificate of incorporation).

In January 2017, we entered into a note purchase agreement with certain existing holders of our redeemable convertible preferred stock pursuant to which we sold, in a private placement, an aggregate of $1.0 million of convertible promissory notes. The January 2017 Notes accrued interest at a rate of 8% per annum and were due six months from the date of issuance, subject to their earlier conversion in the event we completed a qualified equity financing or a qualified initial public offering, or at the option of the investor at any time prior to the maturity date or upon the occurrence of a liquidation (as defined in our sixteenth amended and restated certificate of incorporation).

In February 2017, we entered into a note purchase agreement with certain existing holders of our redeemable convertible preferred stock pursuant to which we sold, in a private placement, an aggregate of $1.5 million of convertible promissory notes. The February 2017 Notes accrued interest at a rate of 8% per annum and were due six months from the date of issuance, subject to their earlier conversion in the event we completed a qualified equity financing or a qualified initial public offering, or at the option of the investor at any time prior to the maturity date or upon the occurrence of a liquidation (as defined in our sixteenth amended and restated certificate of incorporation).

In April 2017, we entered into a note purchase agreement with certain existing holders of our redeemable convertible preferred stock pursuant to which we sold, in a private placement, an aggregate of $1.3 million of convertible promissory notes. The April 2017 Notes accrued interest at a rate of 8% per annum and were due six months from the date of issuance, subject to their earlier

conversion in the event we completed a qualified equity financing or a qualified initial public offering, or at the option of the investor at any time prior to the maturity date or upon the occurrence of a liquidation (as defined in our sixteenth amended and restated certificate of incorporation).

The June 2016 Notes, August 2016 Notes, October 2016 Notes, November 2016 Notes, December 2016 Notes, January 2017 Notes, February 2017 Notes and April 2017 Notes are collectively referred to herein as the 2016 / 2017 Notes. Each of the 2016 / 2017 Notes were subordinated to borrowings under our Term Loan Agreement, dated October 10, 2013, with Capital Royalty Partners II L.P., Capital Royalty Partners II—Parallel Fund "A" L.P., Parallel Investment Opportunities Partners II L.P.

In May 2017, in conjunction with the issuance of Series F redeemable convertible preferred stock, the outstanding principal and accrued interest thereon of each of the 2016 / 2017 Notes, totaling $10.2 million, was converted into 163,785,334 shares of Series F redeemable convertible preferred stock.

Series F Redeemable Convertible Preferred Stock Financing.

In May 2017, we entered into an agreement to issue shares of Series F redeemable convertible preferred stock, which agreement was subsequently amended in August 2017, pursuant to which we sold to investors in an initial closing in May 2017 and subsequent closings between August 2017 and January 2018, in private placements an aggregate of 339,484,788 shares of Series F redeemable convertible preferred stock at a purchase price of $0.078 per share, for an aggregate purchase price of $23.9 million, including the conversion of the outstanding principal and accrued interest on the 2016/2017 Notes of approximately $10.2 million into 163,785,334 shares of our Series F redeemable convertible preferred stock.

Series G Redeemable Convertible Preferred Stock Financing.

In January 2019 we entered into an agreement to issue shares of our Series G redeemable convertible preferred stock, which agreement was subsequently amended in May 2019, pursuant to which we sold to investors in an initial closing in January 2019 and subsequent closings in March 2019 and May 2019, in private placements an aggregate of 148,928,337 shares of our Series G redeemable convertible preferred stock at a purchase price of $0.078 per share, for an aggregate purchase price of approximately $11.6 million. In addition, in May 2019, the Series G preferred stock agreement was amended to include a right by us to require certain holders of Series G redeemable convertible preferred stock, including NMSIC Focused LLC, Hunt Holdings, Limited Partnership and Tullis-Dickerson Capital Focus III, L.P., who are holders of more than 5% of our capital stock, to purchase an additional 32,051,280 shares of Series G redeemable convertible preferred stock at $0.078 per share, for total aggregate proceeds of $2.5 million, at any time after July 31, 2019 and prior to May 31, 2020. This right terminated in connection with our Series H redeemable convertible preferred stock financing in July 2019, as described below.

Series H Redeemable Convertible Preferred Stock Financing and Series G Conversion

In July 2019 we entered into an agreement to issue shares of our Series H redeemable convertible preferred stock, pursuant to which we sold to H.I.G. Bio-Exagen, L.P. in a single closing in July 2019, in a private placement an aggregate of 233,446,519 shares of our Series H redeemable convertible preferred stock at a purchase price of $0.04712 per share, for an aggregate purchase price of approximately $11.0 million.

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 1.6553 shares of Series H redeemable convertible preferred stock, for a total of 246,521,076 shares of Series H redeemable convertible preferred stock.

Each of the warrants to purchase shares of Series E redeemable convertible preferred stock identified in the following table will terminate if not exercised prior to the completion of this offering. Based on the initial public offering price of $14.00 per share, we expect that such warrants will terminate in connection with the offering because the exercise prices of these warrants are higher than the initial public offering price and these warrants otherwise terminate if not exercised prior to the completion of this offering. Each share of Series F redeemable convertible preferred stock and Series H redeemable convertible preferred stock will convert into 0.0054 share of common stock upon completion of this offering.

The following table sets forth the aggregate number of these securities acquired by the listed directors, executive officers or holders of more than 5% of our capital stock, or their affiliates since January 1, 2016.

Participants	Series E Redeemable Convertible Preferred Stock	Warrants to Purchase Series E Redeemable Convertible Preferred Stock	Series F Redeemable Convertible Preferred Stock	Series H Redeemable Convertible Preferred Stock(6)	Common Stock	Warrants to Purchase Common Stock
5% or Greater Stockholders(1)						
Entities affiliated with NMSIC Co-Investment Fund, L.P.(2)	64,239,884	1,135,886	112,958,220	53,054,485	–	349,823
Entities affiliated with Tullis-Dickerson Capital Focus III, L.P.(3)	53,251,030	658,823	81,166,266	59,102,693	–	289,981
H.I.G. Bio-Exagen, L.P.	–	–	–	233,446,519	–	–
Hunt Holdings, L.P.	37,096,550	604,864	60,028,640	54,145,517	–	202,011
Gerrit Johan Krediet	–	–	–	74,276,281	–	–
Directors						
Ebetuel Pallares, Ph.D.(4)	4,423,371	219,978	7,970,686	–	–	24,692
James L.L. Tullis(2)(5)	–	–	7,991,249	742,761	–	–

(1) Additional details regarding these stockholders and their equity holdings are provided herein under “Principal Stockholders.”

(2) Represents securities held by NMSIC Co-Investment Fund, L.P. and NMSIC Focused LLC.

(3) Represents securities held by Tullis-Dickerson Capital Focus III, L.P., Tullis Growth Fund, L.P. and Tullis Growth Fund II, L.P.

(4) Represents securities held by PCM/Exagen, L.P. (formerly known as CCP/Exagen, L.P.).

(5) Represents securities held by James L.L. Tullis, Linda A. Tullis and the HPS Irrevocable Trust #3 U/A Dtd 7/6/93.

(6) Amounts include shares issued upon conversion of Series G redeemable convertible preferred stock, as described above in more detail under “—Series H Redeemable Convertible Preferred Stock Financing and Series G Conversion.”

Some of our directors are associated with our principal stockholders as indicated in the table below:

Director	Principal Stockholder
Brian Birk	NMSIC Co-Investment Fund, L.P.
Bruce C. Robertson, Ph.D.	H.I.G. Bio-Exagen, L.P.
James L.L. Tullis	Tullis-Dickerson Capital Focus III, L.P.

Investors' Rights Agreement

We entered into an amended and restated investors' rights agreement in July 2019 with the holders of our redeemable convertible preferred stock, including entities with which certain of our directors are affiliated. This agreement provides for certain rights relating to the registration of their shares of common stock issuable upon conversion of their redeemable convertible preferred stock and certain additional covenants made by us. Except for the registration rights (including the related provisions pursuant to which we have agreed to indemnify the parties to the investors' rights agreement), all rights under this agreement will terminate upon completion of this offering. The registration rights will continue following this offering and will terminate three years following the completion of this offering, or for any particular holder with registration rights, at such time following this offering when such holder holds less than one percent of our outstanding common stock and may immediately sell all of such shares pursuant to Rule 144 under the Securities Act in a 90-day period. See "Description of Capital Stock—Registration Rights" for additional information.

Stockholders' Agreement

We entered into an amended and restated stockholders' agreement in July 2019, by and among us and certain of our stockholders, pursuant to which the following directors were each elected to serve as members on our board of directors and, as of the date of this prospectus, continue to serve: Brian Birk, Chet Burrell, Jeff Elliott, Tina S. Nova, Ph.D. Ebetuel Pallares, Ph.D., Bruce C. Robertson, Ph.D., Ron Rocca and James L.L. Tullis. Pursuant to the amended and restated stockholders' agreement, Mr. Rocca, as our Chief Executive Officer, was initially selected to serve on our board of directors as a representative of holders of our common stock, as designated by a majority of our common stockholders. Mr. Birk, Mr. Tullis, Dr. Pallares and Dr. Robertson were initially selected to serve on our board of directors as representatives of holders of our redeemable convertible preferred stock, as designated by NMSIC Co-Investment Fund, L.P., Tullis-Dickerson Capital Focus III, L.P., PCM/Exagen, L.P. (formerly known as CCP/Exagen, L.P.) and H.I.G. BioHealth Partners, LLC or its affiliates, respectively. Mr. Burrell, Mr. Elliott and Dr. Nova were selected to serve on our board of directors as designated by the holders of a majority of our outstanding Series H, Series F, Series E, Series D, Series C, and Series B-3 redeemable convertible preferred stock, voting together as a single class. The amended and restated stockholders' agreement also provides for certain other rights, including among others, a right of first refusal to purchase future securities.

The amended and restated stockholders' agreement, and all the rights granted pursuant to it, will terminate upon the completion of this offering, and members previously elected to our board of directors pursuant to this agreement will continue to serve as directors until they resign, are removed or their successors are duly elected by holders of our common stock. The composition of our board of directors after this offering is described in more detail under "Management—Board Composition and Election of Directors."

New Mexico Lease

In 2016 and 2017, we leased office space in New Mexico from a third party which specializes in providing outsourced information technology support services, and a partner in this company was an immediate family member of Wendy Rollstin, our former Chief Financial Officer. We also used the information technology support services of this third party during 2016 and 2017. As of December 31, 2017, we no longer lease this facility and Ms. Rollstin is no longer employed by us. Total expenses related to rent expense and information technology support services provided by this related party for the years ended December 31, 2017 and 2016 was $179,000 and $194,000, respectively.

Employment Agreements

We have entered into an offer letters with each of our named executive officers. For more information regarding these agreements, see the section in this prospectus entitled "Executive and Director Compensation—Narrative Disclosure to Summary Compensation Table—Offer Letters with our Named Executive Officers."

Agreement with Dr. Dervieux

In September 2011, we entered into a license agreement with Dr. Dervieux and his company, DeNovo. The license agreement, covering novel methods for monitoring low-dose methotrexate therapy, relates to technology developed by Dr. Dervieux prior to joining us. The technology has yet to be used by us. Under the agreement, Dr. Dervieux would be eligible to receive up to $600,000 when and if we achieve certain sales milestones and a single-digit percentage royalty on sales on an ongoing basis.

Indemnification Agreements

We have entered into indemnification agreements with each of our directors and executive officers prior to the completion of this offering. These agreements, among other things, require us or will require us to indemnify each director (and in certain cases their related venture capital funds) and executive officer to the fullest extent permitted by Delaware law, including indemnification of expenses such as attorneys' fees, judgments, fines and settlement amounts incurred by the director or executive officer in any action or proceeding, including any action or proceeding by or in right of us, arising out of the person's services as a director or executive officer.

Our amended and restated certificate of incorporation and our amended and restated bylaws provide that we will indemnify each of our directors and officers to the fullest extent permitted by the Delaware General Corporation Law. Further, we have entered into indemnification agreements with each of our directors and officers, and we have purchased a policy of directors' and officers' liability insurance that insures our directors and officers against the cost of defense, settlement or payment of a judgment under certain circumstances. For further information, see "Executive and Director Compensation—Limitations of Liability and Indemnification Matters."

Stock Option Grants to Executive Officers and Directors

We have granted stock options to our executive officers and certain of our directors as more fully described in the section entitled "Executive and Director Compensation."

Participation in this Offering

Certain affiliates of our directors and other existing stockholders have indicated an interest in purchasing an aggregate of approximately $12.0 million in shares of our common stock in this offering at the initial public offering price per share and on the same terms as the other purchasers in this offering. However, because these indications of interest are not binding agreements or commitments to purchase, the underwriters may determine to sell more, less or no shares in this offering to any or all of these stockholders, or any or all of these stockholders may determine to purchase more, less or no shares in this offering.

Policies and Procedures for Related Person Transactions

Our board of directors will adopt written related person transaction policy, to be effective upon the completion of this offering, setting forth the policies and procedures for the review and approval or ratification of related-person transactions. This policy will cover, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships in which we were or are to be a participant, where the amount involved exceeds $120,000 (or, if less, 1% of the average of our total assets at year-end for the last two completed fiscal years) and a related person had or will have a direct or indirect material interest, including, without limitation, purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness and employment by us of a related person. In reviewing and approving

any such transactions, our audit committee is tasked to consider all relevant facts and circumstances, including, but not limited to, whether the transaction is on terms comparable to those that could be obtained in an arm's length transaction and the extent of the related person's interest in the transaction. All of the transactions described in this section occurred prior to the adoption of this policy.

PRINCIPAL STOCKHOLDERS

The following table sets forth information with respect to the beneficial ownership of our common stock as of June 30, 2019, and as adjusted to reflect the sale of shares of common stock in this offering, by:

- each of our named executive officers;
- each of our directors;
- all of our executive officers and directors as a group; and
- each person or group of affiliated persons known by us to beneficially own more than 5% of our common stock.

The number of shares beneficially owned by each stockholder is determined under rules issued by the SEC. Under these rules, beneficial ownership includes any shares as to which a person has sole or shared voting power or investment power. Applicable percentage ownership is based on 7,879,698 shares of common stock outstanding as of June 30, 2019, which gives effect to the automatic conversion of all outstanding shares of redeemable convertible preferred stock into 7,816,643 shares of common stock (including the conversion of 479,967,595 shares of our Series H redeemable convertible preferred stock issued in July 2019 into 2,613,703 shares of common stock). Our calculation of beneficial ownership after the offering gives additional effect to (1) the issuance of 15,072 shares of common stock as a result of the expected net exercise of the Net Exercise Warrants in connection with the completion of this offering based on the initial public offering price of $14.00 per share, which warrants will terminate if not exercised prior to the completion of this offering, and (2) the issuance of 3,600,000 shares of common stock in this offering at the initial public offering price of $14.00 per share. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, shares of common stock subject to options, warrants or other rights held by such person that are currently exercisable or will become exercisable within 60 days of June 30, 2019 are considered outstanding, although these shares are not considered outstanding for purposes of computing the percentage ownership of any other person.

Unless otherwise indicated, the address of each beneficial owner listed below is c/o Exagen Inc., 1261 Liberty Way, Suite C, Vista, California 92081. We believe, based on information provided to us that each of the stockholders listed below has sole voting and investment power with respect to the shares beneficially owned by the stockholder unless noted otherwise, subject to community property laws where applicable.

Certain of our existing stockholders, including entities affiliated with certain of our directors, have indicated an interest in purchasing an aggregate of approximately $12.0 million in shares of our common stock in this offering at the initial public offering price per share and on the same terms as the other purchasers in this offering. However, because these indications of interest are not binding agreements or commitments to purchase, the underwriters may determine to sell more, less or no shares in this offering to any or all of these stockholders, or any or all of these stockholders may determine to purchase more, less or no shares in this offering. The following table does not reflect any such potential purchases by these stockholders or their affiliated entities. If any shares are purchased by these stockholders, the number of shares of common stock beneficially owned after this offering and the percentage of common stock beneficially owned after this offering would increase from that set forth in the table below.

	Shares Beneficially Owned Prior to Offering		Shares Beneficially Owned After Offering	
Name of Beneficial Owner	Number	Percentage	Number	Percentage
5% or Greater Stockholders				
Entities affiliated with NMSIC Co-Investment Fund, L.P.(1)	2,590,397	31.5%	2,590,397	21.9%
Entities Affiliated with Tullis-Dickerson Capital Focus III, L.P.(2)	2,076,933	25.4%	2,076,933	17.6%
Hunt Holdings, L.P.(3)	1,496,364	18.5%	1,496,364	12.8%
H.I.G. Bio-Exagen, L.P.	1,271,252	16.1%	1,271,252	11.1%
Gerrit Johan Krediet	404,477	5.1%	404,477	3.5%
Named Executive Officers and Directors				
Fortunato Ron Rocca	–	*	–	*
Kamal Adawi	–	*	–	*
Thierry Dervieux, Ph.D.	–	*	–	*
Brian Birk(1)	2,590,397	31.5%	2,590,397	21.9%
Chet Burrell	–	*	–	*
Jeff Elliott	–	*	–	*
Tina S. Nova, Ph.D.	–	*	–	*
Ebetuel Pallares, Ph.D.(4)	145,480	1.8%	145,480	1.3%
Bruce C. Robertson, Ph.D.(5)	1,271,252	16.1%	1,271,252	11.1%
James L.L. Tullis(2)(6)	2,124,493	26.0%	2,124,493	18.0%
All executive officers and directors as a group (10 persons)	6,131,622	71.8%	6,131,622	50.4%

* Less than 1%.

(1) Consists of (a) 659,711 shares of common stock held by NMSIC Co-Investment Fund, L.P., or NMSIC, and (b) 1,580,863 shares of common stock and 349,823 shares of common stock issuable upon the exercise of warrants held by NMSIC Focused, LLC, or NMSIC Focused. Excludes (i) 2,281 shares of common stock issuable upon the exercise of warrants to purchase common stock, and (ii) 19,825 shares of common stock issuable upon exercise of warrants to purchase shares of Series E redeemable convertible preferred stock held by NMSIC Focused, all of which warrants will terminate in connection with this offering because the exercise prices for these warrants are higher than the initial public offering price of this offering. The general partner of NMSIC is Sun Mountain Capital Partners LLC, or Sun Mountain. NMSIC is the sole member of NMSIC Focused. The controlling members of Sun Mountain are Brian Birk, one of our directors, Sally Corning and Lee Rand. As a result, each of Sun Mountain, Mr. Birk, Ms. Corning and Mr. Rand may be deemed to possess voting and investment control over, and may be deemed to have indirect beneficial ownership with respect to, all shares held by NMSIC or NMSIC Focused. Neither Sun Mountain, Mr. Birk, Ms. Corning nor Mr. Rand owns directly any of the shares. Each of Sun Mountain, Mr. Birk, Ms. Corning and Mr. Rand disclaims beneficial ownership of the shares held by

NMSIC or NMSIC Focused, except to the extent of their pecuniary interest therein. The address for each of the NMSIC entities is 527 Don Gaspar Avenue, Santa Fe, New Mexico 87505.

(2) Consists of (a) 1,103,125 shares of common stock and 119,536 shares of common stock issuable upon the exercise of warrants held by Tullis-Dickerson Capital Focus III, L.P., or Tullis, (b) 578,374 shares of common stock and 170,445 shares of common stock issuable upon the exercise of warrants held by Tullis Growth Fund, L.P, and (c) 105,453 shares of common stock held by Tullis Growth Fund II, L.P. Excludes (i) 1,361 shares of common stock issuable upon the exercise of warrants to purchase common stock, and 43 shares of common stock issuable upon exercise of warrants to purchase shares of Series E redeemable convertible preferred stock held by Tullis, and (ii) 11,455 shares of common stock issuable upon exercise of warrants to purchase shares of Series E redeemable convertible preferred stock held by Tullis Growth Fund, L.P., all of which warrants will terminate in connection with this offering because the exercise prices for these warrants are higher than the initial public offering price of this offering. Tullis-Dickerson Partners III, LLC ("Tullis Partners") is the general partner of Tullis and may be deemed to beneficially own the securities held by Tullis. Tullis Growth Partners, LLC ("Growth Partners") and Tullis Growth Partners II, LLC ("Growth Partners II") are the general partners of Tullis Growth and Tullis Growth II, respectively, and may be deemed to beneficially own the securities held by Tullis Growth and Tullis Growth II. James L.L. Tullis, one of our directors, is a Principal of each of the foregoing entities and may be deemed to possess voting and investment control over, and may be deemed to have an indirect beneficial ownership interest with respect to, the shares held by Tullis, Tullis Growth and Tullis Growth II. The address for each of the Tullis entities is 500 West Putnam Avenue, Suite 400, Stamford, Connecticut 06830.

(3) Consists of 1,294,353 shares of common stock, and 202,011 shares of common stock issuable upon the exercise of warrants held by Hunt Holdings, L.P. Excludes 1,434 shares of common stock issuable upon the exercise of warrants to purchase common stock held by Hunt Holdings, L.P., and 10,557 shares of common stock issuable upon exercise of warrants to purchase shares of Series E redeemable convertible preferred stock held by Hunt Holdings, L.P., all of which warrants will terminate in connection with this offering because the exercise prices for these warrants are higher than the initial public offering price of this offering. Woody L. Hunt is the majority shareholder of Hunt Guaranty Inc., which is the sole member of HuntVest, LLC, which is the general partner of Hunt Holdings Limited Partnership. As a result, Mr. Hunt and each of the foregoing entities may be deemed to indirectly beneficially own the securities held by Hunt Holdings Limited Partnership, but each disclaims beneficial ownership of such securities. The address of each of the foregoing entities is 4401 N. Mesa St., El Paso, Texas 79902.

(4) Consists of 120,788 shares of common stock and 24,692 shares of common stock issuable upon the exercise of warrants held by PCM/Exagen, L.P., or PCM. Excludes 199 shares of common stock issuable upon the exercise of warrants to purchase common stock held by PCM, and 3,839 shares of common stock issuable upon exercise of warrants to purchase shares of Series E redeemable convertible preferred stock held by PCM, all of which warrants will terminate in connection with this offering because the exercise prices for these warrants are higher than the initial public offering price of this offering. Dr. Pallares, one of our directors, is a co-manager of PCM. As a result, each of PCM and Dr. Pallares may be deemed to possess voting and investment control over, and may be deemed to have an indirect beneficial ownership interest with respect to, all shares held by PCM. Prior to August 6, 2015, PCM was previously known as CCP/Exagen L.P.

(5) H.I.G. Capital, LLC has sole voting and investment control over the shares owned by H.I.G. Bio-Exagen, LLC. Bruce C. Robertson, Ph.D. is a managing director of H.I.G. Capital, LLC and may be deemed to share voting and investment control over, and may be deemed to have an indirect beneficial ownership interest with respect to, all shares held by H.I.G. Bio-Exagen, L.P. The address of H.I.G. Bio-Exagen, LLC is 1450 Brickell Avenue, 31st Floor, Miami, FL 33131.

(6) Consists of (a) 41,592 shares of common stock held by James L.L. Tullis, (b) 1,431 shares of common stock held by Linda A. Tullis, and (c) 4,537 shares of common stock held by the HPS Irrevocable Trust #3 U/A Dtd 7/6/93.

DESCRIPTION OF CAPITAL STOCK

General

The following description summarizes some of the terms of our amended and restated certificate of incorporation and amended and restated bylaws, our outstanding warrants, the amended and restated investors' rights agreement and of the Delaware General Corporation Law. Because it is only a summary, it does not contain all the information that may be important to you. For a complete description you should refer to our amended and restated certificate of incorporation, amended and restated bylaws, warrants and amended and restated investors' rights agreement, copies of which have been filed or incorporated by reference as exhibits to the registration statement of which the prospectus is a part, as well as the relevant provisions of the Delaware General Corporation Law.

Following the completion of this offering, our authorized capital stock will consist of 200,000,000 shares of common stock, $0.001 par value per share, and 10,000,000 shares of preferred stock, $0.001 par value per share.

Common Stock

As of June 30, 2019, there were 7,894,770 shares of our common stock outstanding and held of record by 75 stockholders, assuming (i) the automatic conversion of all outstanding shares of our redeemable convertible preferred stock into shares of common stock, which will occur immediately prior to the completion of this offering, and (ii) the issuance of 15,072 shares of common stock as a result of the expected net exercise of the Net Exercise Warrants in connection with the completion of this offering, based on the initial public offering price of $14.00 per share, which Net Exercise Warrants will terminate if not exercised prior to the completion of this offering. Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders, including the election of directors, and do not have cumulative voting rights. Accordingly, the holders of a majority of the outstanding shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they so choose, other than any directors that holders of any preferred stock we may issue may be entitled to elect. Subject to the supermajority votes for some matters, other matters shall be decided by the affirmative vote of our stockholders having a majority in voting power of the votes cast by the stockholders present or represented and voting on such matter. Our amended and restated certificate of incorporation and amended and restated bylaws also provide that our directors may be removed only for cause and only by the affirmative vote of the holders of at least two-thirds in voting power of the outstanding shares of capital stock entitled to vote thereon. In addition, the affirmative vote of the holders of at least two-thirds in voting power of the outstanding shares of capital stock entitled to vote thereon is required to amend or repeal, or to adopt any provision inconsistent with, several of the provisions of our amended and restated certificate of incorporation. See below under "—Anti-Takeover Effects of Delaware Law and Our Certificate of Incorporation and Bylaws—Amendment of Charter Provisions."

Subject to preferences that may be applicable to any then outstanding preferred stock, holders of common stock are entitled to receive ratably those dividends, if any, as may be declared by the board of directors out of legally available funds. In the event of our liquidation, dissolution or winding up, the holders of common stock will be entitled to share ratably in the assets legally available for distribution to stockholders after the payment of or provision for all of our debts and other liabilities, subject to the prior rights of any preferred stock then outstanding. Holders of common stock have no preemptive or conversion rights or other subscription rights and there are no redemption or sinking funds provisions applicable to the common stock. All outstanding shares of common stock are, and the common stock to be outstanding upon the closing of this offering will be, duly authorized, validly issued, fully paid and nonassessable. The rights, preferences and privileges of holders of common stock are subject to and

may be adversely affected by the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

Preferred Stock

Upon completion of this offering, all of our previously outstanding shares of redeemable convertible preferred stock will have been converted into common stock, there will be no authorized shares of our previously redeemable convertible preferred stock and we will have no shares of preferred stock outstanding. Under the terms of our amended and restated certificate of incorporation, which will become effective immediately prior to the completion of this offering, our board of directors has the authority, without further action by our stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the dividend, voting and other rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon, and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding.

Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in our control and may adversely affect the market price of the common stock and the voting and other rights of the holders of common stock. We have no current plans to issue any shares of preferred stock.

Options

As of June 30, 2019, options to purchase 662,987 shares of our common stock were outstanding under our 2002 Plan and 2013 Plan, of which 20,180 were vested and exercisable as of that date. For additional information regarding the terms of our 2002 Plan and 2013 Plan, see “Executive and Director Compensation—Equity Incentive Award Plans.”

Warrants

As of June 30, 2019, 934,789 shares of our common stock were issuable upon the exercise of outstanding warrants to purchase common stock, with a weighted-average exercise price of $8.49 per share. Following the completion of this offering, 908,385 of these warrants to purchase shares of our common stock will be exercisable for an aggregate of 908,385 shares of our common stock at an exercise price of $1.84 per share. If the remaining warrants to purchase common stock are not exercised prior to the completion of this offering, they will terminate. Of the remaining warrants, we expect warrants to purchase 17,350 shares of common stock with an exercise price of $1.84 per share to be net exercised in connection with the completion of this offering, resulting in the issuance of an aggregate of 15,072 shares of our common stock based on the initial public offering price of $14.00 per share.

As of June 30, 2019, 4,174,430 shares of our Series D redeemable convertible preferred stock were issuable upon exercise of outstanding warrants, with an exercise price of $0.25 per share. These warrants are immediately exercisable. Warrants to purchase 3,186,430 shares of our Series D redeemable convertible preferred stock expire in October 2023 and warrants to purchase 988,000 shares of our Series D redeemable convertible preferred stock expire in November 2023. If these warrants are not exercised prior to the completion of this offering, they will terminate.

As of June 30, 2019, 2,688,181 shares of our Series E redeemable convertible preferred stock were issuable upon exercise of outstanding warrants with an exercise price of $0.25 per share. These

warrants are immediately exercisable and expire in October 2020. If these warrants are not exercised prior to the completion of this offering, they will terminate.

As of June 30, 2019, 19,230,769 shares of our Series F redeemable convertible preferred stock were issuable upon exercise of outstanding warrants with an exercise price of $0.078 per share. Upon conversion of the Series F redeemable convertible preferred stock into common stock in connection with the completion of this offering, these 19,230,769 warrants to purchase shares of our Series F preferred stock warrants will become exercisable for an aggregate of 104,722 shares of our common stock at an exercise price of $14.32 per share. These warrants are immediately exercisable. Warrants to purchase 15,384,615 shares of our Series F redeemable convertible preferred stock will expire in September 2024 and warrants to purchase 3,846,154 shares of our Series F redeemable convertible preferred stock will expire in December 2025.

Each of the above warrants has a net exercise provision under which the holder may, in lieu of payment of the exercise price in cash, surrender the warrant and receive a net amount of shares of our common stock based on the fair market value of our common stock at the time of the net exercise of the warrant after deduction of the aggregate exercise price. These warrants also contain provisions for the adjustment of the exercise price and the aggregate number of shares issuable upon the exercise of the warrants in the event of stock dividends, stock splits, reorganizations and reclassifications and consolidations.

Registration Rights

As of June 30, 2019, upon the completion of this offering, holders of 7,878,463 shares of our common stock, which includes all of the shares of common stock issuable upon the automatic conversion of our redeemable convertible preferred stock immediately prior to the completion of this offering, and holders of warrants to purchase an aggregate of 1,013,107 shares of common stock, will be entitled to the following rights with respect to the registration of such shares for public resale under the Securities Act, pursuant to an investor rights agreement by and among us and certain of our stockholders. The registration of shares of common stock as a result of the following rights being exercised would enable holders to trade these shares without restriction under the Securities Act when the applicable registration statement is declared effective.

Demand Registration Rights

Form S-1. If at any time for a period of three years following the completion of this offering, the holders of at least 50% of the registrable securities request in writing that we effect a registration with respect to their shares in an offering, we may be required to register their shares. We are obligated to effect at most two registrations for the holders of registrable securities in response to these demand registration rights, subject to certain exceptions.

Form S-3. If at any time beginning 180 days following the completion of this offering and we become entitled under the Securities Act to register our shares on Form S-3, a holder of registrable securities requests in writing that we register their shares for public resale on Form S-3 and the price to the public of the offering is $1.0 million or more, we will be required to provide notice to all holders of registrable securities and to use our best efforts to effect such registration; provided, however, that we will not be required to effect such a registration if, within the preceding 12 months, we have already effected two registrations on Form S-3 for the holders of registrable securities.

In each of the above registrations, if the holders requesting registration intend to distribute their shares by means of an underwriting, the managing underwriter of such offering will have the right to limit the numbers of shares to be underwritten for reasons related to the marketing of the shares.

Piggyback Registration Rights

If at any time for a period of three years following the completion of this offering we propose to register any shares of our common stock under the Securities Act, subject to certain exceptions, the holders of registrable securities will be entitled to notice of the registration and to include their shares of registrable securities in the registration. If our proposed registration involves an underwriting, the managing underwriter of such offering will have the right to limit the number of shares to be underwritten for reasons related to the marketing of the shares.

Expenses

Ordinarily, other than underwriting discounts and commissions, we will be required to pay all expenses incurred by us related to any registration effected pursuant to the exercise of these registration rights. These expenses may include all registration and filing fees, printing expenses, fees and disbursements of our counsel, reasonable fees and disbursements of a counsel for the selling securityholders, blue sky fees and expenses and the expenses of any special audits incident to the registration.

Termination of Registration Rights

The registration rights terminate upon the earlier of three years after the completion of this offering, or for any particular holder with registration rights, at such time following this offering when such holder holds less than one percent of our outstanding common stock and may immediately sell all of such shares pursuant to Rule 144 under the Securities Act in a 90-day period.

Anti-Takeover Effects of Delaware Law and Our Certificate of Incorporation and Bylaws

Some provisions of Delaware law, our amended and restated certificate of incorporation and our amended and restated bylaws contain provisions that could make the following transactions more difficult: an acquisition of us by means of a tender offer; an acquisition of us by means of a proxy contest or otherwise; or the removal of our incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in our best interests, including transactions which provide for payment of a premium over the market price for our shares.

These provisions, summarized below, are intended to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of the increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

Undesignated Preferred Stock

The ability of our board of directors, without action by the stockholders, to issue up to 10,000,000 shares of undesignated preferred stock with voting or other rights or preferences as designated by our board of directors could impede the success of any attempt to change control of us. These and other provisions may have the effect of deferring hostile takeovers or delaying changes in control or management of our company.

Stockholder Meetings

Our amended and restated bylaws provide that a special meeting of stockholders may be called only by our chairman of the board, chief executive officer or president, or by a resolution adopted by a majority of our board of directors.

Requirements for Advance Notification of Stockholder Nominations and Proposals

Our amended and restated bylaws establish advance notice procedures with respect to stockholder proposals to be brought before a stockholder meeting and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of directors.

Elimination of Stockholder Action by Written Consent

Our amended and restated certificate of incorporation and amended and restated bylaws eliminate the right of stockholders to act by written consent without a meeting.

Staggered Board

Our board of directors is divided into three classes. The directors in each class will serve for a three-year term (other than the directors initially assigned to Class I whose term shall expire at our first annual meeting of stockholders), one class being elected each year by our stockholders. For more information on the classified board, see “Management—Board Composition and Election of Directors.” This system of electing and removing directors may tend to discourage a third-party from making a tender offer or otherwise attempting to obtain control of us, because it generally makes it more difficult for stockholders to replace a majority of the directors.

Removal of Directors

Our amended and restated certificate of incorporation provides that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two thirds of the total voting power of all of our outstanding voting stock then entitled to vote in the election of directors.

Stockholders Not Entitled to Cumulative Voting

Our amended and restated certificate of incorporation does not permit stockholders to cumulate their votes in the election of directors. Accordingly, the holders of a majority of the outstanding shares of our common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they choose, other than any directors that holders of our preferred stock may be entitled to elect.

Delaware Anti-Takeover Statute

We are subject to Section 203 of the Delaware General Corporation Law, which prohibits persons deemed to be “interested stockholders” from engaging in a “business combination” with a publicly held Delaware corporation for three years following the date these persons become interested stockholders unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, an “interested stockholder” is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation’s voting stock. Generally, a “business combination” includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by the board of directors.

Choice of Forum

Our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative form, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for: (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of breach of a fiduciary duty or other wrongdoing by any of our directors, officers,

employees or agents to us or our stockholders, creditors or other constituents; (iii) any action asserting a claim against us arising pursuant to any provision of the General Corporation Law of the State of Delaware or our amended and restated certificate of incorporation or amended and restated bylaws; (iv) any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or bylaws; or (v) any action asserting a claim governed by the internal affairs doctrine. The provision would not apply to suits brought to enforce a duty or liability created by the Securities Act or the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. To the extent that any such claims may be based upon federal law claims, Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. In any case, stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. Our restated certificate of incorporation also provides that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock will be deemed to have notice of and to have consented to this choice of forum provision.

Amendment of Charter Provisions

The amendment of any of the above provisions, except for the provision making it possible for our board of directors to issue preferred stock, would require approval by holders of at least two thirds of the total voting power of all of our outstanding voting stock.

The provisions of Delaware law, our amended and restated certificate of incorporation and our amended and restated bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in the composition of our board and management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock will be Computershare Trust Company, N.A. The transfer agent and registrar's address is 250 Royal Street, Canton, Massachusetts 02021.

Nasdaq Global Market

Our common stock has been approved for listing on the Nasdaq Global Market under the symbol "XGN."

Limitations of Liability and Indemnification Matters

For a discussion of liability and indemnification, see "Executive and Director Compensation—Limitations of Liability and Indemnification Matters."

SHARES ELIGIBLE FOR FUTURE SALE

Immediately prior to this offering, there was no public market for our common stock. Future sales of substantial amounts of common stock in the public market, or the perception that such sales may occur, could adversely affect the market price of our common stock. Although our common stock has been approved for listing on the Nasdaq Global Market, we cannot assure you that there will be an active public market for our common stock.

Based on the number of shares of our common stock outstanding as of June 30, 2019 and assuming (i) the issuance of 3,600,000 shares in this offering, (ii) the automatic conversion of all outstanding shares of our redeemable convertible preferred stock into 7,816,643 shares of our common stock, which will automatically occur immediately prior to the completion of the offering, (iii) no exercise of the underwriters' option to purchase additional shares of common stock, (iv) the expected net exercise of the Net Exercise Warrants and (v) no exercise of outstanding options or warrants (other than the Net Exercise Warrants), we will have outstanding an aggregate of approximately 11,494,770 shares of common stock.

Of these shares, all shares sold in this offering will be freely tradable without restriction or further registration under the Securities Act, except for any shares purchased by our "affiliates," as that term is defined in Rule 144 under the Securities Act. Shares purchased by our affiliates would be subject to the Rule 144 resale restrictions described below, other than the holding period requirement.

The remaining 7,894,770 shares of common stock will be "restricted securities," as that term is defined in Rule 144 under the Securities Act. These restricted securities are eligible for public sale only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rule 144 or 701 under the Securities Act, each of which is summarized below. We expect that substantially all of these shares will be subject to the 180-day lock-up period under the lock-up agreements described below.

In addition, of the 662,987 shares of our common stock that were subject to stock options outstanding as of June 30, 2019, options to purchase 20,180 of such shares of common stock were vested as of such date. Upon exercise, these shares will be eligible for sale subject to the lock–up agreements described below and Rules 144 and 701 under the Securities Act.

Lock-Up Agreements

We, along with our directors, executive officers and substantially all of our securityholders have agreed with the underwriters that for a period of 180 days, after the date of this prospectus, subject to specified exceptions, we or they will not offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to sale of, or otherwise dispose of or transfer any shares of common stock or any securities convertible into or exercisable or exchangeable for shares of common stock, request or demand that we file a registration statement related to our common stock or enter into any swap or other agreement that transfers to another, in whole or in part, directly or indirectly, the economic consequence of ownership of the common stock. Upon expiration of the lock-up period, certain of our stockholders and warrantholders will have the right to require us to register their shares under the Securities Act. See "—Registration Rights" below and "Description of Capital Stock—Registration Rights."

Cowen and Company, LLC, Cantor Fitzgerald & Co. and William Blair & Company, L.L.C. may, in their sole discretion and at any time or from time to time before the termination of the lock-up period, without public notice, release all or any portion of the securities subject to lock-up agreements. There are no existing agreements between the underwriters and any of our stockholders who will execute a lock-up agreement providing consent to the sale of shares prior to the expiration of the lock-up period.

Upon the expiration of the lock-up period, substantially all of the shares subject to such lock-up restrictions will become eligible for sale, subject to the limitations discussed above.

Rule 10b5-1 Trading Plans

Following the completion of this offering, certain of our officers, directors and significant stockholders may adopt written plans, known as Rule 10b5-1 trading plans, in which they will contract with a broker to buy or sell shares of our common stock on a periodic basis to diversify their assets and investments. Under these 10b5-1 trading plans, a broker may execute trades pursuant to parameters established by the officer, director or stockholder when entering into the plan, without further direction from such officer, director or stockholder. Such sales would not commence until the expiration of the applicable lock-up agreements entered into by such officer, director or stockholder in connection with this offering.

Rule 144

Affiliate Resales of Restricted Securities

In general, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is an affiliate of ours, or who was an affiliate at any time during the 90 days before a sale, who has beneficially owned shares of our common stock for at least six months would be entitled to sell in “broker’s transactions” or certain “riskless principal transactions” or to market makers, a number of shares within any three-month period that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately 114,947 shares immediately after this offering; or
- the average weekly trading volume in our common stock on Nasdaq during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Affiliate resales under Rule 144 are also subject to the availability of current public information about us. In addition, if the number of shares being sold under Rule 144 by an affiliate during any three-month period exceeds 5,000 shares or has an aggregate sale price in excess of $50,000, the seller must file a notice on Form 144 with the SEC and the Nasdaq Global Market concurrently with either the placing of a sale order with the broker or the execution of a sale directly with a market maker.

Non-Affiliate Resales of Restricted Securities

In general, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is not an affiliate of ours at the time of sale, and has not been an affiliate at any time during the three months preceding a sale, and who has beneficially owned shares of our common stock for at least six months but less than a year, is entitled to sell such shares subject only to the availability of current public information about us. If such person has held our shares for at least one year, such person can resell under Rule 144(b)(1) without regard to any Rule 144 restrictions, including the 90-day public company requirement and the current public information requirement.

Non-affiliate resales are not subject to the manner of sale, volume limitation or notice filing provisions of Rule 144.

Rule 701

In general, under Rule 701, any of an issuer’s employees, directors, officers, consultants or advisors who purchases shares from the issuer in connection with a compensatory stock or option plan or other written agreement before the effective date of a registration statement under the Securities Act

is entitled to sell such shares 90 days after such effective date in reliance on Rule 144. An affiliate of the issuer can resell shares in reliance on Rule 144 without having to comply with the holding period requirement, and non-affiliates of the issuer can resell shares in reliance on Rule 144 without having to comply with the current public information and holding period requirements.

Equity Plans

We intend to file one or more registration statements on Form S-8 under the Securities Act to register all shares of common stock subject to outstanding stock options and common stock issuable under our equity incentive plans and ESPP. We expect to file the registration statement covering shares offered pursuant to these stock plans shortly after the date of this prospectus, permitting the resale of such shares by non-affiliates in the public market without restriction under the Securities Act and the sale by affiliates in the public market subject to compliance with the resale provisions of Rule 144.

Registration Rights

As of June 30, 2019, upon the completion of this offering, holders of 7,878,463 shares of our common stock, which includes all of the shares of common stock issuable upon the automatic conversion of our redeemable convertible preferred stock immediately prior to the completion of this offering, or their transferees, and holders of warrants to purchase an aggregate of 1,013,107 shares of common stock, will be entitled to various rights with respect to the registration of these shares under the Securities Act upon the completion of this offering. Registration of these shares under the Securities Act would result in these shares becoming fully tradable without restriction under the Securities Act immediately upon the effectiveness of the registration, except for shares purchased by affiliates. See “Description of Capital Stock—Registration Rights” for additional information. Shares covered by a registration statement will be eligible for sale in the public market upon the expiration or release from the terms of the lock-up agreement.

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS

The following discussion is a summary of the material U.S. federal income tax consequences to Non-U.S. Holders (as defined below) of the purchase, ownership and disposition of our common stock issued pursuant to this offering, but does not purport to be a complete analysis of all potential tax effects. The effects of other U.S. federal tax laws, such as estate and gift tax laws, and any applicable state, local or non-U.S. tax laws are not discussed. This discussion is based on the U.S. Internal Revenue Code of 1986, as amended, or the Code, Treasury Regulations promulgated thereunder, judicial decisions, and published rulings and administrative pronouncements of the U.S. Internal Revenue Service, or the IRS, in each case in effect as of the date hereof. These authorities may change or be subject to differing interpretations. Any such change or differing interpretation may be applied retroactively in a manner that could adversely affect a Non-U.S. Holder of our common stock. We have not sought and will not seek any rulings from the IRS regarding the matters discussed below. There can be no assurance the IRS or a court will not take a contrary position to that discussed below regarding the tax consequences of the purchase, ownership and disposition of our common stock.

This discussion is limited to Non-U.S. Holders that hold our common stock as a "capital asset" within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all U.S. federal income tax consequences relevant to a Non-U.S. Holder's particular circumstances, including the impact of the alternative minimum tax or the Medicare contribution tax on net investment income. In addition, it does not address consequences relevant to Non-U.S. Holders subject to special rules, including, without limitation:

- U.S. expatriates and former citizens or long-term residents of the United States;
- persons holding our common stock as part of a hedge, straddle or other risk reduction strategy or as part of a conversion transaction or other integrated investment;
- banks, insurance companies, and other financial institutions;
- brokers, dealers or traders in securities;
- "controlled foreign corporations," "passive foreign investment companies," and corporations that accumulate earnings to avoid U.S. federal income tax;
- partnerships or other entities or arrangements treated as partnerships for U.S. federal income tax purposes (and investors therein);
- tax-exempt organizations or governmental organizations;
- persons deemed to sell our common stock under the constructive sale provisions of the Code;
- persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation;
- tax-qualified retirement plans;
- "qualified foreign pension funds" as defined in Section 897(l)(2) of the Code and entities all of the interests of which are held by qualified foreign pension funds; and
- persons subject to special tax accounting rules as a result of any item of gross income with respect to the stock being taken into account in an "applicable financial statement" (as defined in the Code).

If an entity treated as a partnership for U.S. federal income tax purposes holds our common stock, the tax treatment of a partner in the partnership will depend on the status of the partner, the activities of the partnership and certain determinations made at the partner level. Accordingly, partnerships holding our common stock and the partners in such partnerships should consult their tax advisors regarding the U.S. federal income tax consequences to them.

THIS DISCUSSION IS FOR INFORMATION PURPOSES ONLY AND IS NOT TAX ADVICE. INVESTORS SHOULD CONSULT THEIR TAX ADVISORS WITH RESPECT TO THE APPLICATION

OF THE U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS AS WELL AS ANY TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK ARISING UNDER THE U.S. FEDERAL ESTATE OR GIFT TAX LAWS OR UNDER THE LAWS OF ANY STATE, LOCAL OR NON-U.S. TAXING JURISDICTION OR UNDER ANY APPLICABLE INCOME TAX TREATY.

Definition of a Non-U.S. Holder

For purposes of this discussion, a "Non-U.S. Holder" is any beneficial owner of our common stock that is neither a "U.S. person" nor an entity treated as a partnership for U.S. federal income tax purposes. A U.S. person is any person that, for U.S. federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation created or organized under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust that (i) is subject to the primary supervision of a U.S. court and the control of one or more "United States persons" (within the meaning of Section 7701(a)(30) of the Code), or (ii) has a valid election in effect to be treated as a United States person for U.S. federal income tax purposes.

Distributions

As described in the section entitled "Dividend Policy," we do not anticipate declaring or paying dividends to holders of our common stock in the foreseeable future. However, if we do make distributions of cash or property on our common stock, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and first be applied against and reduce a Non-U.S. Holder's adjusted tax basis in its common stock, but not below zero. Any excess will be treated as capital gain and will be treated as described below under "—Sale or Other Taxable Disposition."

Subject to the discussion below on effectively connected income, dividends paid to a Non-U.S. Holder of our common stock will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends (or such lower rate specified by an applicable income tax treaty, provided the Non-U.S. Holder furnishes a valid IRS Form W-8BEN or W-8BEN-E (or other applicable documentation) certifying qualification for the lower treaty rate). A Non-U.S. Holder that does not timely furnish the required documentation, but that qualifies for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. Holders should consult their tax advisors regarding their entitlement to benefits under any applicable income tax treaty.

If dividends paid to a Non-U.S. Holder are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such dividends are attributable), the Non-U.S. Holder will be exempt from the U.S. federal withholding tax described above. To claim the exemption, the Non-U.S. Holder must furnish to the applicable withholding agent a valid IRS Form W-8ECI, certifying that the dividends are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States.

Any such effectively connected dividends will be subject to U.S. federal income tax on a net income basis at the regular graduated rates. A Non-U.S. Holder that is a corporation also may be

subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected dividends, as adjusted for certain items. Non-U.S. Holders should consult their tax advisors regarding any applicable tax treaties that may provide for different rules.

Sale or Other Taxable Disposition

A Non-U.S. Holder will not be subject to U.S. federal income tax on any gain realized upon the sale or other taxable disposition of our common stock unless:

- the gain is effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such gain is attributable);
- the Non-U.S. Holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition and certain other requirements are met; or
- our common stock constitutes a U.S. real property interest, or USRPI, by reason of our status as a U.S. real property holding corporation, or USRPHC, for U.S. federal income tax purposes.

Gain described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis at the regular graduated rates. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected gain, as adjusted for certain items.

Gain described in the second bullet point above will be subject to U.S. federal income tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty), which may be offset by U.S. source capital losses of the Non-U.S. Holder (even though the individual is not considered a resident of the United States), provided the Non-U.S. Holder has timely filed U.S. federal income tax returns with respect to such losses.

With respect to the third bullet point above, we believe we currently are not, and do not anticipate becoming, a USRPHC. Because the determination of whether we are a USRPHC depends, however, on the fair market value of our USRPIs relative to the fair market value of our non-U.S. real property interests and our other business assets, there can be no assurance we currently are not a USRPHC or will not become one in the future. Even if we are or were to become a USRPHC, gain arising from the sale or other taxable disposition by a Non-U.S. Holder of our common stock will not be subject to U.S. federal income tax if our common stock is "regularly traded," as defined by applicable Treasury Regulations, on an established securities market, and such Non-U.S. Holder owned, actually and constructively, 5% or less of our common stock throughout the shorter of the five-year period ending on the date of the sale or other taxable disposition or the Non-U.S. Holder's holding period.

Non-U.S. Holders should consult their tax advisors regarding potentially applicable income tax treaties that may provide for different rules.

Information Reporting and Backup Withholding

Payments of dividends on our common stock will not be subject to backup withholding, provided the applicable withholding agent does not have actual knowledge or reason to know the holder is a United States person and the holder either certifies its non-U.S. status, such as by furnishing a valid IRS Form W-8BEN, W-8BEN-E or W-8ECI, or otherwise establishes an exemption. However, information returns are required to be filed with the IRS in connection with any dividends on our common stock paid to the Non-U.S. Holder, regardless of whether any tax was actually withheld. In addition, proceeds of the sale or other taxable disposition of our common stock within the United

States or conducted through certain U.S.-related brokers generally will not be subject to backup withholding or information reporting, if the applicable withholding agent receives the certification described above and does not have actual knowledge or reason to know that such holder is a United States person, or the holder otherwise establishes an exemption. Proceeds of a disposition of our common stock conducted through a non-U.S. office of a non-U.S. broker generally will not be subject to backup withholding or information reporting.

Copies of information returns that are filed with the IRS may also be made available under the provisions of an applicable treaty or agreement to the tax authorities of the country in which the Non-U.S. Holder resides or is established.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a Non-U.S. Holder's U.S. federal income tax liability, provided the required information is timely furnished to the IRS.

Additional Withholding Tax on Payments Made to Foreign Accounts

Withholding taxes may be imposed under Sections 1471 to 1474 of the Code (such Sections commonly referred to as the Foreign Account Tax Compliance Act, or FATCA) on certain types of payments made to non-U.S. financial institutions and certain other non-U.S. entities. Specifically, a 30% withholding tax may be imposed on dividends on, or (subject to the proposed Treasury Regulations discussed below) gross proceeds from the sale or other disposition of, our common stock paid to a "foreign financial institution" or a "non-financial foreign entity" (each as defined in the Code), unless (i) the foreign financial institution undertakes certain diligence and reporting obligations, (ii) the non-financial foreign entity either certifies it does not have any "substantial United States owners" (as defined in the Code) or furnishes identifying information regarding each substantial United States owner, or (iii) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. If the payee is a foreign financial institution and is subject to the diligence and reporting requirements in (i) above, it must enter into an agreement with the U.S. Department of the Treasury requiring, among other things, that it undertake to identify accounts held by certain "specified United States persons" or "United States owned foreign entities" (each as defined in the Code), annually report certain information about such accounts, and withhold 30% on certain payments to non-compliant foreign financial institutions and certain other account holders. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing FATCA may be subject to different rules.

Under the applicable Treasury Regulations and administrative guidance, withholding under FATCA generally applies to payments of dividends on our common stock. While withholding under FATCA would have applied also to payments of gross proceeds from the sale or other disposition of stock on or after January 1, 2019, recently proposed Treasury Regulations eliminate FATCA withholding on payments of gross proceeds entirely. Taxpayers generally may rely on these proposed Treasury Regulations until final Treasury Regulations are issued.

Prospective investors should consult their tax advisors regarding the potential application of withholding under FATCA to their investment in our common stock.

UNDERWRITING

We and the underwriters for the offering named below have entered into an underwriting agreement with respect to the common stock being offered. Subject to the terms and conditions of the underwriting agreement, each underwriter has severally agreed to purchase from us the number of shares of our common stock set forth opposite its name below. Cowen and Company, LLC, Cantor Fitzgerald & Co. and William Blair & Company, L.L.C. are the representatives of the underwriters.

Underwriter	Number of Shares
Cowen and Company, LLC	1,440,000
Cantor Fitzgerald & Co.	1,080,000
William Blair & Company, L.L.C.	1,080,000
Total	3,600,000

The underwriting agreement provides that the obligations of the underwriters are subject to certain conditions precedent and that the underwriters have agreed, severally and not jointly, to purchase all of the shares sold under the underwriting agreement if any of these shares are purchased, other than those shares covered by the option to purchase additional shares described below. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the non-defaulting underwriters may be increased or the underwriting agreement may be terminated.

We have agreed to indemnify the underwriters against specified liabilities, including liabilities under the Securities Act, and to contribute to payments the underwriters may be required to make in respect thereof.

The underwriters are offering the shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel and other conditions specified in the underwriting agreement. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Certain of our existing stockholders, including entities affiliated with certain of our directors, have indicated an interest in purchasing an aggregate of approximately $12.0 million in shares of our common stock in this offering at the initial public offering price per share and on the same terms as the other purchasers in this offering. However, because these indications of interest are not binding agreements or commitments to purchase, the underwriters may determine to sell more, less or no shares in this offering to any or all of these stockholders, or any or all of these stockholders may determine to purchase more, less or no shares in this offering. The underwriters will receive the same underwriting discount on any shares purchased by these stockholders as they will on any other shares sold to the public in this offering.

Option to Purchase Additional Shares. We have granted to the underwriters an option to purchase up to 540,000 additional shares of common stock at the public offering price, less the underwriting discount. This option is exercisable for a period of 30 days. To the extent that the underwriters exercise this option, the underwriters will purchase additional shares from us in approximately the same proportion as shown in the table above.

Discounts and Commissions. The following table shows the public offering price, underwriting discount and proceeds, before expenses to us. These amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

We estimate that the total expenses of the offering, excluding underwriting discount, will be approximately $2.3 million and are payable by us. We have agreed to reimburse the underwriters for certain of their expenses in an amount up to $40,000.

		Total	
	Per Share	Without Option to Purchase Additional Shares Exercise	With Option to Purchase Additional Shares Exercise
Public offering price	$ 14.00	$ 50,400,000	$ 57,960,000
Underwriting discount	$ 0.98	$ 3,528,000	$ 4,057,200
Proceeds, before expenses, to us	$ 13.02	$ 46,872,000	$ 53,902,800

The underwriters propose to offer the shares of common stock to the public at the public offering price set forth on the cover of this prospectus. The underwriters may offer the shares of common stock to securities dealers at the public offering price less a concession not in excess of $0.588 per share. If all of the shares are not sold at the public offering price, the underwriters may change the offering price and other selling terms.

Discretionary Accounts. The underwriters do not intend to confirm sales of the shares to any accounts over which they have discretionary authority.

Market Information. Prior to this offering, there has been no public market for shares of our common stock. The initial public offering price was determined by negotiations between us and the representatives of the underwriters. In addition to prevailing market conditions, the factors to be considered in these negotiations will include:

- the history of, and prospects for, our company and the industry in which we compete;
- our past and present financial information;
- an assessment of our management; its past and present operations, and the prospects for, and timing of, our future revenue;
- the present state of our development;
- the above factors in relation to market values and various valuation measures of other companies engaged in activities similar to ours.

An active trading market for the shares may not develop. It is also possible that after the offering the shares will not trade in the public market at or above the initial public offering price.

Our common stock has been approved for listing on the Nasdaq Global Market under the symbol “XGN.”

Stabilization. In connection with this offering, the underwriters may engage in stabilizing transactions, overallotment transactions, syndicate covering transactions, penalty bids and purchases to cover positions created by short sales.

- Stabilizing transactions permit bids to purchase shares of common stock so long as the stabilizing bids do not exceed a specified maximum, and are engaged in for the purpose of preventing or retarding a decline in the market price of the common stock while the offering is in progress.
- Overallotment transactions involve sales by the underwriters of shares of common stock in excess of the number of shares the underwriters are obligated to purchase. This creates a syndicate short position which may be either a covered short position or a naked short

position. In a covered short position, the number of shares over-allotted by the underwriters is not greater than the number of shares that they may purchase in the option to purchase additional shares. In a naked short position, the number of shares involved is greater than the number of shares in the option to purchase additional shares. The underwriters may close out any short position by exercising their option to purchase additional shares and/or purchasing shares in the open market.

- Syndicate covering transactions involve purchases of common stock in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of shares to close out the short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared with the price at which they may purchase shares through exercise of the option to purchase additional shares. If the underwriters sell more shares than could be covered by exercise of the option to purchase additional shares and, therefore, have a naked short position, the position can be closed out only by buying shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that after pricing there could be downward pressure on the price of the shares in the open market that could adversely affect investors who purchase in the offering.
- Penalty bids permit the representatives to reclaim a selling concession from a syndicate member when the common stock originally sold by that syndicate member is purchased in stabilizing or syndicate covering transactions to cover syndicate short positions.

These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock in the open market may be higher than it would otherwise be in the absence of these transactions. Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price of our common stock. These transactions may be effected on the Nasdaq Global Market, in the over-the-counter market or otherwise and, if commenced, may be discontinued at any time.

Passive Market Making. In connection with this offering, underwriters and selling group members may engage in passive market making transactions in our common stock on the Nasdaq Global Market in accordance with Rule 103 of Regulation M under the Exchange Act during a period before the commencement of offers or sales of common stock and extending through the completion of the distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker's bid, such bid must then be lowered when specified purchase limits are exceeded.

Lock-Up Agreements. Pursuant to certain "lock-up" agreements, we and our executive officers, directors and substantially all of our securityholders have agreed, subject to certain exceptions, not to offer, sell, assign, transfer, pledge, contract to sell, or otherwise dispose of or announce the intention to otherwise dispose of, or enter into any swap, hedge or similar agreement or arrangement that transfers, in whole or in part, the economic consequence of ownership of, directly or indirectly, or make any demand or request or exercise any right with respect to the registration of, or file with the SEC a registration statement under the Securities Act relating to, any common stock or securities convertible into or exchangeable or exercisable for any common stock without the prior written consent of Cowen and Company, LLC, Cantor Fitzgerald & Co. and William Blair & Company, L.L.C., for a period of 180 days after the date of the pricing of the offering.

This lock-up provision applies to common stock and to securities convertible into or exchangeable or exercisable for common stock. It also applies to common stock owned now or acquired later by the person executing the agreement or for which the person executing the agreement later acquires the

power of disposition. The lock-up provision will not restrict broker-dealers from engaging in market making and similar activities conducted in the ordinary course of their business.

Cowen and Company, LLC, Cantor Fitzgerald & Co. and William Blair & Company, L.L.C., in their sole discretion, may release our common stock and other securities subject to the lock-up agreements described above in whole or in part at any time. When determining whether or not to release our common stock and other securities from lock-up agreements, Cowen and Company, LLC, Cantor Fitzgerald & Co. and William Blair & Company, L.L.C. will consider, among other factors, the holder's reasons for requesting the release, the number of shares for which the release is being requested and market conditions at the time of the request. In the event of such a release or waiver for one of our directors or officers, Cowen and Company, LLC, Cantor Fitzgerald & Co. and William Blair & Company, L.L.C. shall provide us with notice of the impending release or waiver at least three business days before the effective date of such release or waiver and we will announce the impending release or waiver by issuing a press release at least two business days before the effective date of the release or waiver.

Electronic Offer, Sale and Distribution of Shares. A prospectus in electronic format may be made available on the websites maintained by one or more of the underwriters or selling group members, if any, participating in this offering and one or more of the underwriters participating in this offering may distribute prospectuses electronically. The representatives may agree to allocate a number of shares to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the underwriters and selling group members that will make internet distributions on the same basis as other allocations. Other than the prospectus in electronic format, the information on these websites is not part of this prospectus or the registration statement of which this prospectus forms a part, has not been approved or endorsed by us or any underwriter in its capacity as underwriter, and should not be relied upon by investors.

Other Relationships. Certain of the underwriters and their affiliates have provided in the past to us and our affiliates and may provide from time to time in the future certain commercial banking, financial advisory, investment banking and other services for us and such affiliates in the ordinary course of their business, for which they have received and may continue to receive customary fees and commissions. In addition, from time to time, certain of the underwriters and their affiliates may effect transactions for their own account or the account of customers, and hold on behalf of themselves or their customers, long or short positions in our debt or equity securities or loans, and may do so in the future.

Selling Restrictions.

Canada. The common stock may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 *Prospectus Exemptions* or subsection 73.3(1) of the *Securities Act* (Ontario), and are permitted clients, as defined in National Instrument 31-103 *Registration Requirements, Exemptions and Ongoing Registrant Obligations*. Any resale of the common stock must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 *Underwriting Conflicts* (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

European Economic Area. In relation to each member state of the European Economic Area (each, a "Member State"), no shares have been offered or will be offered pursuant to the offering to the public in that Member State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Member State or, where appropriate, approved in another Member State and notified to the competent authority in that Member State, all in accordance with the Prospectus Regulation), except that offers of shares may be made to the public in that Member State at any time under the following exemptions under the Prospectus Regulation:

(a) to any legal entity which is a qualified investor as defined under the Prospectus Regulation;

(b) to fewer than 150 natural or legal persons (other than qualified investors as defined under the Prospectus Regulation), subject to obtaining the prior consent of the underwriter for any such offer; or

(c) in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of shares shall require us or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

For the purposes of this provision, the expression an "offer to the public" in relation to any shares in any Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares, and the expression "Prospectus Regulation" means Regulation (EU) 2017/1129.

United Kingdom. In addition, in the United Kingdom, this document is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at persons who are "qualified investors" (as defined in the Prospectus Directive) (i) who have professional experience in matters relating to investments falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the "Order") and/or (ii) who are high net worth companies (or persons to whom it may otherwise be lawfully communicated) falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as "relevant persons") or otherwise in circumstances which have not resulted and will not result in an offer to the public of the shares in the United Kingdom within the meaning of the Financial Services and Markets Act 2000 (as amended).

Any person in the United Kingdom that is not a relevant person should not act or rely on the information included in this document or use it as basis for taking any action. In the United Kingdom, any investment or investment activity that this document relates to may be made or taken exclusively by relevant persons.

France. This prospectus has not been prepared in the context of a public offering of financial securities in France within the meaning of Article L.411-1 of the French Code Monétaire et Financier and Title I of Book II of the Reglement Général of the Autorité des marchés financiers, or the AMF, and therefore has not been and will not be filed with the AMF for prior approval or submitted for clearance to the AMF. Consequently, the shares of our common stock may not be, directly or indirectly, offered or sold to the public in France and offers and sales of the shares of our common stock may only be made in France to qualified investors (investisseurs qualifiés) acting for their own, as defined in and in

accordance with Articles L.411-2 and D.411-1 to D.411-4, D.734-1, D.744-1, D.754-1 and D.764-1 of the French Code Monétaire et Financier. Neither this prospectus nor any other offering material may be released, issued or distributed to the public in France or used in connection with any offer for subscription on sale of the shares of our common stock to the public in France. The subsequent direct or indirect retransfer of the shares of our common stock to the public in France may only be made in compliance with Articles L.411-1, L.411-2, L.412-1 and L.621-8 through L.621-8-3 of the French Code Monétaire et Financier.

Germany. Each person who is in possession of this prospectus is aware of the fact that no German securities prospectus (wertpapierprospekt) within the meaning of the securities prospectus act (wertpapier-prospektgesetz), or the act, of the federal republic of Germany has been or will be published with respect to the shares of our common stock. In particular, each underwriter has represented that it has not engaged and has agreed that it will not engage in a public offering in the federal republic of Germany (ôffertliches angebot) within the meaning of the act with respect to any of the shares of our common stock otherwise than in accordance with the act and all other applicable legal and regulatory requirements.

Switzerland. The shares common stock may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or SIX, or on any other stock exchange or regulated trading facility in Switzerland. This document does not constitute a prospectus within the meaning of, and has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, us, or the shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of shares will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA (FINMA), and the offer of shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of shares.

Netherlands. The offering of the shares of our common stock is not a public offering in The Netherlands. The shares of our common stock may not be offered or sold to individuals or legal entities in The Netherlands unless (i) a prospectus relating to the offer is available to the public, which has been approved by the Dutch Authority for the Financial Markets (Autoriteit Financiële Markten) or by the competent supervisory authority of another state that is a member of the European Union or party to the Agreement on the European Economic Area, as amended or (ii) an exception or exemption applies to the offer pursuant to Article 5:3 of The Netherlands Financial Supervision Act (Wet op het financieel toezicht) or Article 53 paragraph 2 or 3 of the Exemption Regulation of the Financial Supervision Act, for instance due to the offer targeting exclusively “qualified investors” (gekwalificeerde beleggers) within the meaning of Article 1:1 of The Netherlands Financial Supervision Act.

Japan. The shares have not been and will not be registered under the Financial Instruments and Exchange Act. Accordingly, the shares may not be offered or sold, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to or for the benefit of a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the Financial Instruments and Exchange Act and any other applicable laws, regulations and ministerial guidelines of Japan.

Hong Kong. The shares have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (i) to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance; or (ii) in other circumstances which do not result in the document being a "prospectus" as defined in the Companies Ordinance (Cap. 32) of Hong Kong or which do not constitute an offer to the public within the meaning of that Ordinance. No advertisement, invitation or document relating to our common stock has been or may be issued or has been or may be in the possession of any person for the purposes of issue, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to our common stock which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the Securities and Futures Ordinance and any rules made under that Ordinance.

Singapore. This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore, or the SFA, (ii) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275, of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

securities (as defined in Section 239(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares pursuant to an offer made under Section 275 of the SFA except:

- to an institutional investor or to a relevant person defined in Section 275(2) of the SFA, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;
- where no consideration is or will be given for the transfer;
- where the transfer is by operation of law;
- as specified in Section 276(7) of the SFA; or
- as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore.

Solely for the purposes of its obligations pursuant to Section 309B of the SFA, we have determined, and hereby notify all relevant persons (as defined in the CMP Regulations 2018), that the shares are "prescribed capital markets products" (as defined in the CMP Regulations 2018) and Excluded Investment Products (as defined in MAS Notice SFA 04-N12: Notice on the Sale of Investment Products and MAS Notice FAA-N16: Notice on Recommendations on Investment Products).

We have not authorized and do not authorize the making of any offer of securities through any financial intermediary on our behalf, other than offers made by the underwriters and their respective affiliates, with a view to the final placement of the securities as contemplated in this document. Accordingly, no purchaser of the shares, other than the underwriters, is authorized to make any further offer of shares on our behalf or on behalf of the underwriters.

LEGAL MATTERS

The validity of the shares of common stock offered hereby will be passed upon for us by Latham & Watkins LLP, San Diego, California. The underwriters are being represented by Cooley LLP, San Diego, California.

EXPERTS

The financial statements as of December 31, 2018 and 2017 and for the years then ended included in this prospectus and in the registration statement have been so included in reliance on the report of BDO USA, LLP, an independent registered public accounting firm, appearing elsewhere herein and in the registration statement, given on the authority of said firm as experts in auditing and accounting.

CHANGE IN INDEPENDENT ACCOUNTANT

On June 15, 2017, the Audit Committee of the board of directors dismissed PricewaterhouseCoopers LLP, or PwC, and retained BDO USA, LLP, or BDO, as our independent registered public accounting firm on July 14, 2017.

PwC did not issue a report on our audited financial statements for each of the two fiscal years ended December 31, 2018 and December 31, 2017. We had no disagreements with PwC on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedure, which disagreements, if not resolved to its satisfaction, would have caused PwC to make reference in connection with its opinion to the subject matter of the disagreement during its audits for each of the two fiscal years prior to its dismissal or the subsequent interim period through June 15, 2017. During the two most recent fiscal years preceding PwC's dismissal, and the subsequent interim period through June 15, 2017, there were no "reportable events" as such term is defined in Item 304(a)(1)(v) of Regulation S-K.

We have provided PwC with a copy of the foregoing disclosure and have requested that PwC furnish us with a letter addressed to the SEC stating whether or not PwC agrees with the above statements and, if not, stating the respects in which it does not agree. A copy of the letter from PwC is filed as an exhibit to the registration statement of which this prospectus is a part.

During the two years ended December 31, 2016 and the subsequent interim period through July 14, 2017, neither we, nor anyone acting on our behalf, consulted with BDO on matters that involved the application of accounting principles to a specified transaction, either completed or proposed, the type of audit opinion that might be rendered on our audited financial statements, and neither a written report nor oral advice was provided to us by BDO that BDO concluded was an important factor considered by us in reaching a decision as to the accounting, auditing or financial reporting issue or any other matter that was the subject of a disagreement as that term is used in Item 304 (a)(1)(iv) of Regulation S-K and the related instructions to Item 304 of Regulation S-K or a reportable event as that term is used in Item 304(a)(1)(v) and the related instructions to Item 304 of Regulation S-K.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits and schedules filed therewith. For further information about us and the common stock offered hereby, we refer you to the registration statement and the exhibits and schedules filed thereto. Statements contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the registration statement. Upon the completion of this offering, we will be required to file periodic reports, proxy statements and other information with the SEC pursuant to the Exchange Act. You may read and copy this information at the Public Reference Room of the SEC, 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You may obtain information on the operation of the public reference rooms by calling the SEC at 1-800-SEC-0330. The SEC also maintains an Internet website that contains reports, proxy statements and other information about registrants, like us, that file electronically with the SEC. The address of that website is *www.sec.gov*.

Upon the completion of this offering, we will become subject to the information and periodic reporting requirements of the Exchange Act and, in accordance therewith, will file periodic reports, proxy statements and other information with the SEC. Such periodic reports, proxy statements and other information will be available for inspection and copying at the public reference room and website of the SEC referred to above. We maintain a website at www.exagen.com. Upon the completion of this offering, you may access our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act with the SEC free of charge at our website as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. The reference to our website address does not constitute incorporation by reference of the information contained on our website, and you should not consider the contents of our website in making an investment decision with respect to our common stock.

EXAGEN INC.

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Stockholders and the Board of Directors
Exagen Inc.
Vista, California

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Exagen Inc. ("the Company") (formerly known as Exagen Diagnostics, Inc.) as of December 31, 2017 and 2018, the related statements of operations, redeemable convertible preferred stock and stockholders' deficit, and cash flows for the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2017 and 2018, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Change in Accounting Method Related to Revenue

As discussed in Notes 2 and 3 to the financial statements, the Company has changed its accounting method for revenue from contracts with customers effective January 1, 2018 due to the adoption of Accounting Standards Codification 606, *Revenue from Contracts with Customers*.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ BDO USA, LLP

We have served as the Company's auditor since 2017.

San Diego, California

May 31, 2019, except for Note 16, which is as of August 23, 2019 and the "Reverse Stock Split" paragraph of Note 17 which is as of September 9, 2019

Exagen Inc.

Balance Sheets
(in thousands, except share and per share data)

	December 31, 2017	December 31, 2018 (As Revised)	June 30, 2019 (Unaudited)	June 30, 2019 Pro Forma (Unaudited)
Assets				
Current assets:				
Cash and cash equivalents	$ 11,241	$ 13,164	$ 16,237	
Accounts receivable, net	604	5,952	6,733	
Prepaid expenses and other current assets	1,415	2,196	1,961	
Total current assets	13,260	21,312	24,931	
Property and equipment, net	1,343	1,566	1,239	
Intangible assets, net	141	–	–	
Goodwill	5,506	5,506	5,506	
Other assets	140	503	1,412	
Total assets	$ 20,390	$ 28,887	$ 33,088	
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Deficit				
Current liabilities:				
Accounts payable	$ 1,772	$ 1,279	$ 1,494	
Accrued liabilities	3,218	3,923	5,227	
Proceeds received prior to issuance of Series G redeemable convertible preferred stock	–	3,750	–	
Total current liabilities	4,990	8,952	6,721	
Borrowings—non-current portion, net of discounts and debt issuance costs	18,809	24,617	25,331	
Redeemable convertible preferred stock warrant liabilities	896	1,503	1,036	$ –
Deferred tax liabilities	214	245	245	
Other non-current liabilities	119	304	463	
Total liabilities	25,028	35,621	33,796	
Commitments and contingencies (Note 8)				
Redeemable convertible preferred stock, $0.001 par value—750,300,000, 750,300,000 and 955,500,000 shares authorized at December 31, 2017 and 2018 and June 30, 2019 (unaudited), respectively; 497,691,757, 532,606,084 and 681,534,421 shares issued and outstanding at December 31, 2017 and 2018 and June 30, 2019 (unaudited), respectively; liquidation preference of $131,390, $163,316 and $180,741 at December 31, 2017 and 2018 and June 30, 2019 (unaudited), respectively; no shares issued and outstanding, pro forma (unaudited)	92,046	105,232	121,026	–
Stockholders' deficit:				
Common stock, $0.001 par value—1,470,000,000, 1,470,000,000 and 1,675,200,000 shares authorized at December 31, 2017 and 2018 and June 30, 2019 (unaudited), respectively; 63,005, 63,005 and 63,055 shares issued and outstanding at December 31, 2017 and 2018 and June 30, 2019 (unaudited), respectively; 7,894,770 shares issued and outstanding, pro forma (unaudited)	–	–	–	8
Additional paid-in capital	50,954	40,598	36,319	169,223
Accumulated deficit	(147,638)	(152,564)	(158,053)	(157,903)
Total stockholders' deficit	(96,684)	(111,966)	(121,734)	$ 11,328
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	$ 20,390	$ 28,887	$ 33,088	

The accompanying notes are an integral part of these financial statements

Exagen Inc.

Statements of Operations
(in thousands, except share and per share data)

	Years Ended December 31,		Six Months Ended June 30,	
	2017	2018 (As Revised)	2018 (Unaudited)	2019 (Unaudited)
Revenue	$ 26,807	$ 32,440	$ 14,576	$ 19,734
Operating expenses:				
Costs of revenue (excluding amortization of purchased technology)	14,137	15,379	7,524	9,434
Selling, general and administrative expenses	18,820	19,675	9,487	13,481
Research and development expenses	1,551	2,125	1,067	1,103
Amortization of intangible assets	186	141	94	–
Change in fair value of acquisition-related liabilities	(51)	–	–	–
Total operating expenses	34,643	37,320	18,172	24,018
Loss from operations	(7,836)	(4,880)	(3,596)	(4,284)
Interest expense	(2,948)	(2,868)	(1,394)	(1,811)
Loss on extinguishment of share purchase rights and 2013 Term Loan	(6,050)	–	–	–
Change in fair value of financial instruments	(9,391)	(318)	–	467
Other income, net	45	112	51	139
Loss before income taxes	(26,180)	(7,954)	(4,939)	(5,489)
Income tax (benefit) expense	(549)	58	–	–
Net loss	(25,631)	(8,012)	(4,939)	(5,489)
Accretion of redeemable convertible preferred stock	(5,353)	(9,318)	(3,694)	(4,302)
Deemed dividend recorded in connection with financing transactions	(1,790)	(1,152)	(1,152)	–
Net loss attributable to common stockholders (Note 2)	$ (32,774)	$ (18,482)	$ (9,785)	$ (9,791)
Net loss per share attributable to common stockholders, basic and diluted (Note 2)	$ (520.18)	$ (293.34)	$ (155.31)	$ (155.33)
Weighted-average number of shares used to compute net loss per share attributable to common stockholders, basic and diluted (Note 2)	63,005	63,005	63,005	63,033
Pro forma net loss per share attributable to common stockholders, basic and diluted (Note 2, unaudited)		$ (1.46)		$ (1.02)
Pro forma weighted-average number of shares used to compute net loss per share attributable to common stockholders, basic and diluted (Note 2, unaudited)		5,277,265		5,831,017

The accompanying notes are an integral part of these financial statements

Exagen Inc.

Statements of Cash Flows
(in thousands)

	Years Ended December 31,		Six Months Ended June 30,	
	2017	2018 (As Revised)	2018 (Unaudited)	2019
Cash flows from operating activities:				
Net loss	$(25,631)	$ (8,012)	$ (4,939)	$ (5,489)
Adjustments to reconcile net loss to net cash used in operating activities:				
Revaluation of acquisition-related liabilities	(51)	–	–	–
Depreciation and amortization	670	731	378	363
Amortization of debt discount and debt issuance costs	498	587	288	393
Non-cash interest expense	502	515	251	320
Revaluation of embedded derivatives, share purchase rights, and warrant liabilities	9,391	318	–	(467)
Loss on extinguishment of share purchase rights	5,744	–	–	–
Loss on extinguishment of 2013 Term Loan	306	–	–	–
Deferred income taxes	(554)	31	–	–
(Gain) loss on disposal of assets	(14)	6	–	217
Stock-based compensation	187	114	90	23
Changes in assets and liabilities:				
Accounts receivable, net	(198)	(2,262)	(452)	(782)
Prepaid expenses and other current assets	178	(781)	(158)	234
Other assets	4	(8)	(6)	23
Accounts payable	44	(824)	(449)	(173)
Accrued and other liabilities	254	284	(411)	1,220
Repayment of accrued PIK interest in conjunction with repayment of 2013 Term Loan	(2,298)	–	–	–
Net cash used in operating activities	(10,968)	(9,301)	(5,408)	(4,118)
Cash flows from investing activities:				
Purchases of property and equipment	(567)	(199)	(68)	(375)
Proceeds from sale of property and equipment	57	–	–	300
Purchases of short-term investments	–	(2,000)	(2,000)	–
Maturities of short-term investments	–	2,000	–	–
Net cash used in investing activities	(510)	(199)	(2,068)	(75)
Cash flows from financing activities:				
Principal payment on capital lease obligations	(22)	(38)	(10)	(57)
Proceeds from the issuance of preferred stock purchase rights, net of issuance costs	3,763	–	–	–
Proceeds from issuance of 2017 Term Loan, net of issuance costs of $465 and $5, respectively	19,535	4,995	–	–
Repayment of 2013 Term Loan	(15,000)	–	–	–
Proceeds from the issuance of preferred stock, net of issuance costs	10,880	2,716	2,716	–
Proceeds received prior to and for the issuance of Series G redeemable convertible preferred stock	–	3,750	–	7,742
Payments of deferred offering costs	–	–	–	(419)
Net cash provided by financing activities	19,156	11,423	2,706	7,266
Increase (decrease) in cash, cash equivalents and restricted cash	7,678	1,923	(4,770)	3,073
Cash, cash equivalents and restricted cash, beginning of period	3,663	11,341	11,341	13,264
Cash, cash equivalents and restricted cash, end of period	$ 11,341	$ 13,264	$ 6,571	$16,337
Supplemental disclosure of cash flow information:				
Cash paid for interest expense	$ 1,989	$ 1,730	$ 1,114	$ 1,095
Supplemental disclosure of non-cash items:				
Accretion to redemption value of redeemable convertible preferred stock	$ 5,353	$ 9,318	$ 3,694	$ 4,302
Equipment purchased under capital lease obligations	$ 108	$ 289	$ –	$ 300
Fair value of warrant liabilities recorded as discount on debt	$ 1,000	$ 289	$ –	$ –
Costs incurred, but not paid, in connection with capital expenditures	$ 8	$ 331	$ 25	$ 5
Deferred offering costs included in accounts payable and accrued liabilities	$ –	$ 355	$ –	$ 475
Fair value of financial instruments extinguished in connection with financing transactions (Note 10)	$ 19,508	$ –	$ –	$ –
Fair value of tranche participation rights recognized in connection with financing transactions (Note 10)	$ 2,308	$ –	$ –	$ –
Beneficial conversion feature recognized in connection with financing transactions (Note 10)	$ 485	$ –	$ –	$ –
Deemed dividend recorded in connection with financing transactions (Note 10)	$ 1,790	$ 1,152	$ 1,152	$ –
Adjustment upon adoption of ASC 606	$ –	$ 3,086	$ 3,086	$ –

The accompanying notes are an integral part of these financial statements

Exagen Inc.

Statements of Redeemable Convertible Preferred Stock and Stockholders' Deficit
(in thousands)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
Balances at December 31, 2016	193,121	$ 49,717	63	$ –	$ 57,425	$ (122,007)	$ (64,582)
Accretion of redeemable convertible preferred stock	–	5,353	–	–	(5,353)	–	(5,353)
Stock-based compensation	–	–	–	–	187	–	187
Beneficial conversion feature	–	(485)	–	–	485	–	485
Issuance of Series F redeemable convertible preferred stock for aggregate proceeds of $0.078 per share, net of issuance costs of $81, in the first tranche closing of the Series F financing (Note 10)	48,077	6,009	–	–	–	–	–
Issuance of Series F redeemable convertible preferred stock upon the conversion of outstanding stock purchase rights in the first tranche closing of the Series F financing (Note 10)	163,785	20,637	–	–	–	–	–
Issuance of Series F redeemable convertible preferred stock for aggregate proceeds of $0.078 per share, net of issuance costs of $10, upon the exercise of the tranche participation rights in the second tranche closing of the Series F financing (Note 10)	38,462	4,804	–	–	–	–	–
Issuance of Series F redeemable convertible preferred stock for aggregate proceeds of $0.078 per share, net of issuance costs of $10, in the third tranche closing of the Series F financing (Note 10)	54,247	6,011	–	–	(1,790)	–	(1,790)
Net loss	–	–			–	(25,631)	(25,631)
Balances at December 31, 2017	497,692	92,046	63	–	50,954	(147,638)	(96,684)
Cumulative effect of changes in accounting principle related to revenue recognition	–	–	–	–	–	3,086	3,086
Accretion of redeemable convertible preferred stock	–	9,318	–	–	(9,318)	–	(9,318)
Stock-based compensation	–	–	–	–	114	–	114
Issuance of Series F redeemable convertible preferred stock for aggregate proceeds of $0.078 per share, net of issuance costs of $7, in the third tranche closing of the Series F financing (Note 10)	34,914	3,868	–	–	(1,152)	–	(1,152)
Net loss (as revised)	–	–	–	–	–	(8,012)	(8,012)
Balances at December 31, 2018 (as revised)	532,606	105,232	63	–	40,598	(152,564)	(111,966)
Accretion of redeemable convertible preferred stock (unaudited)	–	2,114	–	–	(2,114)	–	(2,114)
Stock-based compensation (unaudited)	–	–	–	–	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 10) (unaudited)	97,646	7,520	–	–	–	–	–
Net loss (unaudited)	–	–	–	–	–	(2,704)	(2,704)
Balances at March 31, 2019 (unaudited) (as revised)	630,252	114,866	63	–	38,496	(155,268)	(116,772)
Accretion of redeemable convertible preferred stock (unaudited)	–	2,188	–	–	(2,188)	–	(2,188)
Stock-based compensation (unaudited)	–	–	–	–	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 10) (unaudited)	51,282	3,972	–	–	–	–	–
Net loss (unaudited)	–	–	–	–	–	(2,785)	(2,785)
Balances at June 30, 2019 (unaudited)	681,534	$121,026	63	$ –	$ 36,319	$ (158,053)	$ (121,734)

The accompanying notes are an integral part of these financial statements

Exagen Inc.

Statements of Redeemable Convertible Preferred Stock and Stockholders' Deficit
(in thousands)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
Balances at December 31, 2017	497,692	$ 92,046	63	$ –	$ 50,954	$ (147,638)	$ (96,684)
Cumulative effect of changes in accounting principle related to revenue recognition (unaudited)	–	–	–	–	–	3,086	3,086
Accretion of redeemable convertible preferred stock (unaudited)	–	1,382	–	–	(1,382)	–	(1,382)
Stock-based compensation (unaudited)	–	–	–	–	46	–	46
Issuance of Series F redeemable convertible preferred stock for aggregate proceeds of $0.078 per share, net of issuance costs of $7, in the third tranche closing of the Series F financing (Note 10) (unaudited)	34,914	3,868	–	–	(1,152)	–	(1,152)
Net loss (unaudited)	–	–	–	–	–	(2,793)	(2,793)
Balances at March 31, 2018 (unaudited)	532,606	97,296	63	–	48,466	(147,345)	(98,879)
Accretion of redeemable convertible preferred stock (unaudited)	–	2,312	–	–	(2,312)	–	(2,312)
Stock-based compensation (unaudited)	–	–	–	–	44	–	44
Net loss (unaudited)	–	–	–	–	–	(2,146)	(2,146)
Balances at June 30, 2018 (unaudited)	532,606	$ 99,608	63	$ –	$ 46,198	$ (149,491)	$ (103,293)

The accompanying notes are an integral part of these financial statements

Exagen Inc.

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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 suffered 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 December 31, 2018 and June 30, 2019, the Company had cash and cash equivalents of $13.2 million and $16.2 million, respectively, and had an accumulated deficit of $152.6 million (as revised) and $158.1 million, respectively. 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 the next twelve months.

To execute its business plans, the Company will 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 Company's financial statements are prepared in accordance with accounting principles generally accepted in the United States of America (GAAP). The preparation of the accompanying 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 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 financial statements include, but are not limited to revenue recognition, the fair value of the Company's common and redeemable convertible preferred stock, the fair value of financial instruments measured at fair value, the

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recoverability of its long-lived assets (including goodwill) and net deferred tax assets (and related valuation allowance). 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.

Unaudited Interim Financial Information

The accompanying interim balance sheet as of June 30, 2019, the statements of operations, and cash flows for the six months ended June 30, 2018 and 2019 and the statements of redeemable convertible preferred stock and stockholders' deficit for the three and six months ended June 30, 2018 and 2019 and the related footnote disclosures are unaudited. In management's opinion, the unaudited interim financial statements have been prepared on the same basis as the audited financial statements and include all adjustments, which include only normal recurring adjustments, necessary for the fair presentation of the Company's financial position as of June 30, 2019 and its results of operations and cash flows for the six months ended June 30, 2018 and 2019 in accordance with GAAP. The results for the six months ended June 30, 2019 are not necessarily indicative of the results expected for the full fiscal year or any other interim period.

Unaudited Pro Forma Information

The unaudited pro forma balance sheet information as of June 30, 2019 assumes (i) the receipt of aggregate gross proceeds of $11.0 million from the sale of Series H redeemable convertible preferred stock in July 2019 (Note 17), (ii) the conversion of all outstanding shares of redeemable convertible preferred stock (including Series H) into 7,816,643 shares of the Company's common stock and the related reclassification of (a) the carrying value of the redeemable convertible preferred stock to permanent equity and (b) our Series F redeemable convertible preferred stock warrant liabilities to additional paid-in capital and Series D and Series E redeemable convertible preferred stock warrant liabilities to net loss, a component of accumulated deficit, each of which will occur immediately prior to the completion of the Company's planned initial public offering (IPO), and (iii) the issuance of 15,072 shares of common stock upon the net exercise of all outstanding warrants to purchase common stock that have an exercise price less than the initial public offering price of $14.00 per share, and if not exercised prior to the IPO would terminate. Shares of common stock issued in the IPO and any related net proceeds are excluded from the pro forma information.

The unaudited pro forma basic and diluted net loss per share attributable to common stockholders has been computed to give effect to (i) the conversion of all convertible preferred stock into 7,816,643 shares of common stock as if the conversion had occurred as of the later of the beginning of the period or the original date of issuance; and (ii) the issuance of 15,072 shares of common stock upon the assumed net exercise of all outstanding warrants to purchase common stock that have an exercise price less than the initial public offering price of $14.00 per share, and if not exercised prior to the completion of the IPO would terminate.

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.

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Significant payers 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, revenue as a percentage of total revenue and accounts receivable as a percentage of total accounts receivable are as follows:

	Revenue			
	Years Ended December 31,		Six Months Ended June 30,	
	2017	2018	2018	2019
Medicare	30%	30%	31%	27%
Blue Shield	13%	14%	13%	13%
United Healthcare	15%	12%	13%	10%
Medicare Advantage	*	10%	10%	11%

* less than 10%

	Accounts Receivable		
	December 31,		June 30,
	2017	2018	2019
Medicare	84%	26%	25%
Blue Shield	—%	16%	15%
United Healthcare	—%	11%	11%
Medicare Advantage	—%	11%	9%

For the years ended December 31, 2017 and 2018 and the six months ended June 30, 2018 and 2019, approximately 89%, 82%, 86%, 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. An interruption in the supply of these materials would temporarily impact the Company's ability to perform testing services.

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;

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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.

The Company's acquisition-related liabilities, share purchase rights, tranche participation rights, and redeemable convertible preferred stock warrant liabilities are measured at fair value on a recurring basis and are classified as Level 3 liabilities. The Company records subsequent adjustments to reflect the increase or decrease in estimated fair value at each reporting date in current period earnings.

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 $100,000 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 statements of cash flows consist of the following (in thousands):

	December 31,		June 30,
	2017	2018	2019
Cash and cash equivalents	$11,241	$13,164	$16,237
Restricted cash	100	100	100
	$11,341	$13,264	$16,337

Accounts Receivable

Upon the adoption of ASC 606 on January 1, 2018, accounts receivable are recorded net of estimated contractual allowances on an accrual basis for tests billed (see revenue recognition discussion below). As a result, there was no bad debt expense recorded for the year ended December 31, 2018 or the six months ended June 30, 2018 and 2019 because any accounts receivable balance outstanding more than twelve months is considered as current period changes in allowances and recorded as reductions to revenues. Prior to January 1, 2018, the Company recorded

an allowance for doubtful accounts against its accounts receivable based on estimates consistent with historical payment experience. The Company's allowance for doubtful accounts as of December 31, 2017 was $48,000 and total bad debt expense recorded for the year ended December 31, 2017 was $34,000.

Deferred Offering Costs

The Company has deferred offering costs consisting of legal, accounting and other fees and costs directly attributable to its planned IPO. The deferred offering costs will be offset against the proceeds received upon the completion of the planned IPO. In the event the planned IPO is terminated, all of the deferred offering costs will be expensed within the Company's statements of operations. As of December 31, 2018 and June 30, 2019, $0.4 million and $1.2 million, respectively, of deferred offering costs were recorded within other assets in the accompanying balance sheets.

Property and Equipment

Property and equipment are stated at cost, net of depreciation and amortization. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, generally between three and five years. Leasehold improvements are amortized on a straight-line basis over the lesser of the estimated useful life or the remaining term of the related lease. Maintenance and repairs are charged to expense as incurred, and improvements and betterments are capitalized. When assets are retired or otherwise disposed of, the cost and accumulated depreciation are removed from the balance sheet and any resulting gain or loss is reflected in other income or expense in the statements of operations in the period realized.

Long-lived Assets

The Company's long-lived assets are comprised principally of its property and equipment, finite lived intangible assets, and goodwill.

If the Company identifies a change in the circumstances related to its long-lived assets, such as property and equipment and intangible assets (other than goodwill), that indicates the carrying value of any such asset may not be recoverable, the Company will perform an impairment analysis. A long-lived asset (other than goodwill) is deemed to be impaired when the undiscounted cash flows expected to be generated by the asset (or asset group) are less than the asset's carrying amount. Any required impairment loss would be measured as the amount by which the asset's carrying value exceeds its fair value, and would be recorded as a reduction in the carrying value of the related asset and a charge to operating expense.

Goodwill is reviewed for impairment annually (during the fourth quarter) or more frequently if indicators of impairment exist. As the Company operates in a single operating segment and reporting unit, the Company first assesses qualitative factors to determine whether it is more likely than not that the fair value of the reporting unit is less than its carrying amount as a basis for determining whether it is necessary to perform a quantitative assessment. If, after assessing qualitative factors, the Company determines it is not more likely than not that the fair value of a reporting unit is less than its carrying amount, then performing a quantitative assessment is unnecessary. If deemed necessary, a quantitative assessment compares the fair value of the reporting unit with its carrying amount, including goodwill. If the fair value of the reporting unit exceeds its carrying amount, goodwill is not considered

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impaired; otherwise, an impairment loss is recorded. There was no indication of impairment of goodwill for any periods presented.

Clinical Studies

From time to time, the Company engages in efforts to scientifically measure and document the application and efficacy of its various testing products. These arrangements typically require the Company to pay a fee to a third-party scientific investigator (usually a physician or research institution) for each subject enrolled in a clinical study, and the Company accrues expenses associated with these efforts as subjects are enrolled in each study. Expenses associated with clinical study activities are recorded in research and development expenses in the accompanying statement of operations.

Redeemable Convertible Preferred Stock

The Company has multiple classes of redeemable convertible preferred stock, all of which are classified as temporary equity in the balance sheet. Shares of Series A-3 redeemable convertible preferred stock have been classified as temporary equity in the balance sheet as holders of the Series A-3 redeemable convertible preferred stock can cause the redemption of the shares upon certain events such as a change in control or a significant transfer of the Company's assets to a third party, which are outside of the Company's control.

Shares of Series B-3, Series C, Series D, Series E, Series F and Series G redeemable convertible preferred stock are redeemable at any time after December 28th, 2023, upon the written request of the holders of 52% of the outstanding shares of these issuances, voting together as a single class. Redeemable convertible preferred stock which is redeemable on or after a certain date at the option of the holder is accreted to its redemption value from the date of issuance to the earliest redemption date.

Redeemable Convertible Preferred Stock Warrants

The Company accounts for its redeemable convertible preferred stock warrants as liabilities based upon the characteristics and provisions of each instrument. The redeemable convertible preferred stock warrants classified as liabilities are recorded on the Company's balance sheets at their fair value on the date of issuance and are revalued on each subsequent balance sheet date, with fair value changes recognized as increases or reductions in the statement of operations. The Company adjusts the liability for changes in fair value of these redeemable convertible preferred stock warrants until the earlier of: (i) exercise of warrants; (ii) expiration of redeemable convertible preferred stock warrants; (iii) a change of control of the Company; or (iv) the consummation of the Company's IPO. At that time, the redeemable convertible preferred stock warrant liabilities will be adjusted to fair value in the statement of operations with the final fair value reclassified to additional paid-in capital.

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

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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. 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.

The Company early adopted Topic 606 as of January 1, 2018 using a cumulative-effect adjustment to the opening balance of accumulated deficit and accounts receivable of $3.1 million. See Note 3 for further discussion.

Janssen Promotion Agreement

In December 2018, the Company entered into a co-promotion agreement with Janssen, or the Janssen agreement, to co-promote SIMPONI® in the United States. The Company is responsible for the costs associated with its sales force 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 ranging from $750 to $1,250 per prescription based on the incremental increase in total prescribed units of SIMPONI® for that quarter over a predetermined baseline. The promotion fee is determined on a sliding rate, ranging from the high hundreds of dollars to the low one thousands per prescribed unit of SIMPONI®, depending on the number of increased prescriptions, and varies per increased prescription. 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 the treatment of indications covered by the agreement without first obtaining Janssen's written consent.

The term of the Janssen agreement expires on June 30, 2020, unless extended by the Company for an additional 18 months upon 180 days written notice prior to the end of the initial term. Janssen can terminate the agreement at any time for any reason upon 30 days' notice to the Company, and the Company can terminate the agreement for any reason at the end of any calendar quarter upon 30 days' notice to Janssen. Either party may terminate the 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 the benefits

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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. As of December 31, 2018, there were no performance obligations under the agreement or consideration received. The Company began co-promoting SIMPONI® in early 2019 and recognized revenue of approximately $404,000 during the six months ended June 30, 2019. 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 $1.3 million, $1.4 million, $0.7 million, and $0.7 million for the years ended December 31, 2017 and 2018 and the six months ended June 30, 2018 and 2019, respectively, and are included in selling, general and administrative expenses in the accompanying statements of operations.

Shipping and Handling Costs

Costs incurred for shipping and handling are included in costs of revenue in the accompanying statements of operations and totaled approximately $1.1 million, $1.2 million, $0.6 million, and $0.7 million for the years ended December 31, 2017 and 2018 and six months ended June 30, 2018 and 2019, respectively.

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 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.

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Due to the absence of a public market for the Company's common stock, it has been necessary to estimate the fair value of the common stock underlying the Company's stock-based awards when performing fair value calculations using the BSM option pricing model. The fair value of the common stock underlying the Company's stock-based awards was assessed on each grant date by the Company's board of directors (Board of Directors). All options to purchase shares of the Company's common stock have been granted with an exercise price per share no less than the fair value per share of the Company's common stock underlying those options on the date of grant.

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.

Income Taxes

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined on the basis of the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

The Company recognizes net deferred tax assets to the extent that the Company believes these assets are more likely than not to be realized. In making such a determination, management considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If management determines that the Company would be able to realize its deferred tax assets in the future in excess of their net recorded amount, management would adjust the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

The Company records uncertain tax positions on the basis of a two-step process whereby (i) management determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (ii) for those tax positions that meet the more-likely-than-not recognition threshold, management recognizes the largest amount of tax benefit that is more than 50% likely to be realized upon ultimate settlement with the related tax authority. The Company recognizes interest and penalties related to unrecognized tax benefits within income tax expense. Any accrued interest and penalties are included within the related tax liability.

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

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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 plan. For the years ended December 31, 2017 and 2018 and for the six months ended June 30, 2018 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.

The following table summarizes the Company's net loss per share (in thousands, except share and per share data):

	Years Ended December 31,		Six Months Ended June 30,	
	2017	2018 (As Revised)	2018	2019
Numerator				
Net loss	$ (25,631)	$ (8,012)	$ (4,939)	$ (5,489)
Accretion of redeemable convertible preferred stock	(5,353)	(9,318)	(3,694)	(4,302)
Deemed dividend recorded in connection with financing transactions	(1,790)	(1,152)	(1,152)	—
Net loss attributable to common stockholders	$ (32,774)	$ (18,482)	$ (9,785)	$ (9,791)
Denominator				
Weighted-average common shares outstanding, basic and diluted	63,005	63,005	63,005	63,033
Net loss per share attributable to common stockholders, basic and diluted	$ (520.18)	$ (293.34)	$ (155.31)	$ (155.33)

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):

	December 31,		June 30,	
	2017	2018	2018	2019
Redeemable convertible preferred stock	5,012,814	5,202,940	5,202,940	6,013,941
Warrants to purchase redeemable convertible preferred stock	203,549	224,493	203,549	224,493
Warrants to purchase common stock	934,928	934,789	934,789	934,789
Common stock options	69,471	661,180	69,582	662,987
Total	6,220,762	7,023,402	6,410,860	7,836,210

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Unaudited Pro Forma Net Loss Per Share

The following table summarizes the Company's unaudited pro forma net loss per share (in thousands, except share and per share data):

	Year Ended December 31, 2018 (As Revised)	Six Months Ended June 30, 2019
Numerator:		
Net loss attributable to common stockholders	$ (18,482)	$ (9,791)
Add:		
Accretion of redeemable convertible preferred stock	9,318	4,302
Deemed dividend recorded in connection with financing transactions	1,152	—
Change in fair value of redeemable convertible preferred stock warrants	318	(467)
Pro forma net loss attributable to common stockholders, basic and diluted	$ (7,694)	$ (5,956)
Denominator:		
Weighted-average number of common shares outstanding, basic and diluted	63,005	63,033
Pro forma adjustments to reflect:		
Assumed conversion of redeemable convertible preferred stock	5,199,188	5,752,912
Assumed net exercise of warrants to purchase common stock	15,072	15,072
Shares used to compute pro forma net loss per share, basic and diluted	5,277,265	5,831,017
Pro forma net loss per share attributable to common stockholders, basic and diluted	$ (1.46)	$ (1.02)

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. 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 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*

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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 financial statements. The effective date of this guidance for public companies is for reporting periods beginning after December 15, 2018, and periods beginning after December 15, 2019 for private companies. ASU 2016-02 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 ASU 2016-02 on its financial statements.

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. 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 is currently evaluating the impact of ASU 2018-13 on its financial statements.

Recently Adopted Accounting Standards

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which, along with subsequent amendments and addenda to this standard, provides a five-step analysis of transactions to determine when and how revenue is recognized. The core principle is that a company should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The Company elected to apply Topic 606 to all contracts as of the adoption date. The Company early adopted this guidance on January 1, 2018 using a cumulative-effect adjustment to the opening balance of accumulated deficit and accounts receivable of $3.1 million. The cumulative-effect adjustment was the result of an acceleration of revenue recognition since the Company was required to estimate consideration to which it expects to be entitled rather than record revenue on a cash basis.

In November 2016, the FASB issued ASU 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash.* The amendments in this update require that a statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. As a result, entities will no longer present transfers between cash and cash equivalents and restricted cash and restricted cash equivalents in the statement of cash flows. The Company adopted this guidance for its fiscal year beginning January 1, 2018 and adjusted the presentation of its statements of cash flows to include its restricted cash balance with non-restricted cash balances for the periods presented. The Company's restricted cash balance consists of a federally insured certificate of deposit held with an affiliate of a large publicly traded financial institution that secures the Company's corporate credit card program. Due to the duration of this certificate of deposit, the amounts restricted as to use have been classified outside of

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cash and cash equivalents. The adoption of this standard did not have a material impact on its financial statements.

In January 2017, the FASB issued ASU 2017-04, *Simplifying the Test for Goodwill Impairment*. This guidance is intended to simplify the accounting for goodwill impairment for all entities by requiring impairment charges to be based on the first step in today's two-step impairment test under the guidance contained in ASC 350. Specifically, this guidance eliminates the requirement to calculate the implied fair value of goodwill to measure a goodwill impairment charge. Instead, entities will record an impairment charge based on the excess of a reporting unit's carrying amount over its fair value. The Company adopted this guidance on January 1, 2018, and the adoption did not have a material impact on its financial statements since the Company completed a qualitative assessment at December 31, 2018.

Note 3. Adoption of ASU 2014-09, Revenue from Contracts with Customers (Topic 606)

As discussed above, the Company early adopted Topic 606 as of January 1, 2018 using a cumulative-effect adjustment to the opening balance of accumulated deficit and accounts receivable of $3.1 million.

Prior to January 1, 2018, the Company recognized revenue when the following criteria was met: (i) persuasive evidence of an arrangement exists; (ii) delivery has occurred or services have been rendered; (iii) the fee is fixed or determinable; and (iv) collectability is reasonably assured. The assessment of the fixed or determinable nature of the fees charged and the collectability of those fees required significant judgment by management and revenue was recognized upon cash receipt until it had a contractual pricing arrangement with a payer or sufficient history to reliably estimate payment patterns. For the year ended December 31, 2017, revenue was recognized on an accrual basis for one payer, Medicare, and totaled $8.2 million.

In connection with the adoption, the Company utilized the following practical expedients and exemptions:

- Costs to obtain or fulfill a contract are expensed when incurred because the amortization period would have been one year or less.
- No adjustments to promised consideration were made for financing as the Company expects, at contract inception, that the period between the transfer of a promised good or service and when the customer pays for that good or service will be one year or less.

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The following is the impact of the adoption on the Company's statement of operations for the year ended December 31, 2018 and balance sheet as of December 31, 2018 (in thousands):

	As Reported (As Revised)	Amount under previous guidance (As Revised)	Impact of Adoption
Year ended December 31, 2018			
Statement of Operations:			
Revenue	$ 32,440	$ 30,967	$ 1,473
Net loss attributable to common stockholders	(18,482)	(19,955)	1,473
Net loss per share attributable to common stockholders, basic and diluted	(293.34)	(316.72)	23.38
Balance Sheet at December 31, 2018:			
Accounts receivable	$ 5,952	$ 1,393	$ 4,559
Total assets	28,887	24,328	4,559
Accumulated deficit	(152,564)	(157,123)	4,559

Disaggregation of revenue

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

	Years Ended December 31,		Six Months Ended June 30,	
	2017[1]	2018	2018	2019
Revenue:				
Healthcare insurers	$18,172	$21,070	$ 9,615	$11,528
Government	8,234	10,024	4,489	5,299
Client	176	608	257	2,193
Other[2]	225	738	215	310
Janssen (SIMPONI®)	–	–	–	404
Total revenue	$26,807	$32,440	$14,576	$19,734

(1) As noted above, amounts for the year ended December 31, 2017 are presented as originally reported based upon the accounting standards in effect for that period.

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

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Note 4. Other Financial Information

Prepaid Expenses and Other Current Assets

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

	December 31,		June 30,
	2017	2018	2019
Diagnostic testing supplies	$ 871	$1,174	$1,021
Prepaid product royalties	194	176	150
Prepaid maintenance and insurance contracts	334	698	666
Other prepaid assets	16	148	124
Prepaid and other current assets	$1,415	$2,196	$1,961

Property and Equipment

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

	December 31,		June 30,
	2017	2018	2019
Furniture and fixtures	$ 29	$ 25	$ 25
Laboratory equipment	1,538	1,855	2,126
Computer equipment and software	1,464	796	834
Leasehold improvements	367	399	410
Construction in progress	125	310	11
Total property and equipment	3,523	3,385	3,406
Less: accumulated depreciation and amortization	(2,180)	(1,819)	(2,167)
Property and equipment, net	$ 1,343	$ 1,566	$ 1,239

Depreciation and amortization expense for the years ended December 31, 2017 and 2018 and the six months ended June 30, 2018 and 2019 was approximately $484,000, $590,000, $285,000, and $363,000, respectively. At December 31, 2018 and June 30, 2019, the gross book value of assets under capital lease was $412,000 and $712,000, respectively, and is classified in “Laboratory equipment” in the table above.

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Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	December 31,		June 30,
	2017	2018	2019
Accrued payroll and related expenses	$1,974	$2,111	$2,552
Accrued deferred offering costs	–	355	795
Accrued interest	145	178	181
Accrued purchases of goods and services	252	243	312
Accrued royalties	552	602	671
Accrued clinical study activity	114	146	77
Capital lease obligations, current portion	27	81	152
Other accrued liabilities	154	207	487
Accrued liabilities	$3,218	$3,923	$5,227

Note 5. Share Purchase Rights

During 2016 and 2017, the Company entered into a series of agreements with existing holders of its redeemable convertible preferred stock to raise the following amounts in each respective period through the issuance of the following similar financial instruments (in thousands):

Agreement Date	
June 2016	$2,089
August 2016	1,000
October 2016	996
November 2016	996
December 2016	996
January 2017	996
February 2017	1,452
April 2017	1,315
Total proceeds	$9,840

Each tranche of these share purchase rights had an initial maturity date set at six months from the date of issuance (e.g. the June 2016 share purchase rights were set to mature in December 2016). In December of 2016, the holders of these financial instruments agreed to extend the maturity date of the June 2016 instruments until June 2017. In March of 2017, the holders of these financial instruments agreed to extend the maturity date of the August 2016 purchase rights and the October 2016 purchase rights until December 2017. Upon the maturity of each of these instruments, the notional amount of each instrument, plus all accrued interest, was set to convert into shares of Series E redeemable convertible preferred stock at a rate of $0.25 per share. The notional amount of each instrument accrued interest at an annual rate equal to 8%.

Each of these instruments contained a number of additional settlement features which were exercisable by the investors upon the occurrence of certain events: (i) Upon the occurrence of an IPO or subsequent issuance of preferred stock whose aggregate proceeds exceed $10,000,000, all

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instruments issued prior to December 2016 would convert into shares of common or preferred stock (as applicable to the class of shares issued) at an 80% discount to the issuance price of those shares. The instruments issued in February and April of 2017 did not provide for such a discount upon the issuance of preferred stock, but did provide for an 80% discount upon the occurrence of an IPO; (ii) Upon an event which results in the conversion of the outstanding shares of Series E redeemable convertible preferred stock to shares of common stock, or upon the election by the holders of these notes, these instruments would convert into shares of Series E redeemable convertible preferred stock at a rate of $0.25 per share; (iii) Upon a change of control of the Company, and with the consent of the Company's senior lenders, these instruments would be redeemed for 120% (200% for the instruments issued in February and April of 2017) of the principal and accrued interest of these instruments. If the consent of the senior lenders is not received in conjunction with a change in control of the Company, these instruments were to convert into shares of Series E redeemable convertible preferred stock at a rate of $0.25 per share; (iv) Upon a liquidation of the Company, and with the consent of the Company's senior lenders, these instruments were to be redeemed for 100% of the principal and accrued interest of these instruments. If the consent of the senior lenders was not received in conjunction with a liquidation of the Company, these instruments were set to convert into shares of Series E redeemable convertible preferred stock at a rate of $0.25 per share.

Based on an evaluation of the terms of these instruments, the Company concluded each of these instruments represented a single freestanding financial instrument providing each investor the ability to purchase shares of Series E redeemable convertible preferred stock at $0.25 per share upon maturity, and which contain a number of additional settlement features which were exercisable based on the occurrence of events outside of each investor's control. As a result of the contingent redemption features present in the Series E redeemable convertible preferred stock (Note 10), the Company concluded these instruments require classification as liabilities whose fair value will be marked-to-market each reporting period. The Company valued these instruments using a method that considered the expected fair value of each of the potential settlement alternatives available to the investors. The application of this method incorporated management's assumptions related to the likelihood and timing of events which give rise to each settlement alternative available to the investors under the terms of these instruments. The significant assumptions used in the valuation of these instruments include (i) Management's assumptions related to likelihood and timing of occurrence for each settlement feature and (ii) the fair value of the consideration that would be received upon the exercise of each settlement feature.

The following table summarizes the ranges for the significant assumptions utilized in management's estimates for the year ended December 31, 2017:

Estimated per share fair value of preferred stock	$0.11 - $0.13
Assessed likelihood of settlement into preferred shares of preferred stock	65% - 100%
Expected time to settlement event	0.1 years - 0.5 years

In May 2017, as a result of the Series F financing transaction (Note 10), all outstanding share purchase rights were converted into 163,785,334 shares of Series F redeemable convertible preferred stock in accordance with the settlement terms described above and as amended to allow a 20% discount to the per share issuance price for the share purchase rights issued in February 2017 and April 2017. Based on the estimated fair value and number of Series F redeemable convertible

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preferred stock issued based on the settlement terms, the fair value of the outstanding share purchase rights was estimated at $19.5 million, which resulted in expense of $10.1 million representing the change in the fair value of these financial instruments upon settlement.

Note 6. 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 December 31, 2018 and June 30, 2019, no additional amounts remain available to borrow under the 2017 Term Loan.

The interest rate on all borrowings under the 2017 Term Loan is 11.0%, of which 2.5% is paid in-kind in the form of additional term loans, or PIK Loans, until September of 2019, after which interest accrues at an annual rate of 11.0%. The Company has estimated the effective interest rate of this loan to be approximately 14%. Accrued interest is due and payable monthly, unless the Company elects to pay PIK interest. The outstanding principal and accrued interest on the 2017 Term Loan will be repaid in twenty-four equal monthly installments commencing in October 2020. Upon repayment of the final installment under the 2017 Term Loan, 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 2017 Term Loan using the effective interest method. For the years ended December 31, 2017 and 2018 and the six months ended June 30, 2018 and 2019, the Company issued PIK Loans totaling $159,000, $518,000, $251,000 and $320,000, respectively.

If the 2017 Term Loan is repaid prior to the September 7, 2019, the Company will be required to issue Innovatus a warrant to purchase 3,000,000 shares of Series F redeemable convertible preferred stock at an exercise price of $0.078 per share, and pay an additional prepayment premium which ranges between 0.25% and 2.5% of the outstanding term loan principal. If the 2017 Term Loan is prepaid after September 7, 2019, but before September 7, 2020, the 2017 Term Loan requires a prepayment premium of 3% of the aggregate outstanding principal. The prepayment premium decreases by 1% during each subsequent twelve-month period after September 7, 2020.

The 2017 Term Loan is collateralized by a first priority security interest on substantially all of the Company's assets, including intellectual property. The affirmative covenants of the 2017 Term Loan 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, and either (i) gross margins, or (ii) gross profits (collectively referred to as the Interest Only Milestones), as measured quarterly on a rolling twelve month basis, and commencing with the quarter ending December 31, 2017 (1) the interest rate on the 2017 Term Loan will increase by 8% and (2) repayment will commence on the date it is determined the Interest Only Milestones have not been met and over

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the following eighteen months in equal monthly installments. The consequences of failing to achieve the Interest Only Milestones will be waived if, within sixty days of failing to achieve the Interest Only Milestones, the Company issues additional equity securities or subordinated debt with net proceeds of at least $9.5 million. In addition, the 2017 Term Loan requires that the Company maintain certain levels of minimum liquidity. If the Company has achieved the Interest Only Milestones, the Company is required to maintain an unrestricted cash balance of $2,000,000. If the Interest Only Milestones are not met, the Company must maintain unrestricted cash balances totaling at least the trailing four months cash used to fund operating activities.

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 2017 Term Loan 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 December 31, 2018 and June 30, 2019, the Company was in compliance with all covenants of the 2017 Term Loan.

Upon an event of default in any of the 2017 Term Loan covenants, the repayment of the 2017 Term Loan may be accelerated and the applicable interest rate will be increased by 4.0% until the default is cured. Although repayment of the 2017 Term Loan can be accelerated under certain circumstances, the Company believes acceleration of this loan is not probable as of the date of these financial statements. Accordingly, the Company has reflected the amounts of the 2017 Term Loan due beyond twelve months of the balance sheet date as non-current.

In connection with the 2017 Term Loan, the Company paid issuance costs of $449,000 to Innovatus and an additional $119,000 to third parties. These fees were recorded as discounts to the carrying value of the 2017 Term Loan. The Company also issued Innovatus warrants (i) on the closing date of the 2017 Term Loan, to purchase 15,384,615 shares of Series F redeemable convertible preferred stock at an exercise price of $0.078 per share and (ii) on December 7, 2018, to purchase 3,846,154 shares of Series F redeemable convertible preferred stock at an exercise price of $0.078 per share (Note 7). These warrants are immediately exercisable and will expire if unexercised seven years after their issuance. The fair value of the warrants on each of their dates of issuance, determined using BSM option pricing model, was recorded as a discount to long-term debt and an offsetting amount recognized as a liability. The resulting debt discount is being amortized to interest expense using the effective interest method over the term of the 2017 Term Loan.

2013 Term Loan

In October 2013, the Company executed a term loan agreement (the 2013 Term Loan) with Capital Royalty Partners II L.P. and its affiliates Parallel Fund "a" L.P. and Parallel Investment Opportunities

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Partners II L.P. (collectively Capital Royalty). The total outstanding principal borrowed under the 2013 Term Loan was $15.0 million dollars. Amounts borrowed on the 2013 Loan accrued interest at 14.0% per annum with interest-only payments due on a quarterly basis with payment dates fixed at the end of each calendar quarter, or Payment Dates, through September 30, 2017. Under the terms of the loan, the Company elected to pay interest as follows: 10.0% per annum in cash and 4.0% per annum paid in-kind in the form of additional term loans, or PIK Loans. For the year ended December 31, 2017, the Company issued PIK Loans totaling $342,000.

In connection with the 2013 Term Loan, the Company issued a total of 4,174,430 warrants to purchase shares of Series D redeemable convertible preferred stock (Note 7) and an additional 17,350 warrants to purchase shares of common stock (Note 7) to Capital Royalty and a third party.

In September 2017, at the time of the repayment of all outstanding amounts, the difference between the carrying value of the 2013 Term Loan and the total principal and accrued interest of $306,000 was recorded within Loss on extinguishment of share purchase rights and 2013 Term Loan in the accompanying statement of operations.

Future Minimum Payments on the Outstanding Borrowings

Future minimum aggregate payments, including interest, for outstanding borrowings under the 2017 Term Loan are as follows (in thousands):

	December 31, 2018	June 30, 2019
2019	$ 2,372	$ 1,284
2020	6,125	6,125
2021	14,937	14,937
2022	11,250	11,250
Total	34,684	33,596
Less:		
Unamortized debt discount and issuance costs	(1,061)	(667)
Interest	(9,006)	(7,598)
Total borrowings, net of discounts and debt issuance costs	$ 24,617	$25,331

Note 7. Warrants to Purchase Common or Preferred Stock

Warrants to Purchase Common Stock

2013 Loan Common Stock Warrants

In connection with the 2013 Term Loan issued in October 2013 (Note 6), the Company issued warrants, or the 2013 Loan Common Stock Warrants, to purchase 17,350 shares of common stock exercisable at $1.84 per share. The 2013 Loan Common Stock Warrants are classified as a component of equity and are immediately exercisable and have a ten-year contractual term. The warrants expire in October 2023 and remain outstanding as of December 31, 2018 and June 30, 2019. All outstanding 2013 Loan Common Stock Warrants terminate if not exercised prior to the completion of an IPO.

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2016 Common Stock Warrants

In connection with the issuance of Series E redeemable convertible preferred stock during 2016, the Company issued 908,385 warrants to purchase common stock, or the 2016 Common Stock Warrants, exercisable at $1.84 per share. The 2016 Common Stock Warrants are classified as component of equity and are immediately exercisable and have a ten-year contractual term. The 2016 Common Stock Warrants remain outstanding as of December 31, 2018 and June 30, 2019.

In addition to the above, the Company has 9,054 common stock warrants outstanding as of December 31, 2018 and June 30, 2019 which are currently exercisable at $688.63 per share. These common stock warrants expire between May 2019 and October 2021. No amounts have been recorded for these common stock warrants as their fair value was determined to be immaterial. These common stock warrants terminate if not exercised prior to the completion of an IPO.

Warrants to Purchase Redeemable Convertible Preferred Stock

2013 Loan Redeemable Convertible Preferred Stock Warrants

In connection with the 2013 Term Loan issued in October 2013 (Note 6), the Company issued 3,186,430 and 988,000 warrants to purchase shares of Series D redeemable convertible preferred stock at $0.25 per share to its lender, Capital Royalty, and a third-party investment adviser, respectively. The Company collectively refers to the warrants described above as the 2013 Loan Redeemable Convertible Preferred Stock Warrants. The $1.0 million aggregate fair value of the warrants was recorded as a discount to the carrying value of the 2013 Term Loan and was amortized to interest expense over its respective term. The 2013 Term Loan was repaid in conjunction with the issuance of the 2017 Term Loan (Note 6). The 3,186,430 warrants issued to Capital Royalty and the 988,000 warrants issued to the third-party investment adviser are immediately exercisable and expire in October 2023 and November 2023, respectively, and remain outstanding at December 31, 2018 and June 30, 2019. All outstanding 2013 Loan Redeemable Convertible Preferred Stock Warrants terminate if not exercised prior to the completion of an IPO.

The 2013 Loan Redeemable Convertible Preferred Stock Warrants are classified as liabilities, with changes in fair value recorded through earnings, as the underlying shares of Series D redeemable convertible preferred stock can be redeemed by the holders of these shares upon the occurrence of certain events that are outside of the control of the Company (Note 10). The Company estimated the fair value of the 2013 Loan Redeemable Convertible Preferred Stock Warrants using an option pricing model. The significant inputs to this valuation methodology included the rights and preferences of each class of Company's shares (Note 10), Management's assumptions related to the expected timing of a liquidation event, and the Company's estimated equity value and volatility assumptions on the valuation date, which are based on management's analysis of comparable publicly traded peer companies.

For the years ended December 31, 2017 and 2018, the change in fair value of 2013 Loan Redeemable Convertible Preferred Stock Warrants was a benefit of $37,000 and an expense of $17,000 (as revised), respectively. For the six months ended June 30, 2018 and 2019, the change in the fair value of 2013 Loan Redeemable Convertible Preferred Stock Warrants was $0 and an expense of $87,000, respectively. All changes in fair value were recorded in change in fair value of financial instruments in the accompanying statements of operations.

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2015 Warrants

In 2015, the Company issued a variable number of warrants, the 2015 Warrants, which became a fixed and immediately exercisable warrant to purchase 2,688,181 shares of Series E redeemable convertible preferred stock at an exercise price of $0.25 per share as a result of the issuance of Series E redeemable convertible preferred stock in January 2016. Upon issuance, the Company estimated the fair value of the 2015 Warrants to be $87,000. The 2015 Warrants expire in October 2020 and remain outstanding at December 31, 2018 and June 30, 2019. All outstanding 2015 Warrants terminate if not exercised prior to the completion of an IPO, a change in control, reorganization, or liquidation.

The 2015 Warrants are classified as liabilities, with changes in fair value recorded through earnings, as the underlying shares of Series E redeemable convertible preferred stock can be redeemed by the holders of these shares upon the occurrence of certain events that are outside of the control of the Company (Note 10). For the years ended December 31, 2017 and 2018, the Company recognized a benefit of $19,000 and an expense of $5,000 (as revised), respectively, for the change in fair value of the 2015 Warrants. For the six months ended June 30, 2018 and 2019, the change in the fair value of the 2015 Warrants was $0 and a benefit of $40,000, respectively. All changes in fair value of the 2015 Warrants were recorded in change in fair value of financial instruments in the accompanying statements of operations and were computed using the methodology described above.

2017 and 2018 Warrants

In connection with the issuance of the 2017 Term Loan (Note 6) in September 2017, the Company issued warrants to Innovatus (the 2017 Warrants), which are immediately exercisable to purchase 15,384,615 shares of Series F redeemable convertible preferred stock at an exercise price of $0.078 per share. The 2017 Warrants are classified as liabilities, with subsequent changes in fair value recorded through earnings, as the underlying shares of Series F redeemable convertible preferred stock can be redeemed by the holders of these shares upon the occurrence of certain events that are outside of the control of the Company (Note 10). Upon their issuance, the fair value of the 2017 Warrants were estimated to be $1.0 million using the methodology described above. Since the 2017 Warrants are to be measured at fair value and were issued in conjunction with the 2017 Term Loan, the estimated fair value of the warrants issued was recorded as a discount to the carrying value of the 2017 Term Loan upon issuance.

In connection with additional borrowings made in December 2018 under the 2017 Term Loan (Note 6), the Company issued warrants to Innovatus (the 2018 Warrants), which are immediately exercisable to purchase 3,846,154 shares of Series F redeemable convertible preferred stock at an exercise price of $0.078 per share. The 2018 Warrants are classified as liabilities, with subsequent changes in fair value recorded through earnings, as the underlying shares of Series F redeemable convertible preferred stock can be redeemed by the holders of these shares upon the occurrence of certain events that are outside of the control of the Company (Note 10). Upon their issuance, the fair value of the 2018 Warrants was estimated to be $0.3 million using the methodology described above. Since the 2018 Warrants are to be measured at fair value and were issued in conjunction with the 2017 Term Loan, the estimated fair value of the warrants issued was recorded as a discount to the carrying value of the 2017 Term Loan upon issuance.

For the year ended December 31, 2017, the change in the fair value of the 2017 Warrants was a benefit of $185,000. For the year ended December 31, 2018, the change in the fair value of the 2017

and 2018 Warrants was an expense of $296,000 (as revised). For the six months ended June 30, 2018 and 2019, the change in the fair value of the 2017 and 2018 Warrants was $0 and a benefit of $514,000, respectively. These changes in fair value of the 2017 and 2018 Warrants were recorded in change in fair value of financial instruments in the accompanying statements of operations and were computed using the methodology described above.

The 2017 and 2018 Warrants will expire in September 2024 and December 2025, respectively, and remain outstanding at December 31, 2018 and June 30, 2019. All outstanding 2017 and 2018 Warrants terminate if not exercised prior to the completion of a change in control. If, in the Company's next round of equity financing, the Company issues preferred stock at a price per share lower than $0.078, the 2017 and 2018 Warrants will become exercisable at the issuance price of, and for that class of preferred shares issued. The number of such shares to be issued will be adjusted to equal $1,500,000 divided by the issuance price.

Note 8. Commitments and Contingencies

Leases

The Company leases approximately 14,000 square feet of office and laboratory space in Vista, California, under a lease that expires in January 2021, with options to extend the lease for two additional 36-month periods. In addition, the Company also leases approximately 19,500 square feet of office space in Vista, California, under a lease that expires in January 2021 with an option to extend the lease for an additional 24-month period. The Company's lease payments under each of these leases are subject to escalation clauses.

Minimum annual lease payments under non-cancelable lease arrangements at December 31, 2018 are as follows (in thousands):

Year Ending December 31,	Capital Leases	Operating Leases
2019	$ 92	$ 399
2020	92	411
2021	92	34
2022	65	–
2023	47	–
Total minimum lease payments	388	$ 844
Less: amount representing interest	(28)	
Present value of future minimum lease payments	360	
Less: current portion	(81)	
Long-term capital lease obligations	$ 279	

For the years ended December 31, 2017 and 2018 and the six months ended June 30, 2018 and 2019, rent expense was $424,000, $446,000, $227,000, and $235,000, 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. The Company has accounted for the related liabilities at fair value at each period end, using a probability weighted discounted revenue model. At December 31, 2016, the fair value of the obligations under these agreements was $51,000 and related to licensing agreements with Cellatope and Royalty Pharma.

In January of 2017, the Company amended its agreements with Cellatope. As a result of this amendment, the obligation to pay Cellatope a one-time payment of $3.0 million upon the launch of a monitoring product incorporating Cell-Bound Complement Activation Products (CB-CAPs) technology was replaced with an agreement to pay Cellatope a one-time payment of $100,000 upon the launch of such a product, plus a 7.5% royalty based on future cash collections from sales of that product which incorporate the licensed technology. Future royalties payable under this arrangement are limited to the lesser of $3,000,000 (including the upfront payment of $100,000) or the total royalty earned through January 1, 2024.

In February of 2017, the Company amended its agreements with Royalty Pharma relating to the launch of monitoring product using CB-CAPs technology. As a result of this amendment, the obligation to make a one-time payment of $1.0 million upon the launch of a monitoring product incorporating CB-CAPs technology was replaced with an agreement to pay Royalty Pharma a one-time payment of $100,000 upon the launch of such a product, plus a 2.5% royalty based on future cash collections from sales of that product which incorporate the licensed technology. Future royalties under this arrangement are limited to the lesser of $1,200,000 (including the upfront payment of $100,000) or the total royalty earned through January 1, 2024.

Based on an evaluation of the facts and circumstances leading to these amendments, including the length of time between these amendments and the original agreements with Cellatope and Royalty Pharma that were assigned to the Company in the acquisition of Cypress Bioscience, Inc. in 2010, and the concessions offered by the licensees, the Company concluded that these amendments should be accounted for separately from the original agreements with Cellatope and Royalty Pharma. As such, future royalties from the sale of monitoring products which incorporate the licensed technologies will be accrued upon the collection of cash from sale of such products and the Company will no longer recognize or remeasure a contingent liability for these obligations. As a result of the derecognition of this liability upon the execution of these amendments, the Company recorded a benefit of $51,000 to change in fair value of acquisition-related liabilities in the accompanying statement of operations.

Also in connection with the acquisition of Cypress Bioscience, Inc. in 2010, the obligation for an additional $2.0 million milestone payment to Prometheus exists for which the fair value of the obligation was determined to be nil at December 31, 2017 and 2018 and June 30, 2019.

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 3.0% to 20.0%. Royalties are accrued when earned and recorded in costs of revenue in the accompanying statement of operations.

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Supply Agreement

In January 2018, the Company entered into a supply agreement with one supplier for reagents which includes a minimum annual purchase commitment of $3.25 million for each of the three years covered by the agreement, which terminates in 2021.

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. 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. 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

The Company is not a party to any litigation and does not have contingent reserves established for any litigation liabilities.

Note 9. 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):

	December 31, 2017			
	Total	Level 1	Level 2	Level 3
Assets:				
Money market funds	$9,961	$9,961	$ –	$ –
Liabilities:				
Redeemable convertible preferred stock warrant liabilities	$ 896	$ –	$ –	$ 896

	December 31, 2018			
	Total (As Revised)	Level 1	Level 2	Level 3 (As Revised)
Assets:				
Money market funds	$ 8,618	$8,618	$ –	$ –
Liabilities:				
Redeemable convertible preferred stock warrant liabilities	$ 1,503	$ –	$ –	$ 1,503

	June 30, 2019			
	Total	Level 1	Level 2	Level 3
Assets:				
Money market funds	$15,690	$15,690	$ –	$ –
Liabilities:				
Redeemable convertible preferred stock warrant liabilities	$ 1,036	$ –	$ –	$1,036

The inputs and assumptions used to estimate the fair value of, warrants to purchase redeemable convertible preferred stock and acquisition-related liabilities are discussed in Note 7 and Note 8, respectively. The fair value of the Company's money market funds is based on quoted market prices.

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The following table includes a roll-forward of the financial instruments measured on a recurring basis and classified within Level 3 of the fair value hierarchy (in thousands):

	Total Amounts	Acquisition-Related Liabilities	Liability Classified Warrants (As Revised)	Share Purchase Rights	Tranche Participation Rights
Balances at December 31, 2016	$ 5,839	$ 51	$ 137	$ 5,651	$ –
Issuance of share purchase rights for cash (Note 5)	3,763	–	–	3,763	–
Conversion of share purchase rights in connection with the first tranche issuance of Series F redeemable convertible preferred stock (Note 10)	(19,508)	–	–	(19,508)	–
Issuance of tranche participation rights in connection with the first tranche closing of Series F redeemable convertible preferred stock (Note 10)	2,308	–	–	–	2,308
Exercise of tranche participation rights in connection with second tranche closing of Series F redeemable convertible preferred stock (Note 10)	(1,846)	–	–	–	(1,846)
Issuance of warrants to purchase shares of Series F redeemable convertible preferred stock in connection with 2017 Term Loan (Note 6)	1,000	–	1,000	–	–
Remeasurement of financial instruments	9,340	(51)	(241)	10,094	(462)
Balances at December 31, 2017	896	–	896	–	–
Issuance of warrants to purchase shares of Series F redeemable convertible preferred stock in connection with 2017 Term Loan (Note 6)	289	–	289	–	–
Remeasurement of financial instruments	318	–	318	–	–
Balances at December 31, 2018 and March 31, 2019	1,503	–	1,503	–	–
Remeasurement of financial instruments	(467)	–	(467)	–	–
Balances at June 30, 2019	$ 1,036	$ –	$ 1,036	$ –	$ –

Changes in the fair value of the Company's acquisition-related liabilities are recorded in the line item change in fair value of acquisition-related liabilities in the accompanying statement of operations.

Changes in the fair value of the Company's liability classified warrants, share purchase rights, and tranche participation rights are recorded in the line item change in fair value of financial instruments in the accompanying statement of operations.

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Note 10. Redeemable Convertible Preferred Stock

Description of Redeemable Convertible Preferred Stock

On January 2, 2019, the Company amended and restated its restated certificate of incorporation to, among other things, increase its authorized shares of convertible preferred stock from 750,300,000 to 955,500,000 shares, of which 205,200,000 shares are designated as Series G convertible preferred stock and set forth the rights, preferences and privileges of the Series G convertible preferred stock.

At December 31, 2017, the Company's redeemable convertible preferred stock consists of the following:

Series	Shares Authorized	Shares Outstanding	Per Share Liquidation Preference	Per Share Redemption Price	Carrying Value (in thousands)
Series A-3	1,400,000	1,369,185	$ 7.50	$ 7.50	$ 753
Series B-3	3,100,000	3,030,584	0.25	0.25	43
Series C	16,700,000	16,637,570	0.50	0.50	6,862
Series D	9,800,000	5,533,898	0.38	0.38	3,212
Series E	169,300,000	166,550,058	0.38	0.38	42,718
Series F	550,000,000	304,570,462	0.156	0.156	38,458
Total	750,300,000	497,691,757			$ 92,046

At December 31, 2018, the Company's redeemable convertible preferred stock consists of the following:

Series	Shares Authorized	Outstanding	Per Share Liquidation Preference	Per Share Redemption Price	Carrying Value (in thousands)
Series A-3	1,400,000	1,369,185	$ 7.50	$ 7.50	$ 753
Series B-3	3,100,000	3,030,584	0.25	0.25	79
Series C	16,700,000	16,637,570	0.50	0.50	7,174
Series D	9,800,000	5,533,898	0.38	0.38	3,212
Series E	169,300,000	166,550,058	0.38	0.38	46,632
Series F	550,000,000	339,484,789	0.234	0.234	47,382
Total	750,300,000	532,606,084			$ 105,232

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At June 30, 2019, the Company's redeemable convertible preferred stock consists of the following:

Series	Shares Authorized	Outstanding	Per Share Liquidation Preference	Per Share Redemption Price	Carrying Value (in thousands)
Series A-3	1,400,000	1,369,185	$ 7.50	$ 7.50	$ 753
Series B-3	3,100,000	3,030,584	0.25	0.25	99
Series C	16,700,000	16,637,570	0.50	0.50	7,281
Series D	9,800,000	5,533,898	0.38	0.38	3,212
Series E	169,300,000	166,550,058	0.38	0.38	48,014
Series F	550,000,000	339,484,789	0.234	0.234	49,824
Series G	205,200,000	148,928,337	0.117	0.117	11,843
Total	955,500,000	681,534,421			$ 121,026

The significant rights and preferences of the Company's redeemable convertible preferred stock are as follows:

Dividends

With the exception of Series A-3 redeemable convertible preferred stock, each holder of preferred stock is entitled to noncumulative dividends at an annual rate of $0.02 per share when and if declared by the Board of Directors. Dividends are paid in the following order of preference: (i) Series G, (ii) Series F, (iii) Series E, (iv) Series D (v) Series C, (vi) Series B-3, (vii) Series A-3, and (viii) common stock.

No dividend shall be declared or be payable on the outstanding shares of the Series B-3 redeemable convertible preferred stock without the consent of the holders of at least 53% of the outstanding shares of the Series G, Series F, Series E, Series D, and Series C redeemable convertible preferred stock, voting together as a single class, and no dividend shall be declared or be payable on the outstanding shares of the Series A-3 redeemable convertible preferred stock or the common stock, other than a dividend on shares of common stock payable entirely in shares of common stock, without the consent of the holders of at least 52% of the outstanding shares of the Series G, Series F, Series E, Series D, Series C, and Series B-3 redeemable convertible preferred stock. As of December 31, 2018 and June 30, 2019, the Board of Directors has not declared any dividends.

Liquidation

In the event of a liquidation, the Series G liquidation preference is paid prior to any other preferences. Upon the satisfaction of the Series G preference, the Series F liquidation preference is paid prior to any additional preferences. Upon the satisfaction of the Series G and Series F preferences, incremental proceeds from a liquidation event will be split between holders of Series F and Series E shares based on the ratio of the total aggregate purchase price of Series F shares and Series E shares, respectively, to the sum of the aggregate purchase price of Series F shares and the aggregate liquidation preference of the then outstanding Series E shares until the incremental proceeds received by Series E holders in this manner equals the Series E liquidation preference. After the Series E liquidation preference has been satisfied, the Series D liquidation preference is paid prior to the preferences for Series C, Series B-3, and Series A-3, the Series C liquidation preference is paid prior to the preferences for Series B-3 and A-3, the Series B-3 liquidation preference is paid prior to the

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preference for Series A-3, then the Series A-3 preference is paid. Following the satisfaction of the liquidation preferences, all shares participate in any remaining distribution based on the number of common shares into which their shares are convertible.

Conversion

Each share of redeemable convertible preferred stock is automatically convertible into common stock at its then effective conversion price (discussed above) (i) upon the election of the holders of at least 52% of the then outstanding shares of preferred stock, voting together as a single class, or (ii) upon the completion of a firm underwritten public offering of the Company's common stock with net proceeds (after underwriter's discounts and commissions) of at least $30.0 million, at a minimum valuation of $130,000,000.

In addition, each share of the Company's redeemable convertible preferred stock are convertible, at the option of the holder, into shares of common stock by dividing the initial conversion prices by the conversion price in effect at the time of conversion. As a result of the issuance of Series F redeemable convertible preferred stock in 2017, the conversion price of Series B-3, Series C, Series D and Series E redeemable convertible preferred stock was adjusted to $14.32.

The following table summarizes the number of shares of common stock into which each share of redeemable convertible preferred stock can be converted at December 31, 2018 (for all Series other than Series G) and June 30, 2019:

Series	Initial Conversion Price	Current Conversion Price	Conversion Ratio to Common Stock
Series A-3	$ 7.500	$1,377.26	0.0054
Series B-3	$ 0.250	$ 14.32	0.0175
Series C	$ 0.250	$ 14.32	0.0175
Series D	$ 0.250	$ 14.32	0.0175
Series E	$ 0.250	$ 14.32	0.0175
Series F	$ 0.078	$ 14.32	0.0054
Series G	$ 0.078	$ 14.32	0.0054

The conversion price of Series B-3, Series C, Series D, Series E, Series F and Series G redeemable convertible preferred stock is subject to adjustment for recapitalization (i.e. stock dividends, stock splits, reorganization, reclassification, combination of shares), or upon the issuance of shares at a price less than the then current conversion price.

Voting

With the exception of the Series A-3 redeemable convertible preferred stock, the holder of each share of preferred stock is entitled to one vote for each share of common stock into which it would convert. The holders of Series A-3 redeemable convertible preferred stock have no voting rights, except as required by law.

Redemption

Upon the request in writing of the holders of 52% of the outstanding shares of Series B-3, Series C, Series D, Series E, Series F, and Series G redeemable convertible preferred stock, voting together

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as a single class, at any time after December 28, 2023, the holders may redeem the outstanding Series B-3, Series C, Series D, Series E, Series F and Series G redeemable convertible preferred stock at the stated redemption price as noted in the table above, plus any declared but unpaid dividends.

At December 31, 2018, the Company was accreting the carrying amounts of the preferred stock up to the redemption amount at May 10, 2022, the earliest possible redemption date at that time, using the effective interest method. On January 2, 2019, upon the amendment of its Amended and Restated Certificate of Incorporation, the Company began accreting the carrying amounts of the preferred stock up to the redemption amount at December 28, 2023, the earliest possible redemption date, using the effective interest method.

Shares of Series A-3 redeemable convertible preferred stock have been included in temporary equity in the balance sheets as certain events such as a change in control or a significant a transfer of Company assets to a third party can compel the Company to redeem the shares of Series A-3 redeemable convertible preferred stock. These events have been deemed to be outside the control of the Company because they can be compelled by the holders of the Company's Series B-3, Series C, Series D, Series E, Series F and Series G redeemable convertible preferred stock through their voting interests.

Series F Financing

In May 2017, the Company entered into an agreement with certain existing preferred shareholders, who were also the holders of the Company's then outstanding share purchase rights (Note 5), to issue shares of Series F redeemable convertible preferred stock (Series F) in multiple separate closings at per share price of $0.078 in each closing. All investors in the first tranche closing were obligated to participate in a second tranche closing, and had the option to participate in any additional closings the Company might offer. The second tranche closing required all investors in the first closing to purchase an aggregate of 48,076,833 additional shares of Series F at $0.078 per share. Shares of Series F were issuable under the Series F preferred stock purchase agreement until the earlier of December 31, 2017 or the issuance of all authorized Series F shares, as specified in the Company's amended and restated certificate of incorporation.

In the first tranche closing of the Series F financing in May, 2017, the Company issued 48,076,833 shares of Series F at $0.078 per share for aggregate proceeds of $3.7 million and an additional 163,785,334 shares of Series F in exchange for the extinguishment of the outstanding notional amount (including accrued interest) of all outstanding share purchase rights (Note 5), which totaled $10.2 million.

The issuance price of Series F also resulted in adjustments to the conversion rates of the Company's previously outstanding shares of Series B-3, Series C, Series D and Series E redeemable convertible preferred stock. Prior to the issuance of shares of Series F, each of these shares were convertible into a single share of common stock. As a result of the issuance of shares of Series F, each of these shares is convertible into 0.0175 shares of common stock. As a result of the change in the conversion ratio, the Company recognized a beneficial conversion feature totaling $485,000 as a discount to the carrying value of the Company's preferred stock and an increase to additional paid-in capital in the accompanying balance sheet. This discount will be accreted against income available to

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common stockholders through the fifth anniversary of the issuance of Series F, which is the earliest period these preferred shares can be redeemed.

The Company concluded that the first closing of the Series F preferred stock purchase agreement contained two freestanding financial instruments: (1) shares of Series F and (2) tranche participation rights which, for a fixed amount of consideration in the second closing, required investors to purchase Series F in the second tranche closing at a fixed price of $0.078 per share. The Company evaluated the various conversion and redemption features embedded in shares of Series F (which are summarized above) and concluded that none of these features should be bifurcated from the Series F share and accounted for as a separate derivative instrument. The Company further evaluated the conversion features embedded in shares of Series F and determined they did not represent beneficial conversion features, as described in the related accounting literature. The Company determined there were no embedded features requiring bifurcation in the tranche participation rights.

The Company estimated the total fair value of Series F and participation rights purchased by investors that were issued in the first closing as $26.7 million. The Company estimated the fair value of a share of Series F using an option pricing method (OPM) which estimates the fair value of each class of equity securities as the net value of a series of call options, representing the present value of the expected future returns to each class of equity securities. The Company determined that the tranche participation rights represented a liability of $2.3 million on the date of the Series F financing as it was predominantly indexed to an obligation to purchase shares of Series F. This liability was marked to market through earnings. Due to the short duration of the participation rights, the Company estimated the fair value of the tranche participation rights using a method that considered the difference between the estimated fair value and issuance price of shares of Series F to be issued in the second tranche closing and the time value of money.

Since all investors in the first closing are existing preferred stockholders of the Company, the Company accounted for the $5.7 million difference between the fair value of shares of Series F, the proceeds received, the tranche participation rights issued, and the carrying value of the share purchase rights converted as a loss on the extinguishment of the share purchase rights, which was recorded in Loss on extinguishment of share purchase rights and 2013 Term Loan in the accompanying statement of operations.

In August 2017, the investors in the first tranche closing modified the terms of the participation rights to reduce the number of shares of Series F required to be purchased at $0.078 per share to 38,461,539 and to allow for the participation of an additional investor in the second tranche closing. As a result of this modification, the Company estimated the fair value of the tranche participation right to be $1.8 million and recorded the resulting benefit of $462,000 through earnings in the line item change in fair value of financial instruments in the accompanying statement of operations.

In August 2017, the Company completed the second tranche closing with an additional investor under the Series F preferred stock purchase agreement. The Company concluded that the second tranche closing of the Series F preferred stock purchase agreement contained a single freestanding financial instrument, shares of Series F, and, as discussed above, the Company determined there were no embedded features requiring bifurcation in shares of Series F. The Company determined that the change in the fair value of the tranche participation rights between the dates of the first and second

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closing was immaterial. The second tranche closing resulted in the issuance of 38,461,539 additional shares of Series F for aggregate proceeds of $3.0 million, and the reduction of $1.8 million to the estimated fair value of the previously recognized tranche participation rights.

The following table presents a summary of the accounting for the completion of the first and second tranche closings (in thousands):

Fair value of Series F shares issued	$ 31,540
Cash received upon issuance of Series F shares	(6,750)
Conversion of share purchase rights in conjunction with first tranche closing (Note 5)	(19,508)
Change in fair value of tranche participation rights in conjunction with modification in second tranche closing	462
Loss on extinguishment of share purchase rights in conjunction with first and second tranche closing	$ 5,744

In December 2017, the Company's Board of Directors authorized a third tranche closing of the Series F financing, which was completed between December 2017 and January 2018. In December 2017, a group of existing investors of the Company purchased 54,246,756 shares of Series F at a per share price of $0.078 for aggregate cash proceeds of $4.2 million. In early January 2018, a group of existing investors of the Company purchased an additional 34,914,327 shares of Series F at a per share price of $0.078 for aggregate cash proceeds of $2.7 million.

The Company concluded that the third tranche closing of the Series F preferred stock purchase agreement contained a single freestanding financial instrument, shares of Series F, and the Company determined there were no embedded features requiring bifurcation in the shares of Series F issued in the third tranche closing. The Company accounted for the difference between the estimated fair value and the $0.078 per share purchase price of shares of Series F issued in the third tranche closing as a deemed dividend since all investors in the third closing are existing preferred shareholders of the Company, and the Company did not identify any elements to the transaction which it believes were compensatory in nature. As a result, the Company recognized a deemed dividend in the amount of $1.8 million and $1.2 million in the years ended December 31, 2017 and 2018, respectively, that was recorded as additional paid-in capital (in the absence of retained earnings) in the accompanying statement of redeemable convertible preferred stock and stockholders' deficit.

Series G Financing

In January 2019, the Company entered into an agreement with new and certain existing preferred shareholders to issue shares of Series G redeemable convertible preferred stock (Series G) in multiple separate closings at per share price of $0.078 in each closing. Shares of Series G were issuable under the Series G preferred stock purchase agreement until the earlier of March 31, 2019 or the issuance of all authorized Series G shares, as specified in the Company's amended and restated certificate of incorporation.

In January 2019 and March 2019, the Company sold 88,030,905 and 9,615,384 shares, respectively, of Series G redeemable convertible preferred stock for aggregate gross proceeds of approximately $7.6 million to new and existing investors, of which $3.75 million of gross proceeds had been received as of December 31, 2018 and are included in the accompanying December 31, 2018 balance sheet.

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In May 2019, the Company sold an additional 51,282,048 shares of Series G redeemable convertible preferred stock for aggregate gross proceeds of approximately $4.0 million to existing investors.

In addition, in May 2019, the Series G Preferred Stock Agreement was amended to include the right of the Company to require certain holders of Series G redeemable convertible preferred stock to purchase an additional 32,051,280 shares of Series G redeemable convertible preferred stock at $0.078 per share, for total aggregate proceeds of $2.5 million, at any time after July 31, 2019 and prior to May 31, 2020. This right terminated in connection with the issuance of the Series H redeemable convertible stock in July (see Note 16).

The Company concluded that the closings of the Series G preferred stock purchase agreement in January and March 2019, contained a single freestanding financial instrument, shares of Series G, and the Company determined there were no embedded features requiring bifurcation in the shares of Series G issued. The Company concluded the closing in May 2019 contained two freestanding financial instruments, shares of Series G and the Company call right, and the Company concluded there were no embedded features requiring bifurcation in the shares of Series G issued. The Company call right was deemed to have nominal value since it was with insiders with knowledge of the imminent closing of Series H redeemable convertible stock.

Note 11. Stockholders' Deficit

Common Stock

Common stockholders are entitled to dividends as and when declared by the Board of Directors, subject to the rights of holders of all classes of stock outstanding having priority rights as to dividends. There have been no dividends declared to date. The holder of each share of common stock is entitled to one vote.

In May 2017, the Company's certificate of incorporation was amended and restated to authorize the issuance of up to 550,000,000 shares of Series F redeemable convertible preferred stock, and increase the number of authorized shares of common stock from 850,000,000 to 1,470,000,000.

On January 2, 2019, the Company amended and restated its restated certificate of incorporation to (i) increase its authorized shares of common stock from 1,470,000,000 to 1,675,200,000 shares and (ii) increase its authorized shares of convertible preferred stock from 750,300,000 to 955,500,000 shares, of which 205,200,000 shares are designated as Series G convertible preferred stock.

Exagen Inc.

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The Company had common shares reserved for future issuance upon the exercise or conversion of the following:

	December 31,		
	2017	2018	June 30, 2019
Redeemable convertible preferred stock	5,012,814	5,202,940	6,013,941
Warrants to purchase redeemable convertible preferred stock	203,549	224,493	224,493
Warrants to purchase common stock	934,928	934,789	934,789
Common stock option grants issued and outstanding	69,471	661,180	662,987
Common shares available for grant under the stock option plan	7,737	12,856	10,999
Total common shares reserved for future issuance	6,228,499	7,036,258	7,847,209

Note 12. Stock Option Plan

In December 2012, the Company's Board of Directors adopted the 2013 Stock Option Plan (the Plan). Pursuant to the Plan, employees, consultants, and directors may be granted either incentive stock options or non-qualified stock options to purchase shares of the Company's common stock. In October 2018, the shares reserved for future issuance under the 2013 Stock Option Plan were increased by 621,378 shares to a total of 669,806 shares. As of December 31, 2018 and June 30, 2019, 12,856 shares and 10,999 shares, respectively, remained available for future awards.

The exercise price of each stock option is established by the Board of Directors and is based on the estimated fair value of the Company's common stock on the grant date. 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 no longer than four years from the date of grant.

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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, 2017	69,471	$ 27.76	5.63	$ –
Granted	639,707	$ 0.26		
Exercised	–	$ –		
Forfeited	(220)	$ 1.84		
Expired	(47,778)	$ 27.54		
Outstanding, December 31, 2018	661,180	$ 1.22	9.62	$ 6,198
Granted	2,138	$ 9.92		
Exercised	(50)	$ 1.84		
Forfeited	(180)	$ 3.62		
Expired	(101)	$ 48.31		
Outstanding, June 30, 2019	662,987	$ 1.24	9.13	$ 8,916
Vested and expected to vest, December 31, 2018	661,180	$ 1.22	9.62	$ 6,198
Options exercisable, December 31, 2018	19,548	$ 31.53	5.17	$ 9
Vested and expected to vest, June 30, 2019	662,987	$ 1.24	9.13	$ 8,916
Options exercisable, June 30, 2019	20,180	$ 31.14	4.76	$ 18

The weighted-average grant date fair value per share of employee options granted to employees during the years ended December 31, 2017 and 2018 was $0.59 and $0.17, respectively. 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. The fair value of the Company's common stock is $0.37 per share, $9.92 per share and $14.14 per share at December 31, 2017 and 2018 and June 30, 2019, respectively.

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:

	Years Ended December 31,		Six Months Ended June 30,	
	2017	2018	2018	2019
Expected volatility	48% - 70%	70%	70%	59%
Risk-free interest rate	0.9% - 1.4%	1.4% - 2.6%	1.4%	2.6%
Dividend yield	–	–	–	–
Expected term (in years)	6.08	6.08	6.08	6.08

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

	Years Ended December 31,		Six Months Ended June 30,	
	2017	2018	2018	2019
Cost of revenue	$ 21	$ 12	$ 10	$ 2
Selling, general and administrative	154	93	74	18
Research and development	12	9	6	3
Total	$ 187	$ 114	$ 90	$ 23

As of December 31, 2017 and 2018 and June 30, 2019, total unrecognized compensation cost was $117,000, $112,000 and $102,000, respectively, which is expected to be recognized over a remaining weighted-average vesting period of 1.3 years, 3.8 years and 3.3 years, respectively.

Note 13. Income Taxes

The (benefit) provision for income taxes consists of the following (in thousands):

	Years Ended December 31,	
	2017	2018
Current:		
Federal	$ –	$ –
State	5	27
Total current	5	27
Deferred:		
Federal	(625)	10
State	71	21
Total deferred	(554)	31
(Benefit) provision for income tax	$ (549)	$ 58

The Tax Cuts and Jobs Act (the Act) was enacted on December 22, 2017. The Act reduces the U.S. federal corporate tax rate from 35% to 21%. At December 31, 2017, the Company re-measured its deferred tax assets and liabilities based on the rates at which they are expected to reverse in the future, which is generally 21%. As a result of the re-measurement of the Company's deferred tax assets and liabilities, the Company recognized income tax expense of $10.6 million. This amount was offset by a reduction in the valuation allowance of $11.1 million. $549,000 of the reduction in the valuation allowance resulted from the reclassification of certain of the Company's deferred tax assets as indefinite-lived, as a result of the Act, which are now able to offset the Company's indefinite-lived deferred tax liabilities.

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The effective tax rate of our (benefit) provision for income taxes differs from the federal statutory rate as follows:

	Years Ended December 31,	
	2017	2018 (As Revised)
Federal statutory tax rate	(34.0)%	(21.0)%
State income taxes, net of federal tax benefits	(1.2)%	(3.9)%
Change in fair value of share purchase rights and preferred stock liabilities	12.5%	0.8%
Loss on extinguishment	7.9%	–%
Enactment of Tax Cuts and Job Act	40.3%	–%
Change in valuation allowance	(27.6)%	23.2%
Other	–%	1.6%
Effective tax rate	(2.1)%	0.7%

Significant components of the Company's deferred tax assets at December 31, 2017 and 2018 are shown below. A valuation allowance has been established as realization of the Company's deferred tax assets has not met the more likely-than-not threshold requirement. If the Company's judgment changes and it is determined that the Company will be able to realize these deferred tax assets, the tax benefits relating to any reversal of the valuation allowance on deferred tax assets will be accounted for as a reduction to income tax expense (in thousands).

	December 31,	
	2017	2018 (As Revised)
Deferred tax assets:		
Net operating loss carryforwards	$ 18,044	$ 18,937
Accrued revenue(1)	1,543	–
Research and development tax credits	96	313
Accruals, reserves and other	412	1,394
Interest expense	–	691
Basis differences in fixed and intangible assets	222	230
Total gross deferred tax assets	20,317	21,565
Less: Valuation allowance	(19,929)	(21,138)
Deferred tax assets, net	388	427
Deferred tax liabilities:		
Financing and acquisition-related liabilities	(334)	(338)
Indefinite lived assets	(268)	(334)
Deferred tax liabilities, net	(602)	(672)
Net deferred tax liabilities	$ (214)	$ (245)

(1) The deferred tax liability for uncollectible accounts has been netted with the accrued revenue deferred tax asset for presentation purposes as the nature of these deferred items are related.

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Changes in the valuation allowance for deferred tax assets during the years ended December 31, 2017 and 2018, which related primarily to increases in net operating loss carryforwards, accrued revenue and accruals and reserves, and impacts of the Tax Cuts and Jobs Act were as follows (in thousands):

	December 31,	
	2017	2018 (As Revised)
Valuation allowance at the beginning of the year	$27,146	$ 19,929
Decreases recorded as benefits to income tax provision	(7,217)	–
Increases recorded to income tax provision	–	1,209
Valuation allowance at the end of the year	$19,929	$ 21,138

At December 31, 2017 and 2018, the Company had federal net operating loss carryforwards of approximately $77.8 million and $80.8 million, respectively. At December 31, 2017 and 2018, the Company had state net operating loss carryforwards of $30.3 million and $30.6 million (as revised), respectively. Approximately $77.7 million (as revised) of the federal tax loss carryforwards will begin to expire in 2022, unless previously utilized. The federal net operating loss carryforwards generated in 2018 of $3.1 million (as revised) will carryforward indefinitely and be available to offset up to 80% of future taxable income each year. The Company's state tax loss carryforwards will expire in 2032, unless previously utilized.

Pursuant to Internal Revenue Code (IRC), Section 382 and 383, use of the Company's U.S. federal and state net operating loss and research and development income tax credit carryforwards may be limited in the event of a cumulative change in ownership of more than 50.0% within a three-year period. The Company had an ownership change in 2008 and, as a result, certain carryfowards are subject to an annual limitation, reducing the amount available to offset income tax liabilities absent the limitation.

The Company is subject to taxation in the U.S. and in various state jurisdictions. The Company's tax years for 2002 and forward are subject to examination by the U.S. and state tax authorities due to the carryforward of unutilized net operating losses and research and development credits.

The Company recognizes interest and / or penalties related to income tax matters in its provision for income taxes. The Company does not have any accruals for, and did not recognize any, interest or penalties in these financial statements in any period presented.

Uncertain Tax Positions

At December 31, 2017 and 2018, the Company had no unrecognized tax benefits.

The Company does not believe that the balance of unrecognized tax benefits will materially change within the next twelve months.

Note 14. Related Parties

The Company entered into various agreements under which directors of the Company are paid for consulting services and for serving on the Board of Directors. In June of 2017, two members of the

Exagen Inc.

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Company's Board of Directors resigned their position as members of the Board of Directors and the Company terminated all previously existing agreements which required payments to board members for their services. Total compensation expense paid to board members under these various agreements for the year ending December 31, 2017 was $81,000, which was recorded in selling, general and administrative expenses in the accompanying statements of operations.

In September 2017, the Company entered into a consulting services agreement with a member of the Company's Board of Directors under which this board member will provide certain scientific consulting services to the Company. Under this agreement, this board member was compensated at a bi-weekly rate of $4,615 (plus reimbursement for certain administrative and travel related expenses) and received options to purchase 544 shares of common stock in November 2017. This agreement was amended in June 2018 and the biweekly compensation rate increased to $5,000. Total amounts paid to this board member under this agreement for the years ending December 31, 2017 and 2018 and the six months ended June 30, 2018 and 2019, were $52,000, $126,000, $61,000, and $65,000, respectively, which was recorded in research and development expenses in the accompanying statements of operations. The Company accounted for the grant of options as an award to a non-employee and measures compensation cost for this award based on the value of the award at the date the consulting services are complete. The options granted to this board member were granted at an exercise price of $0.367 (the estimated fair value of share of common stock on the grant date using an OPM model), and vests over a three-year term expected to coincide with the period the board member is expected to provide consulting services to the Company. The estimated fair value of the awards and related compensation cost recognized during the year ended December 31, 2017 and 2018 and the six months ended June 30, 2018 and 2019 was immaterial. All compensation cost related to these awards is recorded in research and development expenses in the accompanying statements of operations.

In 2016, the Company leased office space in New Mexico on a month-to-month basis from a third party which specializes in providing outsourced information technology support services, and a partner in this company was an immediate family member of an executive at the Company. At December 31, 2017, the Company no longer leases this facility and this executive is no longer employed by the Company. Total expenses related to information technology support services provided by this related party for the years ended December 31, 2017 and 2018 and the six months ended June 30, 2018 and 2019, was $159,000, $157,000, $83,000, and $89,000, respectively. The total rent expense related to this rental agreement for the year ending December 31, 2017 was $20,000, which was recorded in selling, general and administrative expenses in the accompanying statements of operations.

In September 2011, the Company entered into a license agreement with the Company's Chief Scientific Officer, and a related company, De Novo. The license agreement, covering novel methods for monitoring low-dose methotrexate therapy, relates to technology developed by the Company's Chief Scientific Officer prior to joining the Company. The technology has yet to be used by the Company. Under the agreement, the Company's Chief Scientific Officer will be eligible to receive up to $600,000 upon the achievement of certain sales milestones and an ongoing royalty of 5% on sales.

The share purchase rights described in Note 5 were issued to existing holders of the Company's preferred stock. The first and third tranche closings of the Series F financing and the closings of the Series G financing described in Note 10 were issued to existing holders of the Company's redeemable convertible preferred stock.

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Note 15. 401(k) Plan

The Company sponsors an employee savings plan that qualifies as a deferred salary arrangement under Section 401(k) of the Code. Participating employees may defer up to the Internal Revenue Service annual contribution limit. Additionally, the Company may elect to make contributions into the savings plan at its sole discretion. For the years ended December 31, 2017 and 2018 and the six months ended June 30, 2018 and 2019, the Company made contributions to the Plan at 3% of qualified employee compensation, which totaled approximately $362,000, $357,000, $152,000, and $183,000, respectively.

Note 16. Correction of Immaterial Misstatements in the Financial Statements for the Year Ended December 31, 2018

During 2019, Company management identified immaterial misstatements in the financial statements for the year ended December 31, 2018 related to the carrying value of redeemable convertible preferred stock warrant liabilities. Based on a quantitative and qualitative analysis of the error as required by authoritative guidance, management concluded that the correction, which decreased the carrying value of the redeemable convertible preferred stock warrant liabilities with a corresponding decrease in net loss, had no material impact on the Company's previously issued financial statements as of and for the year ended December 31, 2018. These amounts have been adjusted in the accompanying balance sheet and statement of operations.

The revision to the Company's previously reported balance sheet are identified in the table below:

	As of December 31, 2018		
	As Previously Reported	Adjustment	As Revised
Redeemable convertible preferred stock warrant liabilities	$ 2,680	$ (1,177)	$ 1,503
Total liabilities	36,798	(1,177)	35,621
Accumulated deficit	153,741	(1,177)	152,564
Total stockholders' deficit	$113,143	$ (1,177)	$111,966

The revision to the Company's previously reported statement of operations are identified in the table below:

	For Year Ended December 31, 2018		
	As Previously Reported	Adjustment	As Revised
Change in fair value of financial instruments	$ (1,495)	$ 1,177	$ (318)
Loss before income taxes	(9,131)	1,177	(7,954)
Net loss	(9,189)	1,177	(8,012)
Net loss attributable to common stockholders	(19,659)	1,177	(18,482)
Net loss per share attributable to common stockholders, basic and diluted	$(312.02)	$ 18.68	$(293.34)

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A revised rollforward of the Company's warrant liabilities is as follows:

	As Previously Reported	Adjustment	As Revised
Balance, December 31, 2017	$ 896	$ —	$ 896
Issuance of warrants to purchase shares of Series F redeemable convertible preferred stock in connection with 2017 Term Loan (Note 6)	289	—	289
Change in fair value of financial instruments	1,495	(1,177)	318
Balance, December 31, 2018	2,680	(1,177)	1,503
Balance, March 31, 2019 (unaudited) (as revised)	$ 2,680	$ (1,177)	$1,503

Note 17. Subsequent Events

Sale of Series H Redeemable Convertible Preferred Stock

In July 2019, the Company entered into an agreement with a new investor to issue shares of Series H redeemable convertible preferred stock (Series H) at a per share price of $0.04712. Pursuant to the terms of the agreement, the new investor purchased 233,446,519 shares of Series H for gross proceeds of $11.0 million. In connection with the Series H financing, the Company converted all of the 148,928,337 outstanding shares of the Company's Series G redeemable convertible preferred stock into 246,521,076 shares of Series H on a dollar-for-dollar basis.

The Company agreed to reimburse the new investor up to $100,000 of legal expenses incurred in connection with the transaction.

Amended and Restated Certificate of Incorporation

In July 2019, the Company amended and restated its restated certificate of incorporation to, among other things, (1) increase its authorized shares of common stock from 1,675,200,000 to 1,970,000,000 shares, (2) increase its authorized shares of convertible preferred stock from 955,500,000 to 1,038,667,059 shares, of which 479,967,595 shares are designated as Series H, and (3) set forth the rights, preferences and privileges of the Series H.

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The following table summarizes the liquidation preferences, redemption prices and non-cumulative dividends authorized as a result of the adoption of this amendment and restatement.

Series	Shares Authorized	Per Share Liquidation Preference	Per Share Redemption Price	Per Share Non-Cumulative Dividends
Series A-3	1,369,185	$ 7.50	$ 7.50	$ –
Series B-3	3,030,584	0.25	0.25	0.00624
Series C	16,637,570	0.50	0.50	0.00624
Series D	9,708,328	0.38	0.38	0.00624
Series E	169,238,239	0.127	0.127	0.00624
Series F	358,715,558	0.74	0.74	0.00624
Series H	479,967,595	.04712	.04712	0.00377
Total	1,038,667,059			

In addition, the earliest possible redemption date for the outstanding shares of the redeemable convertible preferred stock is now July 12, 2024.

2013 Stock Option Plan

In July 2019, the number of shares of common stock reserved for issuance under the Plan was increased from 669,806 shares to 1,663,681 shares.

2019 Incentive Award Plan

In August 2019 and September 2019, the Company approved a grant to certain employees, executive officers and members of the board of directors of options to purchase an aggregate of 812,745 shares of common stock under the 2019 Incentive Award Plan (the 2019 Plan), contingent and effective upon the approval of the 2019 Plan and the effectiveness of the Form S-1 Registration Statement filed with the Securities and Exchange Commission, with an exercise price that is equal to the initial public offering price.

In September 2019, the Board of Directors adopted, and the Company's stockholders approved 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. A total of (i) 2,011,832 shares of common stock plus (ii) the number of shares subject to awards granted under the 2013 Plan on or before the effective date of the 2019 Plan that become available for issuance under the 2019 Plan will initially be reserved for issuance under the 2019 Plan. In addition, the number of shares of common stock available for issuance under the 2019 Plan will be increased annually on the first day of each fiscal year during the term of the 2019 Plan, beginning with the 2020 fiscal year, by an amount equal to 4% of the total number of shares of capital stock outstanding on December 31st of the preceding calendar year or such smaller other amount as the Board of Directors may determine.

Approval of the Employee Stock Purchase Plan

In September 2019, the Board of Directors adopted the Employee Stock Purchase Plan (the ESPP). The ESPP became effective on the day the ESPP was adopted by our Board of Directors. The ESPP permits participants to purchase common stock through payroll deductions of up to 20% of their

Exagen Inc.

Notes to Financial Statements
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eligible compensation. A total of 120,000 shares of common stock is initially reserved for issuance under the ESPP. In addition, the number of shares of common stock available for issuance under the ESPP will be annually increased on the first day of each fiscal year during the term of the ESPP, beginning with the 2020 fiscal year, by an amount equal to 1% of the total number of shares of common stock outstanding on the effective date of the ESPP.

Reverse Stock Split

On September 6, 2019, the Company effected a one-for-183.635 reverse stock split of its common stock (the Reverse Stock Split). The par value and the authorized shares of the common stock were not adjusted as a result of the Reverse Stock Split. All issued and outstanding common stock and the conversion ratio of the redeemable convertible preferred stock have been retroactively adjusted to reflect this Reverse Stock Split for all periods presented.

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3,600,000 Shares

Common Stock

PROSPECTUS

Joint Book-running Managers

Cowen **Cantor** **William Blair**

September 18, 2019