Section 1: 10-Q (10-Q)

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended March 31, 2019

OR

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

For the transition period from _____ to _____

Commission File Number 000-14656

REPLIGEN CORPORATION
(Exact Name of Registrant as Specified in its Charter)

Delaware	**04-2729386**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
41 Seyon Street, Bldg. 1, Suite 100 Waltham, MA	**02453**
(Address of Principal Executive Offices)	**(Zip Code)**

(781) 250-0111
Registrant's Telephone Number, Including Area Code

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15 (d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
Emerging growth company	☐		

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

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.01 per share	**RGEN**	**The Nasdaq Global Select Market**

The number of shares outstanding of the registrant’s common stock on May 3, 2019 was 47,225,369.

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PART I – FINANCIAL INFORMATION

ITEM 1. Financial Statements

REPLIGEN CORPORATION
CONSOLIDATED BALANCE SHEETS
(Unaudited, amounts in thousands, except share data)

	March 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 196,135	$ 193,822
Accounts receivable, less reserve for doubtful accounts of $226 and $227 at March 31, 2019 and December 31, 2018, respectively	39,341	33,015
Royalties and other receivables	21	136
Unbilled receivables	—	2,602
Inventories, net	44,920	42,263
Prepaid expenses and other current assets	3,660	3,901
Total current assets	284,077	275,739
Property, plant and equipment, net	34,526	32,180
Intangible assets, net	132,648	135,438
Goodwill	326,395	326,735
Deferred tax assets	3,917	4,355
Operating lease right of use assets	16,185	—
Other assets	173	174
Total assets	$ 797,921	$ 774,621
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 9,823	$ 10,489
Operating lease liability	3,100	—
Accrued liabilities	12,760	15,865
Convertible senior notes, current portion	104,595	103,488
Total current liabilities	130,278	129,842
Deferred tax liabilities	25,097	25,086
Operating lease liability, long-term	17,088	—
Other liabilities, long-term	433	4,125
Total liabilities	172,896	159,053
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock, $0.01 par value, 5,000,000 shares authorized, no shares issued or outstanding	—	—
Common stock, $0.01 par value; 80,000,000 shares authorized; 44,073,998 shares at March 31, 2019 and 43,917,378 shares at December 31, 2018 issued and outstanding	441	439
Additional paid-in capital	645,883	642,590
Accumulated other comprehensive loss	(13,784)	(11,893)
Accumulated deficit	(7,515)	(15,568)
Total stockholders' equity	625,025	615,568
Total liabilities and stockholders' equity	$ 797,921	$ 774,621

The accompanying notes are an integral part of these consolidated financial statements.

REPLIGEN CORPORATION
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(Unaudited, amounts in thousands, except per share data)

	For the Three Months Ended March 31,	
	2019	**2018**
Revenue:		
Products	$ 60,612	$ 44,799
Royalty and other revenue	22	31
Total revenue	60,634	44,830
Costs and operating expenses:		
Cost of product revenue	26,845	19,668
Research and development	3,620	3,288
Selling, general and administrative	18,998	15,898
Total costs and operating expenses	49,463	38,854
Income from operations	11,171	5,976
Other income (expenses):		
Investment income	713	181
Interest expense	(1,726)	(1,652)
Other income	358	71
Other expenses, net	(655)	(1,400)
Income before income taxes	10,516	4,576
Income tax provision	2,463	1,128
Net income	$ 8,053	$ 3,448
Earnings per share:		
Basic	$ 0.18	$ 0.08
Diluted	$ 0.17	$ 0.08
Weighted average common shares outstanding:		
Basic	43,968	43,621
Diluted	46,279	44,327
Net income	$ 8,053	$ 3,448
Other comprehensive income (loss):		
Foreign currency translation adjustment	(1,891)	251
Comprehensive income	$ 6,162	$ 3,699

The accompanying notes are an integral part of these consolidated financial statements.

REPLIGEN CORPORATION
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(Unaudited, amounts in thousands, except share data)

	Common Stock					
	Number of Shares	Par Value	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2018	43,917,378	$ 439	$ 642,590	$ (11,893)	$ (15,568)	$ 615,568
Net income	—	—	—	—	8,053	8,053
Exercise of stock options and releases of restricted stock	156,620	2	42	—	—	44
Stock-based compensation expense	—	—	3,251	—	—	3,251
Translation adjustment	—	—	—	(1,891)	—	(1,891)
Balance at March 31, 2019	44,073,998	$ 441	$ 645,883	$ (13,784)	$ (7,515)	$ 625,025

	Common Stock					
	Number of Shares	Par Value	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2017	43,587,079	$ 436	$ 628,983	$ (6,363)	$ (31,508)	$ 591,548
Net income					3,448	3,448
Issuance of common stock for debt conversion	2	0	0	—	—	—
Exercise of stock options and releases of restricted stock	105,222	1	344	—	—	345
Stock-based compensation expense	—	—	2,268	—	—	2,268
Cumulative effect of accounting changes	—	—	—	—	(677)	(677)
Translation adjustment	—	—	—	251	—	251
Balance at March 31, 2018	43,692,303	$ 437	$ 631,595	$ (6,112)	$ (28,737)	$ 597,183

The accompanying notes are an integral part of these consolidated financial statements.

REPLIGEN CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited, amounts in thousands)

	Three Months Ended March 31,	
	2019	**2018**
Cash flows from operating activities:		
Net income	$ 8,053	$ 3,448
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	4,213	3,960
Non-cash interest expense	1,107	1,036
Stock-based compensation expense	3,251	2,268
Deferred tax expense	892	449
Other	—	1
Changes in operating assets and liabilities, excluding impact of acquisitions:		
Accounts receivable	(6,692)	(1,529)
Royalties and other receivables	112	127
Unbilled receivables	2,602	—
Inventories	(1,478)	(1,188)
Prepaid expenses and other assets	215	(1,608)
Operating lease right of use assets	784	—
Accounts payable	(570)	(1,550)
Accrued expenses	(1,855)	(3,839)
Operating lease liability	(840)	—
Long-term liabilities	(6)	(3)
Total cash provided by operating activities	9,788	1,572
Cash flows from investing activities:		
Additions to capitalized software costs	(1,740)	—
Purchases of property, plant and equipment	(2,088)	(1,564)
Total cash used in investing activities	(3,828)	(1,564)
Cash flows from financing activities:		
Exercise of stock options	44	344
Repayment of senior convertible notes	—	(11)
Total cash provided by financing activities	44	333
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(3,691)	(224)
Net increase in cash, cash equivalents and restricted cash	2,313	117
Cash, cash equivalents and restricted cash, beginning of period	193,822	173,759
Cash, cash equivalents and restricted cash, end of period	$196,135	$173,876
Supplemental disclosure of cash flow information:		
Income taxes paid	$ 1,055	$ 937
Supplemental disclosure of non-cash investing and financing activities:		
Non-cash effect of adoption of ASU 2016-16	$ —	$ 5,609

The accompanying notes are an integral part of these consolidated financial statements.

REPLIGEN CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

1. Basis of Presentation

The consolidated financial statements included herein have been prepared by Repligen Corporation (the "Company", "Repligen" or "we") in accordance with generally accepted accounting principles in the United States ("GAAP") and pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC"), for Quarterly Reports on Form 10-Q and Article 10 of Regulation S-X and do not include all of the information and footnote disclosures required by GAAP. These consolidated financial statements should be read in conjunction with the audited consolidated financial statements and accompanying notes thereto included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2018.

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, Repligen Sweden AB, Repligen GmbH, Spectrum LifeSciences, LLC and its subsidiaries ("Spectrum," acquired on August 1, 2017) and Repligen Singapore Pte. Ltd. All significant intercompany accounts and transactions have been eliminated in consolidation.

In the opinion of management, the accompanying unaudited consolidated financial statements include all adjustments, consisting of only normal, recurring adjustments necessary for a fair presentation of the financial position, results of operations and cash flows. The results of operations for the interim periods presented are not necessarily indicative of results to be expected for the entire year.

Recent Accounting Standards Updates

We consider the applicability and impact of all Accounting Standards Updates on our consolidated financial statements. Updates not listed below were assessed and determined to be either not applicable or are expected to have minimal impact on our consolidated financial position or results of operations. Recently issued Accounting Standards Updates which we feel may be applicable to us are as follows:

Recently Issued Accounting Standard Updates – Not Yet Adopted

In August 2018, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update No. ("ASU") 2018-13, *"Fair Value Measurement (Topic 820): Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement."* ASU 2018-13 includes amendments that aim to improve the effectiveness of fair value measurement disclosures. The amendments in this guidance modify the disclosure requirements on fair value measurements based on the concepts in FASB Concepts Statement, *"Conceptual Framework for Financial Reporting—Chapter 8: Notes to Financial Statements,"* including the consideration of costs and benefits. The amendments become effective for the Company in the year ending December 31, 2020 and early adoption is permitted. The Company is currently assessing the impact that this guidance will have on its consolidated financial statements.

In August 2018, the FASB issued ASU 2018-15, *"Intangibles – Goodwill and Other – Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract."* ASU 2018-15 aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software (and hosting arrangements that include an internal-use software license). The guidance also requires the entity to expense the capitalized implementation costs of a hosting arrangement that is a service contract over the term of the hosting arrangement, which includes reasonably certain renewals. The guidance becomes effective for the Company in the year ending December 31, 2020 and early adoption is permitted. The Company is currently assessing the impact that this guidance will have on its consolidated financial statements.

In November 2018, the FASB issued ASU 2018-18, *"Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606."* ASU 2018-18 clarifies the interaction between Topic 808, *"Collaborative Arrangements,"* and Topic 606, *"Revenue from Contracts with Customers,"* by making targeted improvements to GAAP for collaborative arrangements and providing guidance on whether certain transactions between collaborative arrangement participants should be accounted for with revenue under Topic 606. This includes improving comparability in the presentation of revenue for certain transactions between collaborative arrangement participants by allowing presentation of the units of account in collaborative arrangements that are within the scope of Topic 606 together with revenue accounted for under Topic 606. The guidance becomes effective for the Company in the year ending December 31, 2020 and early adoption is permitted. The Company is currently assessing the impact that this guidance will have on its consolidated financial statements.

Recently Issued Accounting Standard Updates – Adopted During the Period

In February 2016, the FASB issued ASU 2016-02, *"Leases (Topic 842)."* ASU 2016-02, along with subsequent ASUs issued to clarify certain provisions of ASU 2016-02 (collectively known as "ASC 842"), establishes a right-of-use ("ROU") model that requires a lessee to record a ROU asset and a lease liability on the consolidated balance sheet for all leases with terms longer than 12 months. Certain qualitative and quantitative disclosures are also required. The Company adopted ASU 2016-02 and related amendments on January 1, 2019 using an optional transition method allowed with the issuance of ASU 2018-11, *"Leases – Targeted Improvements (Topic 842),"* in July 2018. ASU 2018-11 gives entities the option to not provide comparative period financial statements and instead apply the transition requirements as of the effective date of the new standard. Pursuant to additional guidance under ASC 842, the Company also elected the optional package of practical expedients, which allowed the Company to not reassess: (i) whether expired or existing contracts contain leases; (ii) lease classification for any expired or existing leases; and (iii) initial direct costs for any existing leases. As a result, the consolidated balance sheet prior to January 1, 2019 was not restated, continues to be reported under ASC 840, *"Leases"*, which did not require the recognition of operating lease liabilities on the consolidated balance sheet, and is not comparative. Under ASC 842, all leases are required to be recorded on the balance sheet and are classified as either operating leases or finance leases, which is determined at the inception of the lease. The lease classification affects the expense recognition in the consolidated statements of comprehensive income. The expense recognition for operating leases and finance leases under ASC 842 is substantially consistent with ASC 840. Therefore, there is no significant difference in our results of operations presented in our consolidated statements of comprehensive income for each period presented. The Company also elected under the package of practical expedients, to combine lease and non-lease components and not to record leases with an initial term of 12 months or less on the balance sheet. The Company adopted ASC 842 using the optional transition method for all leases existing at January 1, 2019. The adoption had a substantial impact on our balance sheet. The most significant impact was the recognition of the operating lease ROU assets and lease liabilities for operating leases. Upon adoption, leases that were classified as operating leases under ASC 840 were classified as operating leases under ASC 842, and we recorded ROU assets of $17.0 million and lease liabilities of $21.0 million, before considering deferred taxes. The lease liability is based on the present value of the remaining minimum lease payments, determined under ASC 840, discounted using our incremental borrowing rate at the effective date January 1, 2019. The difference between the ROU assets and the lease liabilities is due to approximately $4 million of unamortized lease incentives and deferred rent at the Company's Marlborough and Waltham facilities as of December 31, 2018. There was no impact to our beginning retained earnings upon adoption of ASC 842. See Note 4, *"Leases,"* below for more information on the Company's adoption of ASC 842.

In February 2018, the FASB issued ASU 2018-02, *"Income Statement – Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income,"* which gives entities the option to reclassify to retained earnings tax effects related to items that have been stranded in accumulated other comprehensive income as a result of the Tax Cuts and Jobs Act (the "Act"). Entities can choose whether to apply the amendments retrospectively to each period in which the effect of the Act is recognized or to apply the amendments in the period of adoption. This guidance became effective for the Company in the first quarter of 2019 and had no impact on our consolidated financial statements.

2. Fair Value Measurements

In determining the fair value of its assets and liabilities, the Company uses various valuation approaches. The Company employs a hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the asset or liability and are developed based on the best information available in the circumstances. The fair value hierarchy is broken down into three levels based on the source of inputs as follows:

Level 1 – Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access.

Level 2 – Valuations based on quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active and models for which all significant inputs are observable, either directly or indirectly.

Level 3 – Valuations based on inputs that are unobservable and significant to the overall fair value measurement.

The availability of observable inputs can vary among the various types of financial assets and liabilities. To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. In certain cases, the inputs used to measure fair value may fall into different levels of the fair value hierarchy. In such cases, for financial statement disclosure purposes, the level in the fair value hierarchy within which the fair value measurement is categorized is based on the lowest level input that is significant to the overall fair value measurement.

As of March 31, 2019 and December 31, 2018, cash and cash equivalents on the Company's consolidated balance sheets included $122.3 million and $126.6 million, respectively, in a money market account. These funds are valued on a recurring basis using Level 1 inputs.

In May 2016, the Company issued $115.0 million aggregate principal amount of the Notes due June 1, 2021. Interest is payable semi-annually in arrears on June 1 and December 1 of each year, beginning on December 1, 2016. As of March 31, 2019, the carrying value of the Notes was $104.6 million, net of unamortized discount, and the fair value of the Notes was $214.7 million. The fair value of the Notes is a Level 1 valuation and was determined based on the most recent trade activity of the Notes as of March 31, 2019. The Notes are discussed in more detail in Note 7, *"Convertible Senior Notes"* to these consolidated financial statements.

There were no remeasurements to fair value during the three months ended March 31, 2019 of financial assets and liabilities that are not measured at fair value on a recurring basis.

3. Revenue Recognition

We generate revenue from the sale of bioprocessing products, equipment devices, and related consumables used with these equipment devices to customers in the life science and biopharmaceutical industries. Under ASC 606, *"Revenue from Contracts with Customers,"* revenue is recognized when, or as, obligations under the terms of a contract are satisfied, which occurs when control of the promised products or services is transferred to customers.

Disaggregation of Revenue

Revenues for the three months ended March 31, 2019 and 2018 were as follows:

	Three Months Ended March 31,		Increase/ (Decrease)	
	2019	2018	$ Change	% Change
	(Amounts in thousands)			
Product Revenue	$ 60,612	$ 44,799	$ 15,813	35.3%
Royalty and other income	22	31	(9)	(29.0%)
Total revenue	$ 60,634	$ 44,830	$ 15,804	35.3%

When disaggregating revenue, the Company considered all of the economic factors that may affect its revenues. Because all of its revenues are from bioprocessing customers, there are no differences in the nature, timing and uncertainty of the Company's revenues and cash flows from any of its product lines. However, given that the Company's revenues are generated in different geographic regions, factors such as regulatory and geopolitical factors within those regions could impact the nature, timing and uncertainty of the Company's revenues and cash flows. In addition, a significant portion of the Company's revenues are generated from two customers; therefore, economic factors specific to these two customers could impact the nature, timing and uncertainty of the Company's revenues and cash flows.

Disaggregated revenue from contracts with customers by geographic region can be found in Note 14, *"Segment Reporting,"* below.

Revenue from significant customers is as follows:

	Three Months Ended March 31,	
	2019	2018
	(Amounts in thousands)	
MilliporeSigma	$ 9,407	$ 6,465
GE Healthcare	$ 7,666	$ 7,717

Filtration Products

The Company's filtration products generate revenue through the sale of KrosFlo® hollow fiber ("HF") TFF membranes and modules, ProConnex® single-use flow path connectors, flat sheet TFF cassettes and hardware, and XCell™ alternating tangential flow ("ATF") devices and related consumables.

The Company markets the KrosFlo line of HF cartridges and TFF systems and the ProConnex line of single-use flow path connectors which were acquired as part of the acquisition of Spectrum LifeSciences, LLC (the "Spectrum Acquisition"). These products are used in the filtration, isolation, purification and concentration of biologics and diagnostic products. Sales of large-scale systems generally include components and consumables as well as training and installation services at the request of the customer. Because the initial sale of components and consumables are necessary for the operation of the system, such items are combined with the systems as a single performance obligation. Training and installation services do not significantly modify or customize these systems and therefore represent a distinct performance obligation.

The Company's other filtration product offerings are not highly interdependent of one another and are therefore considered distinct products that represent separate performance obligations. Revenue on these products is generally recognized at a point in time upon transfer of control to the customer. The Company invoices the customer for the installation and training services in an amount that directly corresponds with the value to the customer of the Company's performance to date; therefore, revenue recognized is based on the amount billable to the customer in accordance with the practical expedient under ASC 606-10-55-18.

The Company also markets flat sheet TFF cassettes and hardware. TFF is a rapid and efficient method for separation and purification of biomolecules that is widely used in laboratory, process development and process scale applications in biopharmaceutical manufacturing. The Company's single-use SIUS™ TFF cassettes and hardware are not highly interdependent of one another and are therefore considered distinct products that represent separate performance obligations. SIUS TFF product revenue is generally recognized at a point in time upon transfer of control to the customer.

The Company also markets the XCell™ ATF System, a technologically advanced filtration device used in upstream processes to continuously remove cellular metabolic waste products during the course of a fermentation run, freeing healthy cells to continue producing the biologic drug of interest. ATF Systems typically include a filtration system and consumables (i.e., tube devices, metal stands) as well as training and installation services at the request of the customer. The filtration system and consumables are considered distinct products and therefore represent separate performance obligations. First time purchasers of the systems typically purchase a controller that is shipped with the tube device(s) and metal stand(s). The controller is not considered distinct as it is a proprietary product that is highly interdependent with the filtration system; therefore, the controller is combined with the filtration system and accounted for as a single performance obligation. The training and installation services do not significantly modify or customize the ATF system and therefore represent a distinct performance obligation. ATF system product revenue related to the filtration system (including the controller if applicable) and consumables is generally recognized at a point in time upon transfer of control to the customer. ATF system service revenue related to training and installation services is generally recognized over time, as the customer simultaneously receives and consumes the benefits as the Company performs. The Company invoices the customer for the installation and training services in an amount that directly corresponds with the value to the customer of the Company's performance to date; therefore, revenue recognized is based on the amount billable to the customer in accordance with the practical expedient under ASC 606-10-55-18.

Chromatography Products

The Company's chromatography products include a number of products used in the downstream purification and quality control of biological drugs. The majority of chromatography revenue relates to the OPUS pre-packed chromatography column line and Protein A chromatography resins. OPUS columns typically consist of the outer hardware of the column with a resin as ordered by the customer packed inside of the column. OPUS columns may also be ordered without the packed resin. In either scenario, the OPUS column and resin are not interdependent of one another and are therefore considered distinct products that represent separate performance obligations. Chromatography product revenue is generally recognized at a point in time upon transfer of control to the customer.

Protein Products

The Company's Protein product line generates revenue through the sale of Protein A ligands and growth factors. Protein A ligands are an essential component of Protein A chromatography resins (media) used in the purification of virtually all monoclonal antibody ("mAb")-based drugs on the market or in development. The Company manufactures multiple forms of Protein A ligands under long-term supply agreements with major life sciences companies, who in turn sell their Protein A chromatography media to end users (biopharmaceutical manufacturers). The Company also manufactures growth factors for sale under long-term supply agreements with certain life sciences companies as well as direct sales to its customers. Each protein product is considered distinct and therefore represents a separate performance obligation. Protein product revenue is generally recognized at a point in time upon transfer of control to the customer.

Other Products

The Company's other products include operating room products sold to hospitals. Other product revenue is generally recognized at a point in time upon transfer of control to the customer.

Transaction Price Allocated to Future Performance Obligations

Remaining performance obligations represents the transaction price of contracts for which work has not been performed or has been partially performed. The Company's future performance obligations relate primarily to the installation and training of certain of its systems sold to customers. These performance obligations are completed within one year of receipt of a purchase order from its customers. Accordingly, the Company has elected to not disclose the value of these unsatisfied performance obligations as provided under ASC 606-10-50-14.

Contract Balances from Contracts with Customers

The following table provides information about receivables and deferred revenues from contracts with customers as of March 31, 2019 (amounts in thousands):

	2019
Balances from contracts with customers only:	
Accounts receivable	$39,341
Deferred revenue (included in accrued liabilities in the consolidated balance sheets)	1,287
Revenue recognized during the three-month period ending March 31, 2019 relating to:	
The beginning deferred revenue balance	$ 878
Changes in pricing related to products or services satisfied in previous periods	—

The timing of revenue recognition, billings and cash collections results in the accounts receivables and deferred revenue balances on the Company's consolidated balance sheets. There were no impairment losses on receivables during the three months ended March 31, 2019.

A contract asset is created when the Company satisfies a performance obligation by transferring a promised good to the customer. Contract assets may represent conditional or unconditional rights to consideration. The right is conditional, and recorded as a contract asset, if the Company must first satisfy another performance obligation in the contract before it is entitled to payment from the customer. Contract assets are transferred to billed receivables once the right becomes unconditional. If the Company has the unconditional right to receive consideration from the customer, the contract asset is accounted for as a billed receivable and presented separately from other contract assets. A right is unconditional if nothing other than the passage of time is required before payment of that consideration is due.

When consideration is received, or such consideration is unconditionally due, from a customer prior to transferring goods or services to the customer under the terms of a contract, a contract liability is recorded. Contract liabilities are recognized as revenue after control of the products or services is transferred to the customer and all revenue recognition criteria have been met.

Costs to Obtain or Fulfill a Customer Contract

The Company's sales commission structure is based on achieving revenue targets. The commissions are driven by revenue derived from customer purchase orders which are short term in nature.

Applying the practical expedient in paragraph 340-40-25-4, the Company recognizes the incremental costs of obtaining contracts as an expense when incurred if the amortization period of the assets that the Company otherwise would have recognized is one year or less. These costs are included in selling, general, and administrative expenses. When shipping and handling costs are incurred after a customer obtains control of the products, the Company accounts for these as costs to fulfill the promise and not as a separate performance obligation.

4. Leases

On January 1, 2019, the Company adopted ASC 842 using the optional transition method which allows entities to initially apply the lease accounting transition requirements at the adoption date and recognize a cumulative effect adjustment to the opening balance sheet of retained earnings in the period of adoption without restating comparative prior periods presented. The Company recorded operating lease right of use assets of $17.0 million and operating lease liabilities of $21.0 million as of January 1, 2019. The difference between the right of use assets and the lease liabilities was due to $4.0 million of unamortized lease incentives and deferred rent at the Company's Waltham and Marlborough facilities as of December 31, 2018.

The Company is a lessee under leases of manufacturing facilities, office spaces, machinery, certain office equipment, vehicles and information technology equipment. A majority of the Company's leases are operating leases with remaining lease terms between six months and 11 years. Finance leases are immaterial to our consolidated financial statements. The Company determines if an arrangement qualifies as a lease and what type of lease it is at inception. The Company elected the package of practical expedients permitted under the transition guidance within the new lease standard, which among other things, allowed it to continue to account for existing leases based on the historical lease classification. The Company also elected the practical expedients to combine lease and non-lease components and to exclude right of use assets and lease liabilities for leases with an initial term of 12 months or less from the balance sheet.

Some of the lease agreements the Company enters into include Company options to either extend and/or early terminate the lease, the costs of which are included in our operating lease liabilities to the extent that such options are reasonably certain of being exercised. Leases with renewal options allow the Company to extend the lease term typically between 1 and 5 years per option, some of its leases have multiple options to extend. When determining if a renewal option is reasonably certain of being exercised, the Company considers several economic factors, including but not limited to, the significance of leasehold improvements incurred on the property, whether the asset is difficult to replace, underlying contractual obligations, or specific characteristics unique to that particular lease that would make it reasonably certain that the Company would exercise such options.

As of March 31, 2019, operating lease right of use assets were $16.2 million and operating lease liabilities were $20.2 million. Amounts related to financing leases were immaterial. The maturity of the Company's operating lease liabilities as of March 31, 2019 are as follows (amounts in thousands):

Fiscal Year	Amount
2019 (remaining nine months)	$ 2,949
2020	4,035
2021	3,938
2022	3,006
2023	2,038
2024 and thereafter	8,332
Total future minimum lease payments	24,298
Less amount of lease payment representing interest	4,110
Total operating lease liabilities	$ 20,188

Lease expense for these leases is recognized on a straight-line basis over the lease term, with variable lease payments recognized in the period those payments are incurred. For the three months ended March 31, 2019, total lease cost is comprised of the following:

Lease Cost	Three Months Ended March 31, 2019 (Amounts in thousands)
Operating lease cost	$ 930
Variable operating lease cost	281
Lease cost	$ 1,211

The following information represents supplemental disclosure for the consolidated statements of cash flows related to operating leases (amounts in thousands):

	Three Months Ended March 31, 2019
Operating cash flows from operating leases	$ (985)

Most of the leases do not provide implicit interest rates and therefore we determine the discount rate based on our incremental borrowing rate. The incremental borrowing rate for our leases is determined based on lease term and currency in which the lease payments are made.

The weighted average remaining lease term and the weighted average discount rate used to measure our operating lease liabilities as of March 31, 2019 were:

Weighted average remaining lease term (years)	7.39
Weighted average discount rate	4.62%

As previously disclosed in the Company's 2018 Annual Report on Form 10-K and under the previous lease accounting standard, ASC 840, *"Leases,"* the total commitment for non-cancelable operating leases was $18.0 million as of December 31, 2018 (amounts in thousands):

For the Years Ended December 31,	Amount
2019	$ 4,021
2020	3,599
2021	3,263
2022	2,213
2023	1,316
2024 and thereafter	3,622
Minimum operating lease payments	$ 18,034

5. Goodwill and Other Intangible Assets

Goodwill

Goodwill represents the difference between the purchase price and the estimated fair value of identifiable assets acquired and liabilities assumed. Goodwill acquired in a business combination and determined to have an indefinite useful life is not amortized, but instead is tested for impairment at least annually in accordance with ASC 350. The following table represents the change in the carrying value of goodwill for the three months ended March 31, 2019 (amounts in thousands):

Balance as of December 31, 2018	$326,735
Cumulative translation adjustment	(340)
Balance as of March 31, 2019	$326,395

During each of the fourth quarters of 2018, 2017 and 2016, we completed our annual impairment assessments and concluded that goodwill was not impaired in any of those years. The Company has not identified any "triggering" events which indicate an impairment of goodwill in the three months ended March 31, 2019.

Other Intangible Assets

Intangible assets, except for the ATF tradename, are amortized over their useful lives using the estimated economic benefit method, as applicable, and the amortization expense is recorded within selling, general and administrative expense in the Company's statements of comprehensive income. The Company reviews its indefinite-lived intangible assets not subject to amortization, including the ATF tradename, to determine if adverse conditions exist or a change in circumstances exists that would indicate an impairment. Intangible assets and their related useful lives are reviewed at least annually to determine if any adverse conditions exist that would indicate the carrying value of these assets may not be recoverable. More frequent impairment assessments are conducted if certain conditions exist, including a change in the competitive landscape, any internal decisions to pursue new or different technology strategies, a loss of a significant customer, or a significant change in the marketplace, including changes in the prices paid for our products or changes in the size of the market for our products. An impairment results if the carrying value of the asset exceeds the estimated fair value of the asset. If the estimate of an intangible asset's remaining useful life is changed, the remaining carrying amount of the intangible asset is amortized prospectively over the revised remaining useful life. The Company continues to believe that its intangible assets are recoverable at March 31, 2019.

Intangible assets, net consisted of the following at March 31, 2019:

	March 31, 2019			
	Gross Carrying Value	Accumulated Amortization	Net Carrying Value	Weighted Average Useful Life (in years)
	(Amounts in thousands)			
Finite-lived intangible assets:				
Technology - developed	$ 53,252	$ (6,625)	$ 46,627	19
Patents	240	(240)	—	8
Customer relationships	101,170	(18,253)	82,917	14
Trademarks	2,160	(188)	1,972	20
Other intangibles	1,059	(627)	432	3
Total finite-lived intangible assets	157,881	(25,933)	131,948	16
Indefinite-lived intangible asset:				
Trademarks	700	—	700	—
Total intangible assets	$ 158,581	$ (25,933)	$ 132,648	

Intangible assets consisted of the following at December 31, 2018:

	December 31, 2018			
	Gross Carrying Value	Accumulated Amortization	Net Carrying Value	Weighted Average Useful Life (in years)
	(Amounts in thousands)			
Finite-lived intangible assets:				
Technology - developed	$ 53,315	$ (5,942)	$ 47,373	19
Patents	240	(240)	—	8
Customer relationships	101,460	(16,609)	84,851	14
Trademarks	2,160	(159)	2,001	20
Other intangibles	1,061	(548)	513	3
Total finite-lived intangible assets	158,236	(23,498)	134,738	16
Indefinite-lived intangible asset:				
Trademarks	700	—	700	—
Total intangible assets	$ 158,936	$ (23,498)	$ 135,438	

Amortization expense for finite-lived intangible assets was $2.6 million and $2.7 million for the three months ended March 31, 2019 and 2018, respectively. As of March 31, 2019, the Company expects to record the following amortization expense (amounts in thousands):

For the Three Months Ended March 31,	Estimated Amortization Expense
2019 (remaining nine months)	$ 7,851
2020	9,930
2021	9,453
2022	9,450
2023	9,451
2024 and thereafter	85,813
Total	$ 131,948

6. Consolidated Balance Sheet Detail

Inventories, net

Inventories, net consists of the following:

	As of	
	March 31, 2019	December 31, 2018
	(Amounts in thousands)	
Raw materials	$ 26,899	$ 24,937
Work-in-process	5,437	5,185
Finished products	12,584	12,141
Total inventories, net	$ 44,920	$ 42,263

Property, Plant and Equipment

Property, plant and equipment consist of the following:

	As of	
	March 31, 2019	December 31, 2018
	(Amounts in thousands)	
Land	$ 1,023	$ 1,023
Buildings	764	764
Leasehold improvements	22,782	16,259
Equipment	26,332	24,092
Furniture and fixtures	6,362	5,448
Construction in progress(1)	6,826	12,906
Other	50	—
Total property, plant and equipment	64,139	60,492
Less - Accumulated depreciation	(29,613)	(28,312)
Total property, plant and equipment, net	$ 34,526	$ 32,180

(1) Construction in progress as of December 31, 2018 included $7.3 million for the buildout of our Marlborough facility, which was put into service and began depreciating on January 1, 2019, $2.1 million in capitalized internal-use software development costs and $2.1 million for a casting machine, among other projects.

Depreciation expenses totaled $1.6 million and $1.3 million for the three months ended March 31, 2019 and 2018, respectively.

Accrued Liabilities

Accrued liabilities consist of the following:

	As of	
	March 31, 2019	December 31, 2018
	(Amounts in thousands)	
Employee compensation	$ 6,329	$ 9,953
Taxes	1,155	1,024
Royalty and license fees	645	242
Accrued purchases	527	683
Warranties	600	546
Professional fees	941	942
Deferred revenue	1,287	1,290
Other	1,276	1,185
Total accrued liabilities	$ 12,760	$ 15,865

7. Convertible Senior Notes

The carrying value of the Company's convertible senior notes is as follows:

	As of	
	March 31, 2019	December 31, 2018
	(Amounts in thousands)	
2.125% convertible senior notes due 2021:		
Principal amount	$ 114,989	$ 114,989
Unamortized debt discount	(8,840)	(9,781)
Unamortized debt issuance costs	(1,554)	(1,720)
Total convertible senior notes	$ 104,595	$ 103,488

On May 24, 2016, the Company issued $115.0 million aggregate principal amount of its Notes. The net proceeds from the sale of the Notes, after deducting the underwriting discounts and commissions and other related offering expenses, were $111.1 million. The Notes bear interest at the rate of 2.125% per annum, payable semiannually in arrears on June 1 and December 1 of each year, beginning December 1, 2016.

The Notes will mature on June 1, 2021, unless earlier repurchased, redeemed or converted in accordance with their terms. Prior to March 1, 2021, the Notes will be convertible at the option of holders of the Notes only upon satisfaction of certain conditions and during certain periods, and thereafter, the Notes will be convertible at any time until the close of business on the second scheduled trading day immediately preceding the maturity date. Upon conversion, holders of the Notes will receive shares of the Company's common stock, cash or a combination thereof, at the Company's election. It is the Company's current intent and policy to settle all conversions through combination settlement, which involves satisfying the principal amount outstanding with cash and any note conversion value over the principal amount in shares of the Company's common stock.

Notes with a par value of $11,000 were submitted for conversion in the fourth quarter of 2017, and this conversion was settled in the first quarter of 2018. The conversion resulted in the issuance of a nominal-amount of shares of the Company's common stock, and the Company recorded a loss of $1,000 on the conversion of these Notes. We received notification that $17,000 par value notes were submitted for conversion in March 2019. We expect these conversions to settle in the second quarter of 2019.

During the first quarter of 2019, the closing price of the Company's common stock continued to exceed 130% of the conversion price of the Notes for more than 20 trading days of the last 30 consecutive trading days of the quarter. As a result, the Notes are convertible at the option of the holders of the Notes during the second quarter of 2019, the quarter immediately following the quarter when the conditions were met, as stated in the terms of the Notes. These terms have been met each quarter since the second quarter of 2018 and, expecting to continue meeting these terms, the Company reclassified the carrying value of the Notes from long-term liabilities to current liabilities on the Company's consolidated balance sheet as of June 30, 2018. As of March 31, 2019, the if-converted value of the Notes exceeded the aggregate principal amount by $99.7 million. As of the date of this filing, no Notes were converted by the holders of such Notes in the first quarter of 2019. As mentioned above, $17,000 par value notes were submitted for conversion at the end of the first quarter and the Company expects these conversions to be settled in the second quarter. In the event the closing price conditions are met in the second quarter of 2019 or a future fiscal quarter, the Notes will be convertible at a holder's option during the immediately following fiscal quarter.

The conversion rate for the Notes will initially be 31.1813 shares of the Company's common stock per $1,000 principal amount of Notes, which is equivalent to an initial conversion price of $32.07 per common share, and is subject to adjustment under the terms of the Notes. Holders of the Notes may require the Company to repurchase their Notes upon the occurrence of a fundamental change prior to maturity for cash at a repurchase price equal to 100% of the principal amount of the Notes to be repurchased plus accrued and unpaid interest, if any, to, but excluding, the repurchase date.

The Company will not have the right to redeem the Notes prior to June 5, 2019, but may redeem the Notes, at its option, in whole or in part, on any business day on or after June 5, 2019 and prior to the maturity date if the last reported sale price of the Company's common stock has been at least 130% of the conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period ending on, and including, the trading day immediately preceding the date on which the Company provides written notice of redemption. The redemption price will be equal to 100% of the principal amount of the Notes to be redeemed plus accrued and unpaid interest to, but excluding, the redemption date.

The Notes contain customary terms and events of default. If an event of default (other than certain events of bankruptcy, insolvency or reorganization involving the Company) occurs and is continuing, the holders of at least 25% in aggregate principal amount of the outstanding Notes may declare 100% of the principal of, and any accrued and unpaid interest on, all of the Notes to be due and payable. Upon the occurrence of certain events of bankruptcy, insolvency or reorganization involving the Company, 100% of the

principal of and accrued and unpaid interest, if any, on all of the Notes will become due and payable automatically. Notwithstanding the foregoing, the Notes provide that, to the extent the Company elects and for up to 270 days, the sole remedy for an event of default relating to certain failures by the Company to comply with certain reporting covenants consist exclusively of the right to receive additional interest on the Notes. The Company is not aware of any events of default, current events or market conditions that would allow holders to call or convert the Notes as of March 31, 2019.

The cash conversion feature of the Notes required bifurcation from the Notes and was initially accounted for as an equity instrument classified to stockholders' equity, as the conversion feature was determined to be clearly and closely related to the Company's stock. Based on market data available for publicly traded, senior, unsecured corporate bonds issued by companies in the same industry and asset base and with similar maturity, the Company estimated the implied interest rate, assuming no conversion option. Assumptions used in the estimate represent what market participants would use in pricing the liability component, including market interest rates, credit standing, and yield curves, all of which are defined as Level 2 observable inputs. The estimated implied interest rate was applied to the Notes, which resulted in a fair value of the liability component of $96.3 million upon issuance, calculated as the present value of implied future payments based on the $115 million aggregate principal amount. The equity component of the Notes was recognized as a debt discount, recorded in additional paid-in capital, and represents the difference between the aggregate principal of the Notes and the fair value of the Notes without conversion option on their issuance date. The debt discount is amortized to interest expense using the effective interest method over five years, or the life of the Notes. The Company assesses the equity classification of the cash conversion feature quarterly, and it is not re-measured as long as it continues to meet the conditions for equity classification.

Interest expense recognized on the Notes for the three months ended March 31, 2019 was $0.6 million, $0.9 million and $0.2 million for the contractual coupon interest, the accretion of the debt discount and the amortization of the debt issuance costs, respectively. Interest expense recognized on the Notes during the three months ended March 31, 2018 included $0.6 million, $0.9 million and $0.2 million for the contractual coupon interest, the accretion of the debt discount and the amortization of the debt issuance costs, respectively. The effective interest rate on the Notes is 6.6%, which included the interest on the Notes, amortization of the debt discount and debt issuance costs. As of March 31, 2019, the carrying value of the Notes was $104.6 million and the fair value of the principal was $214.7 million. The fair value of the Notes was determined based on the most recent trade activity of the Notes as of March 31, 2019.

8. Stockholders' Equity

Stock Option and Incentive Plans

At our 2018 annual meeting of shareholders held on May 16, 2018, our shareholders approved the 2018 Stock Option and Incentive Plan (the "2018 Plan"). Under the 2018 Plan the number of shares of our common stock that are reserved and available for issuance is 2,778,000 plus the number of shares of common stock available for issuance under our Amended and Restated 2012 Stock Option and Incentive Plan (the "2012 Plan"). The shares of common stock underlying any awards under the 2018 Plan, 2012 Plan and the Second Amended and Restated 2001 Repligen Corporation Stock Plan (the "2001 Plan," and together with the 2018 Plan and 2012 Plan, the "Plans") that are forfeited, canceled or otherwise terminated (other than by exercise) shall be added back to the shares of stock available for issuance under the 2018 Plan. At March 31, 2019, 2,747,792 shares were available for future grant under the 2018 Plan.

Stock-Based Compensation

For the three months ended March 31, 2019 and 2018, the Company recorded stock-based compensation expense of $3.3 million and $2.3 million, respectively, for share-based awards granted under the Plans. The following table presents stock-based compensation expense in the Company's consolidated statements of comprehensive income:

	Three Months Ended March 31,	
	2019	2018
	(Amounts in thousands)	
Cost of product revenue	$ 324	$ 266
Research and development	321	170
Selling, general and administrative	2,606	1,832
Total stock-based compensation	$ 3,251	$ 2,268

The 2018 Plan allows for the granting of incentive and nonqualified options to purchase shares of common stock, restricted stock and other equity awards. Employee grants under the Plans generally vest over a three- to five-year period, with 20%-33% vesting on the first anniversary of the date of grant and the remainder vesting in equal yearly installments thereafter. Nonqualified options issued to non-employee directors and consultants under the Plans generally vest over one year. In the first quarter of 2018, to

create a longer-term retention incentive, the Company's Compensation Committee granted long-term incentive compensation awards to its Chief Executive Officer consisting of both stock options and restricted stock units ("RSUs") that are subject to time-based vesting over nine years. Options granted under the Plans have a maximum term of ten years from the date of grant and generally, the exercise price of the stock options equals the fair market value of the Company's common stock on the date of grant. At March 31, 2019, options to purchase 1,027,831 shares and 680,549 RSUs were outstanding under the Plans.

The Company uses the Black-Scholes option pricing model to calculate the fair value of stock option awards on the grant date, and the Company uses the value of the common stock as of the grant date to value RSUs. The Company measures stock-based compensation cost at the grant date based on the estimated fair value of the award. The Company recognizes expense on awards with service-based vesting over the employee's requisite service period on a straight-line basis. In the third quarter of 2017, the Company issued performance stock units to certain employees related to the Spectrum Acquisition which were tied to the achievement of certain 2018 revenue and gross margin metrics and the passage of time. Additionally, in the first quarter of 2018, the Company issued performance stock units to certain individuals which are tied to the achievement of certain 2018 revenue metrics and the passage of time. The Company recognizes expense on performance-based awards over the vesting period based on the probability that the performance metrics will be achieved. The Company recognizes stock-based compensation expense for options that are ultimately expected to vest, and accordingly, such compensation expense has been adjusted for estimated forfeitures.

Information regarding option activity for the three months ended March 31, 2019 under the Plans is summarized below:

	Shares	Weighted average exercise price	Weighted-Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value (in Thousands)
Options outstanding at December 31, 2018	998,226	$ 27.54		
Granted	31,498	$ 59.52		
Exercised	(1,893)	$ 22.35		
Forfeited/expired/cancelled	—	$ —		
Options outstanding at March 31, 2019	1,027,831	$ 28.53	7.04	$ 31,469
Options exercisable at March 31, 2019	540,600	$ 21.66	5.54	$ 20,231
Vested and expected to vest at March 31, 2019(1)	985,138		6.96	$ 30,511

(1) Represents the number of vested options as of March 31, 2019 plus the number of unvested options expected to vest as of March 31, 2019 based on the unvested outstanding options at March 31, 2019 adjusted for estimated forfeiture rates of 8% for awards granted to non-executive level employees and 3% for awards granted to executive level employees.

The aggregate intrinsic value in the table above represents the total pre-tax intrinsic value (the difference between the closing price of the common stock on March 29, 2019, the last business day of the first quarter of 2019, of $59.08 per share and the exercise price of each in-the-money option) that would have been received by the option holders had all option holders exercised their options on March 31, 2019. The aggregate intrinsic value of stock options exercised during the three months ended March 31, 2019 and 2018 was $0.1 million and $0.2 million, respectively.

The weighted average grant date fair value of options granted during the three months ended March 31, 2019 and 2018 was $30.21 and $18.27, respectively. The total fair value of stock options that vested during the three months ended March 31, 2019 and 2018 was $2.2 million and $1.3 million, respectively.

Information regarding RSU activity for the three months ended March 31, 2019 under the Plans is summarized below:

	Shares	Weighted-Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value (in Thousands)
Unvested at December 31, 2018	705,413		
Awarded	147,474		
Vested	(154,837)		
Forfeited/expired/cancelled	(17,501)		
Unvested at March 31, 2019	680,549	3.88	$ 40,207
Vested and expected to vest at March 31, 2019(1)	622,851	3.54	$ 36,798

(1) Represents the number of vested RSUs units as of March 31, 2019 plus the number of unvested RSUs expected to vest as of March 31, 2019 based on the unvested outstanding RSUs at March 31, 2019 adjusted for estimated forfeiture rates of 8% for awards granted to non-executive level employees and 3% for awards granted to executive level employees.

The aggregate intrinsic value in the table above represents the total pre-tax intrinsic value (equal to the closing price of the common stock on March 29, 2019, the last business day of the first quarter of 2019, of $59.08 per share, as RSUs do not have an exercise price) that would have been received by the RSU holders had all holders exercised on March 31, 2019. The aggregate intrinsic value of RSUs vested during the three months ended March 31, 2019 and 2018 was $9.5 million and $3.2 million, respectively.

The weighted average grant date fair value of RSUs vested during the three months ended March 31, 2019 and 2018 was $31.79 and $33.80, respectively. The total fair value of RSUs that vested during the three months ended March 31, 2019 and 2018 was $4.9 million and $2.6 million, respectively.

As of March 31, 2019, there was $33.2 million of total unrecognized compensation cost related to unvested share-based awards. This cost is expected to be recognized over a weighted average remaining requisite service period of 4.29 years. The Company expects 1,067,389 unvested options and RSUs to vest over the next five years.

9. Commitments and Contingencies

Lease Commitments

In January 2018, the Company entered into a lease agreement to rent a 63,761 square foot manufacturing facility in Marlborough, Massachusetts. This facility is currently being transitioned to take over production of SIUS TFF from our Shrewsbury, Massachusetts facility. We expect this transition to be fully completed by September 30, 2019 and have extended the lease for the Shrewsbury facility until that time. The lease on the Marlborough facility expires on November 30, 2028 and the total obligations related to this lease are included in the table below.

In 2017, as a result of the Spectrum Acquisition, the Company retained the obligation related to manufacturing space in Rancho Dominguez, California, which original lease expires on July 15, 2020. The space is an approximately 54,000 square foot manufacturing facility which includes manufacturing, quality control and inventory areas as well as clean room suites. This space was expanded by approximately 15,000 square feet in November 2018 when the Company leased space in an adjacent building. This additional lease expires on November 30, 2025. The lease related to the 54,000 square foot facility includes three, five-year options to extend through July 2035. The Company has not executed these renewal options.

In March 2014, the Company entered into an amendment of its existing lease agreement to expand the rented space from approximately 56,000 to approximately 76,000 square feet at 41 Seyon Street, Waltham, Massachusetts. Pursuant to the terms of the amended lease, Repligen leased an additional 19,900 square feet for a period of eight years and one month, commencing on August 1, 2014. The amended lease provides for additional rent expense of $0.4 million on an annualized basis. The amended lease also required an increase to a letter of credit from $0.2 million to $0.5 million and continues to require the Company to pay a proportionate share of certain of the landlord's annual operating costs and real estate taxes. In 2017, the issuing bank no longer required collateral to secure the letter of credit; as a result, the Company released the funds from restricted cash.

The Company leases four adjacent buildings in Lund, Sweden totaling approximately 45,000 square feet of space used primarily for biologics manufacturing and administrative operations. The lease was renewed during 2016 and expires on December 31, 2021.

Licensing and Research Agreements

The Company licenses certain technologies that are, or may be, incorporated into its technology under several agreements and also has entered into several clinical research agreements which require the Company to fund certain research projects. Generally, the license agreements require the Company to pay annual maintenance fees and royalties on product sales once a product has been established using the technologies. Research and development expenses associated with license agreements were immaterial amounts for the three months ended March 31, 2019 and 2018.

In September 2018, we entered into a collaboration agreement with Sartorius Stedim Biotech, a leading international supplier for the biopharmaceutical industry, to integrate XCell™ ATF cell retention control technology into Sartorius's BIOSTAT® STR large-scale, single-use bioreactors to create novel perfusion-enabled bioreactors. As a result of this collaboration, end-users will stand to benefit from a single control system for 50L to 2,000L bioreactors used in perfusion cell culture applications. The single interface is designed to control cell growth, fluid management and cell retention in continuous and intensified bioprocessing and, ultimately, simplify the development and manufacture of biotechnological drugs under current good manufacturing practices.

In June 2018, we secured an agreement with Navigo for the exclusive co-development of multiple affinity ligands for which Repligen holds commercialization rights. We are manufacturing and have agreed to supply the first of these ligands, NGL-Impact™ A, exclusively to Purolite Life Sciences ("Purolite"), who will pair our high-performance ligand with Purolite's agarose jetting base bead technology used in their Jetted A50 Protein A resin product. We also signed a long-term supply agreement with Purolite for NGL-Impact A and other potential additional affinity ligands that may advance from our Navigo collaboration. The Navigo and Purolite agreements are supportive of our strategy to secure and reinforce our proteins business. We made payments to Navigo of $2.4 million during the year ended December 31, 2018 in connection with this program, which were recorded to research and development expenses in our consolidated statements of comprehensive income.

10. Accumulated Other Comprehensive Loss

The following shows the changes in the components of accumulated other comprehensive loss for the three months ended March 31, 2019 which consisted of only foreign currency translation adjustments for the periods shown (amounts in thousands):

	Foreign Currency Translation Adjustment
Balance as of December 31, 2018	$ (11,893)
Other comprehensive loss	(1,891)
Balance as of March 31, 2019	$ (13,784)

11. Income Taxes

The Company's effective tax rate for the three months ended March 31, 2019 was 23.4%, compared to 24.7% for the corresponding period in the prior year. The effective tax rate for the three months ended March 31, 2019 and 2018 was higher than the U.S. statutory rate of 21% due to state tax effects and the impact of the Global Intangible Low-Taxed Income ("GILTI") tax enacted as part of the Act enacted in December 2017.

ASU 2016-16, *"Intra-Entity Transfers of Assets Other Than Inventory,"* requires the income tax consequences of intra-entity transfers of assets other than inventory to be recognized when the intra-entity transfer occurs rather than deferring recognition of income tax consequences until the transfer was made with an outside party. The Company adopted the provisions of this ASU in the first quarter of 2018. The adoption resulted in a decrease of $5.7 million to other assets, a decrease of $5.0 million to deferred tax liabilities and a decrease of $0.7 million to accumulated deficit at January 1, 2018.

At December 31, 2018, the Company had federal business tax credit carryforwards of $2.8 million and state business tax credit carryforwards of $0.4 million available to reduce future domestic income taxes, if any. The business tax credits carryforwards will expire at various dates through December 2038. The net operating loss and business tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and may be limited in the event of certain changes in the ownership interest of significant stockholders.

On December 22, 2017, President Trump signed into law the Act. The Act made significant changes to federal tax law, including, but not limited to, a reduction in the federal income tax rate from 35% to 21%, taxation of certain global intangible low-taxed income, allowing for immediate expensing of qualified assets, stricter limits on deductions for interest and certain executive compensation, and a one-time transition tax on previously deferred earnings of certain foreign subsidiaries.

In December 2017, the SEC staff issued Staff Accounting Bulletin No. 118 to address the application of GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of H.R.1. The Company recognized the provisional tax impacts related to deemed repatriated earnings and the revaluation of deferred tax assets and liabilities and included these amounts in its consolidated financial statements for the year ended December 31, 2017. During 2018, final adjustments noted below were made to the provisional amounts recorded during 2017, and the Company completed its accounting for various tax impacts of the Act.

The Act lowered the Company's U.S. statutory federal tax rate from 35% to 21% effective January 1, 2018. The Company recorded a tax benefit of $12.8 million in the year ended December 31, 2017 for the reduction in its US deferred tax assets and liabilities resulting from the rate change. The accounting for this item is complete and no adjustments were made to this amount during 2018.

The Act included a one-time deemed repatriation transition tax whereby entities that are shareholders of a specified foreign corporation must include in gross income the undistributed and previously untaxed post-1986 earnings and profits of the specified foreign corporation. The Company's provisional amount recorded at December 31, 2017 increased its tax provision by $3.3 million. As of December 31, 2018, the accounting for this item was complete and the Company recorded a tax benefit of $1.3 million as a result of refining our calculations of post-1986 earnings and profits for our foreign subsidiaries.

The Company is subject to a territorial tax system under the Act, in which the Company is required to provide for tax on GILTI earned by certain foreign subsidiaries. The Company has adopted an accounting policy to provide for the tax expense related to GILTI in the year the tax is incurred as a period expense.

The Company's tax returns are subject to examination by federal, state and international tax authorities for the following periods:

Jurisdiction	Fiscal Years Subject to Examination
United States - federal and state	2015-2018
Sweden	2012-2018
Germany	2017-2018
Netherlands	2012-2018

12. Earnings Per Share

The Company reports earnings per share in accordance with ASC 260, *"Earnings Per Share,"* which establishes standards for computing and presenting earnings per share. Basic earnings per share is computed by dividing net income available to common shareholders by the weighted average number of common shares outstanding during the period. Diluted earnings per share is computed by dividing net income available to common shareholders by the weighted-average number of common shares and dilutive common share equivalents then outstanding. Potential common share equivalents consist of restricted stock awards and the incremental common shares issuable upon the exercise of stock options. Under the treasury stock method, unexercised "in-the-money" stock options and warrants are assumed to be exercised at the beginning of the period or at issuance, if later. The assumed proceeds are then used to purchase common shares at the average market price during the period. Share-based payment awards that entitle their holders to receive non-forfeitable dividends before vesting are considered participating securities and are considered in the calculation of basic and diluted earnings per share. There were no such participating securities outstanding during the three-month periods ended March 31, 2019 and 2018.

Basic and diluted weighted average shares outstanding were as follows:

	Three Months Ended March 31,	
	2019	2018
	(Amounts in thousands, except per share data)	
Net income	$ 8,053	$ 3,448
Weighted average shares used in computing net income per share - basic	43,968	43,621
Effect of dilutive shares:		
Stock options and restricted stock awards	725	390
Convertible senior notes	1,586	316
Dilutive potential common shares	2,311	706
Weighted average shares used in computing net income per share - diluted	46,279	44,327
Earnings per share:		
Basic	$ 0.18	$ 0.08
Diluted	$ 0.17	$ 0.08

At March 31, 2019, there were outstanding options to purchase 1,027,831 shares of the Company's common stock at a weighted average exercise price of $28.53 per share and 680,549 shares of common stock issuable upon the vesting of RSUs. For the three months ended March 31, 2019, 210,388 shares of the Company's common stock were excluded from the calculation of diluted earnings per share because the exercise prices of the stock options were greater than or equal to the average price of the common shares and were therefore anti-dilutive.

At March 31, 2018, there were outstanding options to purchase 1,109,353 shares of the Company's common stock at a weighted average exercise price of $25.34 per share and 703,076 shares issuable upon the vesting of RSUs. For the three months ended March 31, 2018, 593,874 options to purchase shares of the Company's common stock were excluded from the calculation of diluted earnings per share because the exercise prices of the stock options were greater than or equal to the average price of the common shares and were therefore anti-dilutive.

As provided by the terms of the indenture underlying the senior convertible notes (the "Convertible Notes"), the Company has a choice to settle the conversion obligation for the Convertible Notes in cash, shares or any combination of the two. The Company currently intends to settle the par value of the Convertible Notes in cash and any excess conversion premium in shares. The Company applies the provisions of ASC 260, *"Earnings Per Share"*, Subsection 10-45-44, to determine the diluted weighted average shares outstanding as it relates to the conversion spread on its Convertible Notes. Accordingly, the par value of the Convertible Notes is not included in the calculation of diluted income per share, but the dilutive effect of the conversion premium is considered in the calculation of diluted net income per share using the treasury stock method. The dilutive impact of the Convertible Notes is based on the difference between the Company's current period average stock price and the conversion price of the Convertible Notes, provided there is a premium. Pursuant to this accounting standard, there is no dilution from the accreted principal of the Convertible Notes for the periods shown.

13. Related Party Transactions

Certain facilities leased by Spectrum LifeSciences, LLC ("Spectrum") are owned by the former owner of Spectrum. This former owner currently holds greater than 10% of the Company's outstanding common stock. The lease amounts paid to this shareholder were negotiated in connection with the Spectrum Acquisition. The Company has incurred rent expense totaling $0.2 million for the three months ended March 31, 2019 related to these leases.

As part of the Spectrum Acquisition, the Company was responsible for filing all tax returns for Spectrum for the period from January 1, 2017 through July 31, 2017, the day before the Spectrum Acquisition. The Company was responsible for collecting any tax refunds from federal and state authorities and remitting these refunds to the former shareholders of Spectrum, including the former owner of Spectrum who currently holds greater than 10% of the Company's outstanding common stock. During 2018, the Company collected $1.7 million of these tax refunds, which the Company paid to the Spectrum shareholders during the fourth quarter of 2018, net of $0.2 million of expenses paid by the Company on behalf of Spectrum for tax preparation and other fees.

14. Segment Reporting

The Company views its operations, makes decisions regarding how to allocate resources and manages its business as one operating segment. As a result, the financial information disclosed herein represents all of the material financial information related to the Company's sole operating segment.

The following table represents product revenues by product line:

	Three Months Ended March 31,		Increase/ (Decrease)	
	2019	2018	$ Change	% Change
	(Amounts in thousands)			
Chromatography products	$ 13,890	$ 10,583	$ 3,307	31.2%
Filtration products	28,882	19,793	9,089	45.9%
Protein products	16,653	13,586	3,067	22.6%
Other	1,187	837	350	41.8%
Total product revenue	$ 60,612	$ 44,799	$ 15,813	35.3%

Revenue from protein products includes our Protein A ligands and cell culture growth factors. Revenue from filtration products includes our XCell ATF Systems and consumables as well as our KrosFlo and SIUS filtration products. Revenue from chromatography products includes our OPUS and OPUS PD chromatography columns, chromatography resins and ELISA test kits. Other revenue primarily consists of revenue from the sale of operating room products to hospitals as well as freight revenue.

The following table represents the Company's total revenue by geographic area (based on the location of the customer):

	Three Months Ended March 31,	
	2019	2018
Revenue by customers' geographic locations:		
North America	47%	45%
Europe	40%	43%
APAC	13%	11%
Other	0%	1%
Total revenue	100%	100%

Concentrations of Credit Risk and Significant Customers

Financial instruments that subject the Company to significant concentrations of credit risk primarily consist of cash and cash equivalents, marketable securities and accounts receivable. Per the Company's investment policy, cash equivalents and marketable securities are invested in financial instruments with high credit ratings and credit exposure to any one issue, issuer (with the exception of U.S. treasury obligations) and type of instrument is limited. At March 31, 2019 and December 31, 2018, the Company had no investments associated with foreign exchange contracts, options contracts or other foreign hedging arrangements.

Concentration of credit risk with respect to accounts receivable is limited to customers to whom the Company makes significant sales. While a reserve for the potential write-off of accounts receivable is maintained, the Company has not written off any significant accounts to date. To control credit risk, the Company performs regular credit evaluations of its customers' financial condition.

Revenue from significant customers as a percentage of the Company's total revenue is as follows:

	Three Months Ended March 31,	
	2019	2018
MilliporeSigma	16%	17%
GE Healthcare	13%	14%

Significant accounts receivable balances as a percentage of the Company's total trade accounts receivable are as follows:

	March 31, 2019	December 31, 2018
GE Healthcare	15%	17%
MilliporeSigma	*	11%

* MilliporeSigma's percentage of the Company's total trade accounts receivable at March 31, 2019 did not exceed 10%.

15. Subsequent Event

Acquisition of C Technologies, Inc.

On April 25, 2019, the Company entered into a Stock Purchase Agreement ("Purchase Agreement") with C Technologies, Inc. ("C Technologies"), a New Jersey corporation, and Craig Harrison, an individual and sole stockholder of C Technologies.

C Technologies, which is headquartered in Bridgewater, New Jersey, designs and manufactures solutions for the biopharmaceutical industry. Specifically, it has developed a unique way to perform UV/Vis analysis using spectroscopy technology. By leveraging the advantages of this technique, C Technologies has been able to create a platform by which its customers can now make off-line concentration measurements of their drug substance, at various points in the manufacturing process. This testing can be performed now by manufacturing personnel, quality control and formulation laboratories within biopharma. After becoming an accepted standard in the industry, C Technologies launched an in-line version of the instrument called FlowVPE which over the next few years will allow manufacturing and production facilities to measure protein concentration in line eliminating the need to send samples to quality control labs for testing.

Consideration Transferred

The Company will account for the C Technologies Acquisition as a purchase of a business under U.S. GAAP. Under the acquisition method of accounting, the assets of C Technologies will be recorded as of the acquisition date, at their respective fair values, and consolidated with those of the Company. The fair value of net assets acquired is expected to be approximately $240.3 million.

The estimated consideration and preliminary purchase price information has been prepared using a preliminary valuation. The Company engaged a third-party valuation firm to assist with this valuation. An updated purchase price valuation and allocation will be completed in the second quarter of 2019. The preparation of the valuation required the use of significant assumptions and estimates. Critical estimates included, but were not limited to, future expected cash flows, including projected revenues and expenses, and the applicable discount rates. These estimates were based on assumptions that the Company believes to be reasonable. However, actual results may differ from these estimates.

Total consideration to be transferred is as follows (amounts in thousands):

Cash consideration	$ 192,335
Equity consideration	48,000
Plus: estimated working capital adjustment	—
Fair value of net assets acquired	**$240,335**

Acquisition related costs are not included as a component of consideration transferred but are expensed in the periods in which the costs are incurred. The Company expects to incur approximately $1 million in transaction costs related to the C Technologies Acquisition, of which approximately $0.5 million was incurred during the three months ended March 31, 2019. The transaction costs are included in selling, general and administrative expenses in the consolidated statements of comprehensive income.

Fair Value of Net Assets Acquired

The allocation of purchase price is based on the fair value of assets acquired and liabilities based on the preliminary valuation. The components and allocation of the purchase price consists of the following amounts (amounts in thousands):

Cash and cash equivalents	$ 7,693
Restricted cash	26,928
Accounts receivable	3,302
Inventory	2,976
Prepaid expenses and other current assets	31
Fixed assets	44
Customer relationships	57,390
Developed technology	28,390
Trademark and tradename	1,560
Non-competition agreements	520
Other assets	17
Goodwill	142,458
Accounts payable	(345)
Accrued liabilities	(29,282)
Deferred revenue	(1,176)
Deferred tax liability	(171)
Fair value of net assets acquired	**$240,335**

The preliminary purchase price allocation is subject to adjustment as purchase accounting is finalized. The final purchase price allocation will be determined upon completion of final valuation analysis, and the fair value allocation of assets acquired and liabilities assumed could differ materially from the preliminary valuation analysis. The final allocation may include, but not be limited to, changes in the fair value of property, plant and equipment and changes in allocation to intangible assets and goodwill, as well as changes in the values of other assets and liabilities.

Public Offering of Common Stock

On May 3, 2019, the Company completed a public offering in which 3,144,531 shares of its common stock, which includes the underwriters' exercise in full of an option to purchase up to an additional 410,156 shares, were sold to the public at a price of $64.00 per share. The total proceeds received by the Company from this offering, net of underwriting discounts and commissions, totaled approximately $190.2 million.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Overview

Repligen and its subsidiaries, collectively doing business as Repligen Corporation ("Repligen", "we", "our", or "the Company") is a leading provider of advanced bioprocessing technologies and solutions used in the process of manufacturing biologic drugs. Our products are made to substantially increase biopharmaceutical manufacturing efficiencies and flexibility. As the global biologics market continues to experience strong growth and expansion, our customers – primarily large biopharmaceutical companies and contract manufacturing organizations – face critical production cost, capacity, quality and time pressures that our products are made to address. Our commitment to bioprocessing is helping set new standards for the way our customers manufacture biologic drugs – including monoclonal antibodies ("mAb"), recombinant proteins, vaccines and gene therapies. We are dedicated to "inspiring advances in bioprocessing" as a trusted partner in the production of biologic drugs that improve human health worldwide.

Our chromatography products feature pre-packed chromatography ("PPC") columns under our OPUS® brand. OPUS columns, which we deliver to our customers pre-packed with their choice of chromatography resin, are single-campaign ("single-use") disposable columns that replace the use of traditional and more permanent glass columns used in downstream purification processes. By designing OPUS to be a technologically advanced and flexible option for the purification of biologics from process development through clinical-scale and some commercial manufacturing, Repligen has become a leader in PPC columns.

Our filtration products offer a number of advantages to manufacturers of biologic drugs at volumes that span from pilot studies to clinical and commercial-scale production. XCell ATF™ systems are used primarily in upstream perfusion, or continuous manufacturing, processes to increase cell concentration and significantly improve biologic product yield from a bioreactor. To address increasing industry demand for "plug-and-play" technology, we developed and launched in 2016 single-use formats of the original stainless steel XCell ATF device. In December 2016, we acquired TangenX Technology Corporation ("TangenX"), balancing our upstream XCell ATF offering with a downstream portfolio of flat-sheet filters and cassettes used in biologic drug purification and formulation processes. The TangenX portfolio includes the single-use SIUS™ TFF brand, providing customers with a high-performance, low-cost alternative to reusable TFF products. In August 2017, we completed our acquisition of Spectrum LifeSciences, LLC ("Spectrum"). Our Spectrum filtration brands include the KrosFlo® family of products, ProConnex® disposable flow-path products, TFF systems and others. The Spectrum Acquisition significantly strengthened our Filtration product line and diversifies our end markets beyond mAbs to include vaccine, recombinant protein and gene therapies.

We are a leading OEM manufacturer and supplier of Protein A ligands to life sciences companies. Protein A ligands are an essential "binding" component of Protein A chromatography resins used in the purification of virtually all mAb based drugs on the market or in development that our customers sell to end users, including biopharmaceutical manufacturers, for use in downstream purification of mAbs. We also manufacture and sell growth factor products used to supplement cell culture media in order to increase cell growth and productivity in a bioreactor.

Customers use our products to produce initial quantities of drug for clinical studies and then scale-up to larger volumes as the drug progresses to commercial production following regulatory approval. Detailed specifications for a drug's manufacturing process are included in the applications that biopharmaceutical companies file for marketing approval with regulators, such as the U.S. Food and Drug Administration and the European Medicines Agency, throughout the clinical trial process and prior to final commercial approval. As a result, products that become part of the manufacturing specifications of a late-stage clinical or commercial process can be very sensitive given the costs and uncertainties associated with displacing them.

C Technologies Acquisition

On April 25, 2019, the Company entered into a Stock Purchase Agreement ("Purchase Agreement") with C Technologies, Inc. ("C Technologies"), a New Jersey corporation, and Craig Harrison, an individual and sole stockholder of C Technologies.

C Technologies, which is headquartered in Bridgewater, New Jersey, designs and manufactures solutions for the biopharmaceutical industry. Specifically, it has developed a unique way to perform UV/Vis analysis using spectroscopy technology. By leveraging the advantages of this technique, C Technologies has been able to create a platform by which its customers can now make off-line concentration measurements of their drug substance, at various points in the manufacturing process. This testing can be performed now by manufacturing personnel, quality control and formulation laboratories within biopharma. After becoming an accepted standard in the industry, C Technologies launched an in-line version of the instrument called FlowVPE which over the next few years will allow manufacturing and production facilities to measure protein concentration in line eliminating the need to send samples to quality control labs for testing.

The acquisition of C Technologies (the "C Technologies Acquisition") will be accounted for as a purchase of a business under ASC 805, *"Business Combinations."* At the closing, the C Technologies Acquisition will be funded through payment of approximately $192.3 million in cash and an estimated 857,142 shares of the Company's common stock totaling $48.0 million for a total purchase price of $240.3 million.

Critical Accounting Policies and Estimates

A "critical accounting policy" is one which is both important to the portrayal of our financial condition and results and requires management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. For a description of our critical accounting policies that affect our more significant judgments and estimates used in the preparation of our consolidated financial statements, refer to Management's Discussion and Analysis of Financial Condition and Results of Operations and our significant accounting policies in Note 2 to the consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2018 filed with the SEC.

Results of Operations

The following discussion of the financial condition and results of operations should be read in conjunction with the accompanying consolidated financial statements and the related footnotes thereto.

Revenues

Total revenues for the three months ended March 31, 2019 and 2018 were as follows:

	Three Months Ended March 31,		Increase/ (Decrease)	
	2019	2018	$ Change	% Change
	(Amounts in thousands)			
Product Revenue	$ 60,612	$ 44,799	$ 15,813	35.3%
Royalty and other income	22	31	(9)	(29.0%)
Total revenue	$ 60,634	$ 44,830	$ 15,804	35.3%

Product revenues

Since 2016, we have been increasingly focused on selling our products directly to customers in the pharmaceutical industry and to our contract manufacturers. These direct sales have increased to approximately 73% of our product revenue in the first quarter of 2019. We expect that direct sales will continue to account for an increasing percentage of our product revenues. Sales of our bioprocessing products can be impacted by the timing of large-scale production orders and the regulatory approvals for such antibodies, which may result in significant quarterly fluctuations.

Product revenues were comprised of the following:

	Three Months Ended March 31,		Increase/ (Decrease)	
	2019	2018	$ Change	% Change
	(Amounts in thousands)			
Chromatography products	$ 13,890	$ 10,583	$ 3,307	31.2%
Filtration products	28,882	19,793	9,089	45.9%
Protein products	16,653	13,586	3,067	22.6%
Other	1,187	837	350	41.8%
Total product revenue	$ 60,612	$ 44,799	$ 15,813	35.3%

Revenue from our chromatography products includes our OPUS and OPUS PD chromatography columns, chromatography resins and ELISA test kits. Revenue from our filtration products includes our XCell ATF Systems and consumables, KrosFlo filtration products and SIUS filtration products. Revenue from protein products includes our Protein A ligands and cell culture growth factors. Other revenue primarily consists of revenue from the sale of our operating room products to hospitals as well as freight revenue.

During the first quarter of 2019, product revenue increased by $15.8 million, or 35%, as compared to the same period of 2018. The increase is due to the continued adoption of our products by our key bioprocessing customers, particularly our chromatography and filtration products. Sales of our bioprocessing products are impacted by the timing of orders, development efforts at our customers or end-users and regulatory approvals for biologics that incorporate our products, which may result in significant quarterly fluctuations. Such quarterly fluctuations are expected, but they may not be predictive of future revenue or otherwise indicate a trend.

Royalty revenues

Royalty revenues in the three months ended March 31, 2019 and 2018 relate to royalties received from a third-party systems manufacturer associated with our OPUS PD chromatography columns. Royalty revenues are variable and are dependent on sales generated by our partner.

Costs and operating expenses

Total costs and operating expenses for the three-month periods ended March 31, 2019 and 2018 were comprised of the following:

	Three Months Ended March 31,		Increase/ (Decrease)	
	2019	2018	$ Change	% Change
	(Amounts in thousands, except for percentage data)			
Cost of product revenue	$26,845	$19,668	$ 7,177	36.5%
Research and development	3,620	3,288	332	10.1%
Selling, general and administrative	18,998	15,898	3,100	19.5%
Total costs and operating expenses	$49,463	$38,854	$ 10,609	27.3%

Cost of product revenue

Cost of product revenue increased $7.2 million, or 37%, in the three months ended March 31, 2019, as compared to the same period of 2018 due primarily to the increase in product revenue mentioned above.

Gross margins were 56% in the three months ended March 31, 2019 and 2018. The increase in costs of product revenue was higher than the increase in product revenue during the three months ended March 31, 2019, as compared to the same period of 2018 due to an unfavorable product mix and an increase in manufacturing headcount subsequent to March 31, 2018. Gross margins may fluctuate in future quarters based on expected production volume and product mix.

Research and development expenses

Research and development expenses are related to bioprocessing products which include personnel, supplies and other research expenses. Due to the small size of the Company and the fact that these various programs share personnel and fixed costs, we do not track all of our expenses or allocate any fixed costs by program, and therefore, have not provided historical costs incurred by project. In addition to the legacy product research and development, the current single-use XCell ATF project incurs expenses related to product development, sterilization, validation testing, and other research related expenses.

During the three months ended March 31, 2019, research and development expenses increased by $0.3 million, or 10%, as compared to the same period of 2018. This increase is primarily driven by an increase in research and development headcount subsequent to March 31, 2018. Stock-based compensation expense increased due to the increase in headcount and an increase in share price period over period.

We expect our research and development expenses for the rest of the year to increase in order to support new product development.

Selling, general and administrative expenses

Selling, general and administrative (“SG&A”) expenses include the costs associated with selling our commercial products and costs required to support our marketing efforts, including legal, accounting, patent, shareholder services, amortization of intangible assets and other administrative functions.

During the three months ended March 31, 2019, SG&A costs increased by $3.1 million, or 20%, as compared to the same period of 2018. The increase is due to the continued buildout of our administrative infrastructure, primarily through increased headcount, to support expected future growth and continued expansion of our customer-facing activities to drive sales of our bioprocessing products. In addition, professional fees, specifically accounting and auditing fees, increased and commissions were higher due to the increasing revenue.

Other expenses, net

The table below provides detail regarding our other expenses, net:

	Three Months Ended March 31,		Increase/ (Decrease)	
	2019	2018	$ Change	% Change
	(Amounts in thousands, except for percentage data)			
Investment income	$ 713	$ 181	$ 532	293.9%
Interest expense	(1,726)	(1,652)	(74)	4.5%
Other income	358	71	287	404.2%
Total other expense, net	$ (655)	$ (1,400)	$ 745	(53.2%)

Investment income

Investment income includes income earned on invested cash balances. The increase of $0.5 million for the three months ended March 31, 2019, as compared to the same period of 2018 was attributable to higher average invested cash balances and higher interest rates on such invested cash balances. We expect investment income to vary based on changes in the amount of funds invested and fluctuation of interest rates.

Interest expense

Interest expense primarily relates to interest related to our issuance of 2.125% Convertible Senior Notes due 2021 (the “Notes”) in May 2016. Interest expense increased $0.1 million for the three months ended March 31, 2019, as compared to the same period of 2018 due to the decrease in the balance of debt issuance costs that are being amortized. As these costs decrease the carrying value of the debt increases and interest calculated based on the carrying value increases as well.

Other income

Changes in other income in the three months ended March 31, 2019, compared to the corresponding period of the prior year, is primarily attributable to foreign currency gains related to amounts due from non-Swedish kronor-based customers and cash balance denominated in U.S. dollars and British pounds held by Repligen Sweden AB.

Income tax provision

Income tax provision for the three months ended March 31, 2019 and 2018 was as follows:

	Three Months Ended March 31,		Increase/ (Decrease)	
	2019	2018	$ Change	% Change
	(Amounts in thousands, except for percentage data)			
Income tax provision (benefit)	$ 2,463	$ 1,128	$ 1,335	118.4%
Effective tax rate	23.4%	24.7%		

For the three months ended March 31, 2019, we recorded an income tax provision of $2.5 million. The effective tax rate was 23% in 2019 and is based upon the estimated income from the year and the composition of the income in different jurisdictions. The effective tax rate was higher than the U.S. statutory rate of 21% due to state tax effects and the impact of the Global Intangible Low-Taxed Income tax enacted as part of the Act.

Non-GAAP Financial Measures

We provide non-GAAP adjusted income from operations; adjusted net income; and adjusted EBITDA as supplemental measures to GAAP measures regarding our operating performance. These financial measures exclude the items detailed below and, therefore, have not been calculated in accordance with GAAP. A detailed explanation and a reconciliation of each non-GAAP financial measure to its most comparable GAAP financial measure is provided below.

We include this financial information because we believe these measures provide a more accurate comparison of our financial results between periods and more accurately reflect how management reviews its financial results. We excluded the impact of certain acquisition-related items because we believe that the resulting charges do not accurately reflect the performance of our ongoing operations for the period in which such charges are incurred.

Non-GAAP adjusted income from operations

Non-GAAP adjusted income from operations is measured by taking income from operations as reported in accordance with GAAP and excluding acquisition and integration costs and intangible amortization booked through our consolidated statements of comprehensive income. The following is a reconciliation of income from operations in accordance with GAAP to non-GAAP adjusted income from operations for the three months ended March 31, 2019 and 2018:

	Three Months Ended March 31,	
	2019	2018
	(Amounts in thousands)	
GAAP income from operations	$ 11,171	$ 5,976
Non-GAAP adjustments to income from operations:		
Acquisition and integration costs	1,799	655
Intangible amortization	2,611	2,664
Non-GAAP adjusted income from operations	$ 15,581	$ 9,295

Non-GAAP adjusted net income

Non-GAAP adjusted net income is measured by taking net income as reported in accordance with GAAP and excluding acquisition and integration costs and related tax effects, intangible amortization and related tax effects and non-cash interest expense. The following is a reconciliation of net income in accordance with GAAP to non-GAAP adjusted net income for the three months ended March 31, 2019 and 2018:

	Three Months Ended March 31,			
	2019		2018	
	Amount	Fully Diluted Earnings per Share	Amount	Fully Diluted Earnings per Share
	(Amounts in thousands, except per share data)			
GAAP net income	$ 8,053	$ 0.17	$ 3,448	$ 0.08
Non-GAAP adjustments to net income:				
Acquisition and integration costs	1,799	0.04	655	0.01
Intangible amortization	2,611	0.06	2,664	0.06
Non-cash interest expense	1,107	0.02	1,036	0.02
Tax effect of intangible amortization and acquisition costs	(517)	(0.01)	(271)	(0.01)
Non-GAAP adjusted net income	$ 13,053	$ 0.28	$ 7,532	$ 0.17

Per share totals may not add due to rounding.

Adjusted EBITDA

Adjusted EBITDA is measured by taking net income as reported in accordance with GAAP, excluding investment income, interest expense, taxes, depreciation and amortization, and excluding acquisition and integration costs, inventory step-up charges and contingent consideration expenses booked through our consolidated statements of comprehensive income. The following is a reconciliation of net income in accordance with GAAP to adjusted EBITDA for three months ended March 31, 2019 and 2018:

	Three Months Ended March 31,	
	2019	2018
	(Amounts in thousands)	
GAAP net income	$ 8,053	$ 3,448
Non-GAAP EBITDA adjustments to net income:		
Investment income	(713)	(181)
Interest expense	1,726	1,652
Tax provision	2,463	1,128
Depreciation	1,575	1,284
Amortization	2,638	2,664
EBITDA	15,742	9,995
Other non-GAAP adjustments:		
Acquisition and integration costs	1,799	655
Adjusted EBITDA	$ 17,541	$ 10,650

Liquidity and Capital Resources

We have financed our operations primarily through revenues derived from product sales, research grants, proceeds and royalties from license arrangements, the issuance of the Notes in May 2016 and the issuance of common stock in our July 2017 public offering. Our revenue for the foreseeable future will primarily be limited to our bioprocessing product revenue.

At March 31, 2019, we had cash and cash equivalents of $196.1 million compared to cash, cash equivalents of $193.8 million at December 31, 2018. There were no restrictions on cash for March 31, 2019 and December 31, 2018.

During the first quarter of 2019, the closing price of the Company's common stock exceeded 130% of the conversion price of the Notes for more than 20 trading days of the last 30 consecutive trading days of the quarter. As a result, the Notes are convertible at the option of the holders of the Notes during the second quarter of 2019. The Notes have a face value of $115.0 million and a carrying value of $104.6 million and are classified as current liabilities on the Company's consolidated balance sheet as of March 31, 2019. It is the Company's policy and intent to settle the face value of the Notes in cash and any excess conversion premium in shares of our common stock. Between the end of the fourth quarter and the date of this filing, none of the Notes have been converted by the holders of such Notes.

On May 3, 2019, the Company completed a public offering in which 3,144,531 shares of its common stock, which includes the underwriters' exercise in full of an option to purchase up to an additional 410,156 shares, were sold to the public at a price of $64.00 per share. The total proceeds received by the Company from this offering, net of underwriting discounts and commissions, totaled approximately $190.2 million.

Cash flows

	Three Months Ended March 31,		Increase/(Decrease)
	2019	2018	$ Change
	(Amounts in thousands)		
Operating activities	$ 9,788	$ 1,572	$ 8,216
Investing activities	(3,828)	(1,564)	(2,264)
Financing activities	44	333	(289)
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(3,691)	(224)	(3,467)
Net increase in cash, cash equivalents and restricted cash	$ 2,313	$ 117	$ 2,196

Operating activities

For the three months ended March 31, 2019, our operating activities provided cash of $9.8 million reflecting net income of $8.1 million and non-cash charges totaling $9.5 million primarily related to depreciation, amortization, non-cash interest expense, deferred tax expense and stock-based compensation charges. An increase in accounts receivable consumed $6.7 million of cash and was primarily driven by the 35% quarter over quarter increase in revenues. Payments of accounts payable and accrued liabilities consumed $2.4 million of cash and were mainly due to the timing of payments of payables and payment of 2018 incentive compensation programs. These were offset by a decrease in unbilled receivables of $2.6 million. The remaining cash used in operating activities resulted from net unfavorable changes in various other working capital accounts.

For the three-month period ended March 31, 2018, our operating activities provided cash of $1.6 million reflecting net income of $3.4 million and non-cash charges totaling $7.7 million, primarily related to depreciation, amortization, non-cash interest expense, deferred tax expense and stock-based compensation charges. An increase in accounts receivable consumed $1.5 million of cash and was primarily driven by the 46% quarter over quarter increase in revenues. Payments of accounts payable and accrued liabilities consumed $5.4 million of cash and were mainly due to the timing of payments of payables and payment of 2017 incentive compensation programs. The remaining cash flow used in operations resulted from net unfavorable changes in various other working capital accounts.

Investing activities

Our investing activities consumed $3.8 million of cash all related to capital expenditures. Of these expenditures, $1.7 million represented capitalized costs related to our internal-use software. Our investing activities consumed $1.6 million of cash related to capital expenditures for the three-month period ended March 31, 2018.

Financing activities

Cash provided by financing activities for the three months ended March 31, 2019 included proceeds from stock option exercises during the quarter. For the three-month period ended March 31, 2018, our financing activities provided $0.3 million of cash, primarily due to proceeds received from stock option exercises, partially offset by cash outlays of $11,000 related to the conversion of certain senior convertible notes which were settled in the first quarter of 2018.

Working capital increased by approximately $7.9 million to $153.8 million at March 31, 2019 from $145.9 million at December 31, 2018 due to the various changes noted above.

Our future capital requirements will depend on many factors, including the following:

- the expansion of our bioprocessing business;
- the ability to sustain sales and profits of our bioprocessing products;
- our ability to acquire additional bioprocessing products;
- our identification and execution of strategic acquisitions or business combinations;
- the resources required to successfully integrate our recently acquired businesses and recognize expected synergies;
- the scope of and progress made in our research and development activities;
- the extent of any share repurchase activity; and
- the success of any proposed financing efforts.

Absent acquisitions of additional products, product candidates or intellectual property, we believe our current cash balances are adequate to meet our cash needs for at least the next 24 months from the date of this filing. We expect operating expenses for the rest of the year to increase as we continue to expand our bioprocessing business. We expect to incur continued spending related to the development and expansion of our bioprocessing product lines and expansion of our commercial capabilities for the foreseeable future. Our future capital requirements may include, but are not limited to, purchases of property, plant and equipment, the acquisition of additional bioprocessing products and technologies to complement our existing manufacturing capabilities, and continued investment in our intellectual property portfolio.

We plan to continue to invest in our bioprocessing business and in key research and development activities associated with the development of new bioprocessing products. We actively evaluate various strategic transactions on an ongoing basis, including licensing or acquiring complementary products, technologies or businesses that would complement our existing portfolio. We continue to seek to acquire such potential assets that may offer us the best opportunity to create value for our shareholders. In order to acquire such assets, we may need to seek additional financing to fund these investments. If our available cash balances and anticipated cash flow from operations are insufficient to satisfy our liquidity requirements, including because of any such acquisition-related financing needs or lower demand for our products, we may seek to sell common or preferred equity or convertible debt securities, enter into a credit facility or another form of third-party funding, or seek other debt funding. The sale of equity and convertible debt securities may result in dilution to our stockholders, and those securities may have rights senior to those of our common shares. If we raise additional funds through the issuance of preferred stock, convertible debt securities or other debt financing, these securities or other debt could contain covenants that would restrict our operations. Any other third-party funding arrangement could require us to relinquish valuable rights. We may require additional capital beyond our currently anticipated amounts. Additional capital may not be available on reasonable terms, if at all.

Off-Balance Sheet Arrangements

We do not have any special purpose entities or off-balance sheet financing arrangements as of March 31, 2019.

Net Operating Loss Carryforwards

At December 31, 2018, we had utilized our remaining $19.5 million of net operating loss carryforwards. We had business tax credits carryforwards of $2.9 million available to reduce future federal income taxes, if any. The business tax credits carryforwards will continue to expire at various dates through December 2038. Net operating loss carryforwards and available tax credits are subject to review and possible adjustment by the Internal Revenue Service, state and foreign jurisdictions and may be limited in the event of certain changes in the ownership interest of significant stockholders.

Effects of Inflation

Our assets are primarily monetary, consisting of cash, cash equivalents and marketable securities. Because of their liquidity, these assets are not directly affected by inflation. Since we intend to retain and continue to use our equipment, furniture and fixtures and leasehold improvements, we believe that the incremental inflation related to replacement costs of such items will not materially affect our operations. However, the rate of inflation affects our expenses, such as those for employee compensation and contract services, which could increase our level of expenses and the rate at which we use our resources.

Cautionary Statement Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). The forward-looking statements in this Quarterly Report on Form 10-Q do not constitute guarantees of future performance. Investors are cautioned that statements in this Quarterly Report on Form 10-Q which are not strictly historical statements, including, without limitation, express or implied statements or guidance regarding current or future financial performance and position, potential impairment of future earnings, management's strategy, plans and objectives for future operations or acquisitions, product development and sales, product candidate research, development and regulatory approval, selling, general and administrative expenditures, intellectual property, development and manufacturing plans, availability of materials and product and adequacy of capital resources and financing plans constitute forward-looking statements. These forward-looking statements are based on current expectations, estimates, forecasts and projections about the industry and markets in which the Company operates, and management's beliefs and assumptions. The Company undertakes no obligation to publicly update or revise the statements in light of future developments. In addition, other written and oral statements that constitute forward-looking statements may be made by the Company or on the Company's behalf. Words such as "expect," "seek," "anticipate," "intend," "plan," "believe," "could," "estimate," "may," "target," "project," or variations of such words and similar expressions are intended to identify forward-looking statements. Such forward-looking statements are subject to a number of risks and uncertainties that could cause actual results to differ materially from those anticipated, including, without limitation, risks associated with: the success of current and future collaborative or supply relationships, including our agreements with GE Healthcare and MilliporeSigma, our ability to successfully grow our bioprocessing business, including as a result of acquisitions, commercialization or partnership opportunities, and our ability to develop and commercialize products, our ability to obtain required regulatory approvals, our compliance with all Food and Drug Administration regulations, our ability to obtain, maintain and protect intellectual property rights for our products, the risk of litigation regarding our patent and other intellectual property rights, the risk of litigation with collaborative partners, our limited manufacturing capabilities and our dependence on third-party manufacturers and value-added resellers, our ability to hire and retain skilled personnel, the market acceptance of our products, reduced demand for our products that adversely impacts our future revenues, cash flows, results of operations and financial condition, our ability to compete with larger, better financed life sciences companies, our history of losses and expectation of incurring losses, our ability to generate future revenues, our ability to successfully integrate our recently acquired businesses, our ability to raise additional capital to fund potential acquisitions, our volatile stock price, and the effects of our anti-takeover provisions. Further information on potential risk factors that could affect our financial results are included in the filings made by us from time to time with the Securities and Exchange Commission including under the section entitled "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2018.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

We have historically held investments in commercial paper, U.S. Government and agency securities as well as corporate bonds and other debt securities. As a result, we have been exposed to potential loss from market risks that may occur as a result of changes in interest rates, changes in credit quality of the issuer or otherwise. We do not have any such investments as of March 31, 2019. As a result, a hypothetical 100 basis point increase in interest ratees would have no effect on our cash position as of March 31, 2019.

We generally place our marketable security investments in high quality credit instruments, as specified in our investment policy guidelines. We believe that the conservative nature of our investments mitigates our interest rate exposure, and our investment policy limits the amount of our credit exposure to any one issue, issuer (with the exception of U.S. agency obligations) and type of instrument. We do not expect any material loss from our marketable security investments and therefore believe that our potential interest rate exposure is limited.

Foreign Exchange Risk

The reporting currency of the Company is U.S. dollars, and the functional currency of each of our foreign subsidiaries is its respective local currency. Our foreign currency exposures include the Swedish kronor, Euro, British pound, Chinese yuan, Japanese yen, Singapore dollar, South Korean won and Indian rupee; of these, the primary foreign currency exposures are the Swedish kronor, Euro and British pound. Exchange gains or losses resulting from the translation between the transactional currency and the functional currency are included in net income. Fluctuations in exchange rates may adversely affect our results of operations, financial position and cash flows. We currently do not seek to hedge this exposure to fluctuations in exchange rates.

ITEM 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

The Company's management, with the participation of the principal executive officer and the principal financial officer, has evaluated the effectiveness of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) under the Exchange Act as of the end of the period covered by this report. Based on such evaluation, the principal executive officer and principal financial officer have concluded that, as of the end of such period, the Company's disclosure controls and procedures were effective in ensuring that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, on a timely basis, and is accumulated and communicated to the Company's management, including the Company's principal executive officer and the Company's principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control

There have been no changes in our internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of Securities Exchange Act Rule 13a-15 or Rule 15d-15 that occurred in the three months ended March 31, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

From time to time, we may be subject to legal proceedings and claims in the ordinary course of business. We are not currently aware of any such proceedings or claims that we believe will have, individually or in the aggregate, a material adverse effect on our business, financial condition or results of operations.

ITEM 1A. RISK FACTORS

The matters discussed in this Quarterly Report on Form 10-Q include forward-looking statements that involve risks or uncertainties. These statements are neither promises nor guarantees, but are based on various assumptions by management regarding future circumstances, over many of which Repligen has little or no control. A number of important risks and uncertainties, including those identified under the caption "Risk Factors" in Item 1A in our Annual Report on Form 10-K for the year ended December 31, 2018, as updated in this Quarterly Report on Form 10-Q and in subsequent filings, could cause our actual results to differ materially from those in the forward-looking statements.

Risks Related to the C Technologies Acquisition

C Technologies may have unknown liabilities or liabilities which exceed our estimates. Any such liabilities could adversely affect the financial position of the combined company.

C Technologies' business activities may have associated with them various potential liabilities relating to the conduct of its business prior to the C Technologies Acquisition, including, but not limited to, potential contract claims, export control matters, historical tax matters and other potential liabilities that could adversely affect the financial position of the combined company. Upon consummation of the C Technologies Acquisition, we will assume these potential liabilities. While we continue to evaluate what we believe to be the most significant of these potential liabilities, it is possible that these liabilities may exceed our expectations or that other liabilities, whether currently known or unknown to us, result in substantial losses to us. The Seller's obligations to indemnify us for general representations and warranties and certain special and fundamental representations and warranties under the Purchase Agreement are limited to specified maximum dollar amounts and subject in certain instances to our inability to recover first from the escrow account and subsequently under the representation and warranty insurance policy we obtained in connection with the C Technologies Acquisition, or the R&W Policy. If any issues arise post-closing, we may not be entitled to sufficient, or any, indemnification or recourse from the Seller or under the R&W Policy, which could have a materially adverse impact on our business and results of operations.

The C Technologies Acquisition, if consummated, will create numerous risks and uncertainties, which could adversely affect our financial condition and operating results.

Strategic transactions like the C Technologies Acquisition create numerous uncertainties and risks. Upon consummation of the C Technologies Acquisition, C Technologies will become our wholly owned subsidiary, which will broaden our operations. However, we expect that the C Technologies Acquisition will result in a loss per share on a GAAP basis for Repligen in 2019. Further, the addition of C Technologies to our business will entail many changes, including the integration of C Technologies and certain of its personnel, and changes in systems and employee benefit plans. These transition activities are complex and we may encounter unexpected difficulties, incur unexpected costs or experience business disruptions, including as a result of:

- disruption of our ongoing businesses and increased commitments for the management team, including the need to divert management's attention to integration matters, particularly if we are unable to recruit, hire and retain key personnel;
- difficulties in retaining C Technologies' key personnel;
- difficulties in integrating C Technologies' products, systems, internal controls over financial reporting and technologies;
- difficulties in continuing to obtain adequate supplies and materials to meet C Technologies' manufacturing needs;
- changes in market demand for C Technologies' products;
- risks associated with maintaining and acquiring intellectual property;
- difficulties in operating C Technologies' business profitably;

- difficulties in transitioning and maintaining key manufacturer, customer, distributor and supplier relationships;
- our inexperience with C Technologies' customers and our ability to meet or exceed such customers' service level expectations and C Technologies' contractual obligations with respect to such customers;
- difficulties realizing the revenue projections, growth prospects, financial benefits, synergies, market position and other strategic opportunities anticipated in connection with the Acquisition;
- potential disputes regarding C Technologies' intellectual property;
- potential disputes with the Seller; and
- difficulties in the assimilation and retention of employees, including key personnel responsible for the success of C Technologies' operations.

If any of these factors limits our ability to integrate C Technologies into our operations successfully or on a timely basis, the expectations of future results of operations, including certain synergies expected to result from the C Technologies Acquisition, might not be met. As a result, we may not be able to realize the expected benefits that we seek to achieve from the C Technologies Acquisition, which could result in declines in the market value of our common stock. In addition, we may be required to spend additional time or money on integration that otherwise would be spent on the development and expansion of our business, including efforts to further expand our product portfolio.

We will be subject to business uncertainties while the C Technologies Acquisition is pending, which could adversely affect our business.

In connection with the pendency of the C Technologies Acquisition, it is possible that certain persons with whom we or C Technologies have a business relationship may delay or defer certain business decisions or might decide to seek to terminate, change or renegotiate their relationships with us or C Technologies, as the case may be, as a result of the C Technologies Acquisition, which could negatively affect our revenues, earnings and cash flows, regardless of whether the C Technologies Acquisition is completed.

We have made certain assumptions relating to the C Technologies Acquisition that may prove to be materially inaccurate.

Our assumptions regarding the C Technologies Acquisition may be inaccurate, including as a result of higher than expected transaction and integration costs, and general economic and business conditions that could adversely affect the combined company. Because the purchase price for C Technologies is significantly more than C Technologies' net book value as of December 31, 2018, we will record a substantial amount of goodwill and other intangible assets as a result of the C Technologies Acquisition. In the event that industry, competitive or technological factors become unfavorable, we may incur future impairment of the value of goodwill and other intangible assets acquired through the C Technologies Acquisition. Under GAAP, we are not allowed to amortize goodwill or other indefinite-lived intangible assets. Instead, we are required to periodically determine if our goodwill and other indefinite-lived intangible assets have become impaired, in which case we would write down the impaired portion of our goodwill and/or other indefinite-lived intangible assets. If we were required to write down all or part of our goodwill or other indefinite-lived intangible assets, our net income (loss) and stockholders' equity could be materially and adversely affected.

The consummation of the C Technologies Acquisition is subject to a number of closing conditions, some of which are out of our control. We cannot assure you that the C Technologies Acquisition will be consummated on a timely basis or at all.

The completion of the C Technologies Acquisition is subject to certain conditions contained in the Purchase Agreement, some of which are beyond our control, and we can make no assurances that the transaction will close in a timely manner or at all. Such conditions include, among other things, obtaining prior consent from certain third-party contract counterparties, the accuracy of the representations and warranties made by C Technologies, compliance in all respects by all of the parties with their respective obligations under the Purchase Agreement and the absence of any injunction or order that prohibits or restrains the consummation of the C Technologies Acquisition. There can be no assurance that the conditions to closing of the C Technologies Acquisition will be satisfied or waived or that other events will not intervene to delay or result in the failure to close the C Technologies Acquisition. The Purchase Agreement may be terminated by the parties thereto under certain circumstances, including, without limitation, if the C Technologies Acquisition has not been completed by July 24, 2019, subject to extension under certain circumstances. Delays in closing the C Technologies Acquisition or the failure to close the C Technologies Acquisition may result in our incurring significant additional costs in connection with such delay or termination of the Purchase Agreement. Any delay in closing or a failure to close the C Technologies Acquisition could have a negative impact on the market price of our common stock. If we are unable to consummate the C Technologies Acquisition, we will have incurred significant due diligence, legal, accounting and other transaction costs in connection with the C Technologies Acquisition without realizing the anticipated benefits.

Risks Related to the Business of C Technologies

C Technologies' operating results and financial condition may fluctuate.

C Technologies' operating results and financial condition may fluctuate from quarter to quarter and year to year for a number of reasons. The following events or occurrences, among others, could cause fluctuations in its financial performance from period to period:

- development of new competitive products by others;
- changes in the amount it spends to promote its products and develop new technologies;
- changes in technology that may render its products obsolete;
- increases in the cost of raw materials used to manufacture its products;
- manufacturing and supply interruptions, including failure to comply with manufacturing specifications;
- the impact of third-party patents and other intellectual property rights which C Technologies may be found to infringe, or may be required to license, and the potential damages or other costs it may be required to pay as a result of a finding that it infringes such intellectual property rights;
- the loss of any third-party distributor of C Technologies' products in any territory;
- lower than expected demand for its products;
- its response to price competition;
- expenditures as a result of any potential legal actions;
- the impairment and write-down of goodwill or other intangible assets;
- general economic and industry conditions, including changes in interest rates affecting returns on cash balances and investments that affect customer demand;
- impairment or write-down of investments or long-lived assets;
- costs and outcomes of any tax audits;
- fluctuations in foreign currency exchange rates; and
- risks related to C Technologies' sales of products across numerous countries world-wide and the inherent international economic, regulatory, political and business risks.

As a result, the period-to-period comparisons of C Technologies' results of operations are not necessarily meaningful, and these comparisons should not be relied upon as an indication of future performance. The above factors may cause its operating results to fluctuate and adversely affect its financial condition and results of operations.

C Technologies' business is subject to cybersecurity risks that could disrupt its operations and adversely affect its and our business.

Certain of C Technologies' products incorporate software created by C Technologies or in-licensed from contract counterparties pursuant to reseller agreements. C Technologies' devices, servers and computer systems, and those of its contract counterparties that we use in our operations are vulnerable to cybersecurity risks, including cyber-attacks such as viruses and worms, denial-of-service attacks, and similar disruptions from unauthorized tampering with its servers and computer systems or those of its contract counterparties, which could lead to interruptions, delays, loss of critical data, and loss of customer confidence. Any cyber-attacks on C Technologies' systems, or those of its contract counterparties, if successful, could adversely affect C Technologies' and our business, operating results, and financial condition, and be expensive to remedy.

C Technologies' business could suffer as a result of manufacturing difficulties or delays.

C Technologies' business could suffer if certain manufacturing or other equipment were to become inoperable for a period of time or if historical suppliers to C Technologies are unwilling or unable to continue to supply following the closing of the C Technologies Acquisition. This could occur for various reasons, including catastrophic events such as earthquake, monsoon, hurricane or explosion, unexpected equipment failures or delays in obtaining components or replacements thereof, as well as construction delays or defects and other events, both within and outside of our control. Any inability to timely manufacture its products could have a material adverse effect on C Technologies' results of operations, financial condition and cash flows.

If C Technologies is unable to obtain or maintain its intellectual property, its operations may be adversely affected.

C Technologies endeavors to obtain and maintain the patents and trade secrets that it utilizes in its manufacturing process. Its commercial success will depend, in part, on its ability to:

- obtain and maintain patent protection for its products and manufacturing processes;
- preserve its trade secrets;
- operate without infringing the proprietary rights of third parties; and
- obtain any necessary licenses from others on acceptable terms.

C Technologies cannot be sure that any patent applications relating to its products that it files in the future or that any currently pending applications will issue on a timely basis, if ever. Even if patents are issued, the degree of protection afforded by such patents will depend upon the scope of the patent claims, the validity and enforceability of the claims obtained and C Technologies' willingness and financial ability to enforce its patents.

The patent position of life sciences companies is often highly uncertain and usually involves complex legal and scientific questions. In some cases, litigation or other proceedings may be necessary to assert claims of infringement, to enforce patents issued to C Technologies. Such litigation could result in substantial cost to C Technologies and diversion of its resources. An adverse outcome in any such litigation or proceeding could have a material adverse effect on C Technologies' business, financial condition and results of operations.

C Technologies' global sales operations expose it to risks and challenges associated with conducting business internationally.

C Technologies books sales globally, including in Europe, Asia and North America. C Technologies faces several risks inherent in conducting business internationally, including compliance with international and U.S. laws and regulations that apply to its international operations. These laws and regulations include data privacy requirements, tax laws, anti-competition regulations, import and trade restrictions, export requirements, U.S. laws such as the Foreign Corrupt Practices Act, and other U.S. federal laws and regulations established by the office of Foreign Asset Control, or other local foreign laws which prohibit corrupt payments to governmental officials or certain payments or remunerations to customers. Given the high level of complexity of these laws, however, there is a risk that some provisions may be inadvertently breached by C Technologies, for example through fraudulent or negligent behavior of individual employees, its failure to comply with certain formal documentation requirements, or otherwise. Violations of these laws and regulations could result in fines, criminal sanctions against C Technologies, its officers or its employees, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on C Technologies' ability to offer its products in one or more countries and could materially damage its reputation, brand and operating results.

C Technologies' foreign operations may become less attractive if political and diplomatic relations between the United States and any country where it conducts business operations deteriorates.

The relationship between the United States and the foreign countries where C Technologies conducts business operations may weaken over time. Changes in the state of the relations between any such country and the United States are difficult to predict and could adversely affect C Technologies' future operations. This could lead to a decline in its profitability. Any meaningful deterioration of the political and diplomatic relations between the United States and the relevant country could have a material adverse effect on C Technologies' operations.

C Technologies may be exposed to liabilities under the Foreign Corrupt Practices Act, and any determination that it violated the Foreign Corrupt Practices Act could have a material adverse effect on our business.

C Technologies is subject to the Foreign Corrupt Practice Act, or the FCPA, and other laws that prohibit improper payments or offers of payments to foreign governments and their officials and political parties by U.S. persons and issuers as defined by the statute for the purpose of obtaining or retaining business. A significant portion of C Technologies sales are booked in jurisdictions outside of the U.S., some of which may experience corruption. C Technologies' activities in jurisdictions outside of the U.S. create the risk of unauthorized payments or offers of payments by one of C Technologies' employees, consultants, sales agents or distributors, because these parties have not always been subject to C Technologies' control. Violations of the FCPA may result in severe criminal or civil sanctions, and C Technologies may be subject to other liabilities, which could negatively affect our business, operating results and financial condition.

Prior to the C Technologies Acquisition, C Technologies has been a private company and has not previously been subject to the Sarbanes-Oxley Act of 2002, the rules and regulations of the SEC or other corporate governance requirements.

Prior to its acquisition by us, C Technologies has been a private company and has not been subject to the Sarbanes-Oxley Act of 2002, the rules and regulations of the SEC, or other corporate governance requirements to which public reporting companies may be subject. As a result, we are required to implement the appropriate internal control processes and procedures over C Technologies' financial accounting and reporting. We may incur significant legal, accounting and other expenses in efforts to meet these requirements, which may include additional staffing, infrastructure investments and improving C Technologies' finance function systems and process. Implementing the controls and procedures at C Technologies that are required to comply with the various applicable laws and regulations may place a significant burden on our management and internal resources. The diversion of management's attention and any difficulties encountered in such an implementation could adversely affect our business, financial condition and operating results.

C Technologies is treated as an "S corporation" under Subchapter S of the Internal Revenue Code, and claims of taxing authorities related to its status as an "S corporation" could harm us.

C Technologies is currently treated as an "S corporation" for federal and applicable state income tax purposes. As an "S corporation", C Technologies elects to pass corporate income, losses, deductions, and credits through to its sole stockholder for federal and applicable state income tax purposes. Pursuant to the Purchase Agreement, we plan to make an election under Section 338 of the Internal Revenue Code with respect to the C Technologies Acquisition to treat the C Technologies Acquisition as an asset acquisition rather than a stock purchase for tax purposes. However, if C Technologies has failed to satisfy one or more of the many factors required to be met in order to qualify as an "S corporation" and the Internal Revenue Service or other applicable tax authority were to challenge C Technologies' status as an "S corporation," we may not be able to realize the intended tax benefits from the C Technologies Acquisition. If C Technologies is determined in any such challenge not to have qualified, or to have violated its status as an "S corporation," we may be obligated to pay back taxes for all relevant open tax years on all of C Technologies' taxable income while it was an "S corporation," interest, and possibly penalties.

Furthermore, if C Technologies is determined in any such challenge not to have qualified as an "S corporation" at the time of the C Technologies Acquisition, any tax benefits we realize as a result of the election under Section 338 of the Internal Revenue Code may be denied. Any such determination could result in additional costs to us and could have a material adverse effect on our results of operations and financial condition. While the Purchase Agreement includes indemnification obligations for claims made following closing, including those related to C Technologies' tax status, no assurance can be given that such indemnification obligations will cover all additional costs to us as a result of any such claims.

Risks Related to Our Business

We face competition from numerous competitors, most of whom have far greater resources than we have, which may make it more difficult for us to achieve significant market penetration.

The bioprocessing market is intensely competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants.

Many of our competitors are large, well-capitalized companies with significantly more market share and resources than we have. As a consequence, they are able to spend more aggressively on product development, marketing, sales and other product initiatives than we can. Many of these competitors have:

- significantly greater name recognition;
- larger and more established distribution networks;
- additional lines of products and the ability to bundle products to offer higher discounts or other incentives to gain a competitive advantage;
- greater experience in conducting research and development, manufacturing, clinical trials, marketing, obtaining regulatory approval and entering into collaborative or other strategic partnership arrangements; and
- greater financial and human resources for product development, sales and marketing and patent litigation.

Our current and future competitors, including certain of our customers, may at any time develop additional products that compete with our products. If any company develops products that compete with or are superior to our products, our revenue may decline. In addition, some of our competitors may compete by lowering the price of their products. If prices were to fall, we may not be able to improve our gross margins or sales growth sufficiently to maintain and grow our profitability.

Despite our increasingly diversified client base, we have historically depended on a limited number of customers for a high percentage of our revenues.

The loss of, or a significant reduction in orders from, any of our large customers, including following any termination or failure to renew a long-term supply contract, would significantly reduce our revenues and harm our results of operations. If a large customer purchases fewer of our products, defers orders or fails to place additional orders with us for any reason, including for business continuity purposes, our revenue could decline, and our operating results may not meet market expectations. Under our long-term supply agreements with GE Healthcare ("GE"), we supply Protein A ligands to GE from our manufacturing facilities in Lund, Sweden and Waltham, Massachusetts, or the Lund Agreement and Waltham Agreement, respectively. The Lund Agreement runs, pursuant to its terms, through December 2019 and the Waltham Agreement runs, pursuant to its terms, through December 2021. GE may elect, upon six months' prior notice to us, to reduce its minimum purchase requirements under the Lund Agreement. Even if GE so elects, GE would still be required to continue to purchase at least 50% of its global demand pursuant to the Waltham Agreement through the expiration of this agreement pursuant to its terms on December 31, 2021.

In addition, if our customers order our products, but fail to pay on time or at all, our liquidity and operating results could be materially and adversely affected. Furthermore, if any of our current or future products compete with those of any of our largest customers, these customers may place fewer orders with us or cease placing orders with us, which would negatively affect our revenues and operating results.

If we are unable to expand our product portfolio, our ability to generate revenue could be adversely affected.

We are increasingly seeking to develop and commercialize our portfolio of products. Our future financial performance will depend, in part, on our ability to successfully develop and acquire additional bioprocessing products. There is no guarantee that we will be able to successfully acquire or develop additional bioprocessing products, and the Company's financial performance will likely suffer if we are unable to do so.

If intangible assets and goodwill that we recorded in connection with our acquisitions become impaired, we may have to take significant charges against earnings.

In connection with the accounting for our completed acquisitions, we recorded a significant amount of intangible assets, including developed technology and customer relationships relating to the acquired product lines, and goodwill. Under U.S. GAAP, we must assess, at least annually and potentially more frequently, whether the value of intangible assets and goodwill has been impaired. Intangible assets and goodwill will be assessed for impairment in the event of an impairment indicator. Any reduction or impairment of the value of intangible assets and goodwill will result in a charge against earnings, which could materially adversely affect our results of operations and shareholders' equity in future periods.

Our exposure to political, economic and other risks that arise from operating a multinational business has and may continue to increase.

We operate on a global basis with offices or activities in Japan, South Korea, China, India, Europe and North America. Our operations and sales outside of the United States have increased as a result of our strategic acquisitions and the continued expansion of our commercial organization. Risks related to these increased foreign operations include:

- fluctuations in foreign currency exchange rates, which may affect the costs incurred in international operations and could harm our results of operations and financial condition;
- changes in general economic and political conditions in countries where we operate, particularly as a result of ongoing economic instability within foreign jurisdictions;
- the occurrence of a trade war, or other governmental action related to tariffs or trade agreements;
- being subject to complex and restrictive employment and labor laws and regulations, as well as union and works council restrictions;
- changes in tax laws or rulings in the United States or other foreign jurisdictions that may have an adverse impact on our effective tax rate;
- being subject to burdensome foreign laws and regulations, including regulations that may place an increased tax burden on our operations;

- being subject to longer payment cycles from customers and experiencing greater difficulties in timely accounts receivable collections; and
- required compliance with a variety of foreign laws and regulations, such as data privacy requirements, real estate and property laws, anti-competition regulations, import and trade restrictions, export requirements, U.S. laws such as the Foreign Corrupt Practices Act of 1977 and the U.S. Department of Commerce's Export Administration Regulations, and other U.S. federal laws and regulations established by the office of Foreign Asset Control, local laws such as the U.K. Bribery Act of 2010 or other local laws that prohibit corrupt payments to governmental officials or certain payments or remunerations to customers.

Our business success depends in part on our ability to anticipate and effectively manage these and other related factors. We cannot assure you that these and other related factors will not materially adversely affect our international operations or business as a whole.

In addition, a deterioration in diplomatic relations between the United States and any country where we conduct business could adversely affect our future operations and lead to a decline in profitability.

We may be unable to efficiently manage our growth as a larger and more geographically diverse organization.

Our strategic acquisitions, the continued expansion of our commercial sales operations, and our organic growth have increased the scope and complexity of our business. As a result, we will face challenges inherent in efficiently managing a more complex business with an increased number of employees over large geographic distances, including the need to implement appropriate systems, policies, benefits and compliance programs. Our inability to manage successfully the geographically more diverse (including from a cultural perspective) and substantially larger combined organization could materially adversely affect our operating results and, as a result, the market price of our common stock.

Our business is subject to a number of environmental risks.

Our manufacturing business involves the controlled use of hazardous materials and chemicals and is therefore subject to numerous environmental and safety laws and regulations and to periodic inspections for possible violations of these laws and regulations. In addition to these hazardous materials and chemicals, our facility in Sweden also uses Staphylococcus aureus and toxins produced by Staphylococcus aureus in some of its manufacturing processes. Staphylococcus aureus and the toxins it produces, particularly enterotoxins, can cause severe illness in humans. The costs of compliance with environmental and safety laws and regulations are significant. Any violations, even if inadvertent or accidental, of current or future environmental and safety laws or regulations and the cost of compliance with any resulting order or fine could adversely affect our operations.

Our acquisitions, including the C Technologies Acquisition, expose us to risks that could adversely affect our business, and we may not achieve the anticipated benefits of acquisitions of businesses or technologies.

As a part of our growth strategy, we may make selected acquisitions of complementary products and/or businesses. Any acquisition involves numerous risks and operational, financial, and managerial challenges, including the following, any of which could adversely affect our business, financial condition, or results of operations:

- difficulties in integrating new operations, technologies, products, and personnel;
- problems maintaining uniform procedures, controls and policies with respect to our financial accounting systems;
- lack of synergies or the inability to realize expected synergies and cost-savings;
- difficulties in managing geographically dispersed operations, including risks associated with entering foreign markets in which we have no or limited prior experience;
- underperformance of any acquired technology, product, or business relative to our expectations and the price we paid;
- negative near-term impacts on financial results after an acquisition, including acquisition-related earnings charges;
- the potential loss of key employees, customers, and strategic partners of acquired companies;
- claims by terminated employees and shareholders of acquired companies or other third parties related to the transaction;
- the assumption or incurrence of additional debt obligations or expenses, or use of substantial portions of our cash;
- the issuance of equity securities to finance or as consideration for any acquisitions that dilute the ownership of our stockholders;

- the issuance of equity securities to finance or as consideration for any acquisitions may not be an option if the price of our common stock is low or volatile which could preclude us from completing any such acquisitions;
- any collaboration, strategic alliance and licensing arrangement may require us to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us;
- diversion of management's attention and company resources from existing operations of the business;
- inconsistencies in standards, controls, procedures, and policies;
- the impairment of intangible assets as a result of technological advancements, or worse-than-expected performance of acquired companies;
- assumption of, or exposure to, historical liabilities of the acquired business, including unknown contingent or similar liabilities that are difficult to identify or accurately quantify; and
- risks associated with acquiring intellectual property, including potential disputes regarding acquired companies' intellectual property.

In addition, the successful integration of acquired businesses requires significant efforts and expense across all operational areas, including sales and marketing, research and development, manufacturing, finance, legal, and information technologies. There can be no assurance that any of the acquisitions we may make will be successful or will be, or will remain, profitable. Our failure to successfully address the foregoing risks may prevent us from achieving the anticipated benefits from any acquisition in a reasonable time frame, or at all.

Servicing our debt will require a significant amount of cash, and we may not have sufficient cash flow from our business to make payments on our debt.

We incurred significant indebtedness in the amount of $115.0 million in aggregate principal with additional accrued interest under our 2.125% Convertible Senior Notes due 2021 (the "Notes"). Our ability to make scheduled payments of the principal of, to pay interest on, or to refinance our indebtedness, including the Notes, depends on our future performance, which is subject to economic, financial, competitive and other factors that may be beyond our control. Our business may not generate cash flow from operations in the future sufficient to service our debt and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. In addition, in the event of a fundamental change or a default under the Notes, the holders and/or the trustee under the indentures governing the Notes may accelerate the payment obligations or trigger the holders' repurchase rights under the Notes. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations, including the Notes.

If a make-whole fundamental change, such as an acquisition of our company, occurs prior to the maturity of the Notes, under certain circumstances, the conversion rate for the Notes will increase such that additional shares of our common stock will be issued upon conversion of the Notes in connection with such make-whole fundamental change. The increase in the conversion rate will be determined based on the date on which the make-whole fundamental change occurs or becomes effective and the price paid (or deemed paid) per share of our common stock in such transaction. Upon conversion of the Notes, unless we elect to deliver solely shares of our common stock to settle such conversion (other than paying cash in lieu of delivering any fractional share), we will be required to make cash payments in respect of the Notes being converted. We may not have enough available cash or be able to obtain financing at the time we are required to make repurchases of Notes surrendered therefor or notes being converted. Our failure to repurchase Notes at a time when the repurchase is required by the indenture or to pay any cash payable on future conversions of the Notes as required by the indenture would constitute a default under the indenture. If the repayment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness and repurchase the notes or make cash payments upon conversions thereof.

In addition, our significant indebtedness, combined with our other financial obligations and contractual commitments, could have other important consequences. For example, it could:

- make us more vulnerable to adverse changes in general U.S. and worldwide economic, industry and competitive conditions and adverse changes in government regulation;

- limit our flexibility in planning for, or reacting to, changes in our business and our industry;
- place us at a disadvantage compared to our competitors who have less debt; and
- limit our ability to borrow additional amounts for working capital and other general corporate purposes, including to fund possible acquisitions of, or investments in, complementary businesses, products, services and technologies.

Any of these factors could materially and adversely affect our business, financial condition and results of operations. In addition, if we incur additional indebtedness, the risks related to our business and our ability to service or repay our indebtedness would increase.

Future strategic transactions or acquisitions may require us to seek additional financing, which we may not be able to secure on favorable terms, if at all.

We plan to continue a strategy of growth and development for our bioprocessing business, and we actively evaluate various strategic transactions on an ongoing basis, including licensing or acquiring complementary products, technologies or businesses that would complement our existing portfolio of development programs. In order to complete such strategic transactions, we may need to seek additional financing to fund these investments and acquisitions. Should we need to do so, we may not be able to secure such financing, or obtain such financing on favorable terms because of the volatile nature of the biotechnology marketplace. In addition, future acquisitions may require the issuance or sale of additional equity or debt securities, which may result in additional dilution to our stockholders.

We rely on a limited number of suppliers or, for certain of our products, one supplier, and we may not be able to find replacements or immediately transition to alternative suppliers, which could have a material adverse effect on our financial condition, results of operations and reputation.

There are only a limited number of suppliers of materials for certain of our products. An interruption in operations of the business related to these products could occur if we encounter delays or difficulties in securing the required materials, or if we cannot then obtain an acceptable substitute. Any such interruption could significantly affect the business related to these products and our financial condition, results of operations and reputation.

For example, we believe that only a small number of suppliers are currently qualified to supply materials for the XCell ATF System. The use of materials furnished by these replacement suppliers would require us to alter our operations related to the XCell ATF System. Transitioning to a new supplier for our products would be time consuming and expensive, may result in interruptions in our operations, could affect the performance specifications of our product lines or could require that we revalidate the materials. There can be no assurance that we will be able to secure alternative materials and bring such materials on line and revalidate them without experiencing interruptions in our workflow. If we should encounter delays or difficulties in securing, reconfiguring or revalidating the materials required for our products, our business related to these products and our financial condition, results of operations and reputation could be adversely affected.

As we evolve from a company dependent on others to commercialize our products to a company selling directly to end users, we may encounter difficulties in expanding our product portfolio and our commercial marketing capabilities.

Prior to 2016, we generated most of our revenues through sales of bioprocessing products to a limited number of life sciences companies, such as GE Healthcare, MilliporeSigma and other individual distributors. However, due in part to our recent strategic acquisitions, an increasing amount of our revenue is attributable to our commercialization of bioprocessing products that we sell directly to end-users, including biopharmaceutical companies and contract manufacturing organizations. This has required and will continue to require us to invest additional resources in our sales and marketing capabilities. We may not be able to attract and retain additional sales and marketing professionals, and the cost of building the sales and marketing function may not generate our anticipated revenue growth. In addition, our sales and marketing efforts may be unsuccessful. Our failure to manage these risks may have a negative impact on our financial condition, or results of operations and may cause our stock price to decline.

If we are unable to obtain or maintain our intellectual property, we may not be able to succeed commercially.

We endeavor to obtain and maintain trade secrets and, to a lesser extent with respect to the products that currently account for a majority of our revenue, patent protection when available in order to protect our products and processes from unauthorized use and to produce a financial return consistent with the significant time and expense required to bring our products to market. Our success will depend, in part, on our ability to:

- preserve our trade secrets and know-how;
- operate without infringing the proprietary rights of third parties;
- obtain and maintain patent protection for our products and manufacturing processes; and
- secure any necessary licenses from others on acceptable terms.

We consider trade secrets, know-how and other forms of market protection to be among the most important elements of our proprietary position, in particular, as it relates to the products that currently account for a majority of our revenue. We also own or have exclusive rights to a number of U.S. patents and U.S. pending patent applications as well as corresponding foreign patents and patent applications. We continue to actively and selectively pursue patent protection and seek to expand our patent estate, particularly for our products currently in development, and we cannot be sure that any patent applications that we will file in the future or that any currently pending applications will issue on a timely basis, if ever. We cannot be certain that we were the first to make the inventions covered by each of our pending patent applications or that we were the first to file patent applications for such inventions. Even if patents are issued, the degree of protection afforded by such patents will depend upon the:

- scope of the patent claims;
- validity and enforceability of the claims obtained in such patents; and
- our willingness and financial ability to enforce and/or defend them.

The patent position of life sciences companies is often highly uncertain and usually involves complex legal and scientific questions. Patents which may be granted to us in certain foreign countries may be subject to opposition proceedings brought by third parties or result in suits by us, which may be costly and result in adverse consequences for us.

In some cases, litigation or other proceedings may be necessary to assert claims of infringement, to enforce patents issued to us or our licensors, to protect trade secrets, know-how or other intellectual property rights we own or to determine the scope and validity of the proprietary rights of third parties. Such litigation could result in substantial cost to us and diversion of our resources. An adverse outcome in any such litigation or proceeding could have a material adverse effect on our business, financial condition and results of operations. If our competitors prepare and file patent applications in the United States that claim technology also claimed by us, we may be required to participate in interference proceedings declared by the U.S. Patent and Trademark Office to determine priority of invention, which would result in substantial costs to us.

While one of our U.S. patents covering recombinant Protein A had its term adjusted to expire in 2028, our other U.S. patents covering recombinant Protein A have expired, and as a result, we may face increased competition, which could harm our results of operations, financial condition, cash flow and future prospects.

Other companies could begin manufacturing and selling native or some of the commercial forms of recombinant Protein A in the United States and may directly compete with us on certain Protein A products. This may induce us to sell Protein A at lower prices and may erode our market share, which could adversely affect our results of operations, financial condition, cash flow and future prospects.

Our freedom to develop our products may be challenged by others, and we may have to engage in litigation to determine the scope and validity of competitors' patents and proprietary rights, which, if we do not prevail, could harm our business, results of operations, financial condition, cash flow and future prospects.

There has been substantial litigation and other proceedings regarding the complex patent and other intellectual property rights in the life sciences industry. We have been a party to, and in the future may become a party to, patent litigation or other proceedings regarding intellectual property rights.

Other types of situations in which we may become involved in patent litigation or other intellectual property proceedings include:

- We may initiate litigation or other proceedings against third parties to seek to invalidate the patents held by such third parties or to obtain a judgment that our products or services do not infringe such third parties' patents.
- We may initiate litigation or other proceedings against third parties to seek to enforce our patents against infringement.
- If our competitors file patent applications that claim technology also claimed by us, we may participate in interference or opposition proceedings to determine the priority of invention.
- If third-parties initiate litigation claiming that our processes or products infringe their patent or other intellectual property rights, we will need to defend against such claims.

The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the cost of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. If a patent litigation or other intellectual property proceeding is resolved in a way that is unfavorable to us, we or our collaborative or strategic partners may be enjoined from manufacturing or selling our products and services without a license from the other party and be held liable for significant damages. The failure to obtain any required license on commercially acceptable terms or at all may harm our business, results of operations, financial condition, cash flow and future prospects.

Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time, attention and resources.

We may become involved in litigation or other proceedings with collaborative partners, which may be time consuming, costly and could result in delays in our development and commercialization efforts.

In connection with the Company's decision to focus its efforts on the growth of its core bioprocessing business, we sought development and commercialization partnerships for our remaining portfolio of clinical stage assets. Any disputes with such partners that lead to litigation or similar proceedings may result in us incurring legal expenses, as well as facing potential legal liability. Such disputes, litigation or other proceedings are also time consuming and may cause delays in our development and commercialization efforts. If we fail to resolve these disputes quickly and with terms that are no less favorable to us than the current terms of the arrangements, our business, results of operations, financial condition, cash flow and future prospects may be harmed.

If we are unable to continue to hire and retain skilled personnel, then we will have trouble developing and marketing our products.

Our success depends largely upon the continued service of our management and scientific staff and our ability to attract, retain and motivate highly skilled technical, scientific, management and marketing personnel. We also face significant competition in the hiring and retention of such personnel from other companies, research and academic institutions, government and other organizations who have superior funding and resources. The loss of key personnel or our inability to hire and retain skilled personnel could materially adversely affect our product development efforts and our business.

The market may not be receptive to our new bioprocessing products upon their introduction.

We expect a portion of our future revenue growth to come from introducing new bioprocessing products, including line extensions and new features for our OPUS disposable chromatography columns, our XCell ATF System, our SIUS TFF product line, our Spectrum hollow fiber modules and TFF systems and our growth factors. The commercial success of all of our products will depend upon their acceptance by the life science and biopharmaceutical industries. Many of the bioprocessing products that we are developing are based upon new technologies or approaches. As a result, there can be no assurance that these new products, even if successfully developed and introduced, will be accepted by customers. If customers do not adopt our new products and technologies, our results of operations may suffer and, as a result, the market price of our common stock may decline.

Our products are subject to quality control requirements.

Whether a product is produced by us or purchased from outside suppliers, it is subjected to quality control procedures, including the verification of porosity and with certain products, the complete validation for good manufacturing practices, U.S. Food and Drug Administration, CE and ISO 2001 compliance, prior to final packaging. Quality control is performed by a staff of technicians utilizing calibrated equipment. In the event we, or our manufacturers, produce products that fail to comply with required quality standards, it may incur delays in fulfilling orders, write-downs, damage to our reputation and damages resulting from product liability claims.

If our products do not perform as expected or the reliability of the technology on which our products are based is questioned, we could experience lost revenue, delayed or reduced market acceptance of our products, increased costs and damage to our reputation.

Our success depends on the market's confidence that we can provide reliable, high-quality bioprocessing products. We believe that customers in our target markets are likely to be particularly sensitive to product defects and errors. Our reputation and the public image of our products and technologies may be impaired if our products fail to perform as expected. Although our products are tested prior to shipment, defects or errors could nonetheless occur in our products. Furthermore, the Protein A that we manufacture is subsequently incorporated into products that are sold by other life sciences companies and we have no control over the manufacture and production of those products. In the future, if our products experience, or are perceived to experience, a material defect or error, this could result in loss or delay of revenues, delayed market acceptance, damaged reputation, diversion of development resources, legal claims, increased insurance costs or increased service and warranty costs, any of which could harm our business. Such defects or errors could also narrow the scope of the use of our products, which could hinder our success in the market. Even after any underlying concerns or problems are resolved, any lingering concerns in our target market regarding our technology or any manufacturing defects or performance errors in our products could continue to result in lost revenue, delayed market acceptance, damaged reputation, increased service and warranty costs and claims against us.

If we are unable to manufacture our products in sufficient quantities and in a timely manner, our operating results will be harmed, our ability to generate revenue could be diminished and our gross margin may be negatively impacted.

Our revenues and other operating results will depend in large part on our ability to manufacture and assemble our products in sufficient quantities and in a timely manner. Any interruptions we experience in the manufacturing or shipping of our products could delay our ability to recognize revenues in a particular quarter. Manufacturing problems can and do arise, and as demand for our products increases, any such problems could have an increasingly significant impact on our operating results. While we have not generally experienced problems with, or delays in, our production capabilities that resulted in delays in our ability to ship finished products, there can be no assurance that we will not encounter such problems in the future. We may not be able to quickly ship products and recognize anticipated revenues for a given period if we experience significant delays in the manufacturing process. In addition, we must maintain sufficient production capacity in order to meet anticipated customer demand, which carries fixed costs that we may not be able to offset if orders slow, which would adversely affect our operating margins. If we are unable to manufacture our products consistently, in sufficient quantities, and on a timely basis, our bioprocessing revenue, gross margins and our other operating results will be materially and adversely affected.

Our operating results may fluctuate significantly, our customers' future purchases are difficult to predict and any failure to meet financial expectations may result in a decline in our stock price.

Our quarterly operating results may fluctuate in the future as a result of many factors such as the impact of seasonal spending patterns, changes in overall spending levels in the life sciences industry, the inability of some of our customers to consummate anticipated purchases of our products due to changes in end-user demand, and other unpredictable factors that may affect ordering patterns. Because our revenue and operating results are difficult to predict, we believe that our past results of operations are not necessarily a good indicator of our future performance. Additionally, if revenue declines in a quarter, whether due to a delay in recognizing expected revenue, adverse economic conditions or otherwise, our results of operations will be harmed because many of our expenses are relatively fixed. In particular, a large portion of our manufacturing costs, our research and development, sales and marketing and general and administrative expenses are not significantly affected by variations in revenue. Further, our gross margins are dependent on product mix. A shift in sales mix away from our higher margin products to lower margin products will adversely affect our gross margins. If our quarterly operating results fail to meet investor expectations, the price of our common stock may decline.

Securities or industry analysts may not publish favorable research or reports about our business or may publish no information, which could cause our stock price or trading volume to decline.

The trading market for our common stock is influenced by the research and reports that industry or securities analysts publish about us and our business. We do not have any control over these analysts and we cannot provide any assurance that analysts will cover us or provide favorable coverage. If any of the analysts who cover us issue an adverse opinion regarding our stock price, our business or stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports covering us, we could lose visibility in the market, which in turn could cause our stock price or trading volume to decline.

Health care reform measures could adversely affect our business.

The efforts of governmental and third-party payors to contain or reduce the costs of health care may adversely affect the business and financial condition of pharmaceutical and biotechnology companies, including ours. Specifically, in both the United States and some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the health care system in ways that could affect our ability to sell our products profitably. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (together, the "Affordable Care Act"), was passed, which substantially changes the way health care is financed by both governmental and private insurers and significantly impacts the U.S. life sciences industry. The Affordable Care Act and other federal and state proposals and health care reforms could limit the prices that can be charged for the products we develop and may limit our commercial opportunity. In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, also called the Medicare Modernization Act (the "MMA") changed the way Medicare covers and pays for pharmaceutical products. These cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for any approved products and could seriously harm our business. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors. Efforts by the government and other third-party payors to contain or reduce the costs of health care through various means may limit our commercial opportunities and result in a decrease in the price of our common stock or limit our ability to raise capital.

Recent federal government efforts have been aimed at amending or repealing all or portions of existing health care reform legislation, including the Affordable Care Act. Changes in existing health care reform measures may result in uncertainty with respect to legislation, regulation and government policy that could significantly impact our business and the life sciences industry.

The enactment of legislation implementing changes in taxation of international business activities, the adoption of other corporate tax reform policies, or changes in tax legislation or policies could materially impact our financial position and results of operations.

Corporate tax reform, base-erosion efforts and tax transparency continue to be high priorities in many tax jurisdictions where we have business operations. As a result, policies regarding corporate income and other taxes in numerous jurisdictions are under heightened scrutiny and tax reform legislation is being proposed or enacted in a number of jurisdictions. For example, the Tax Cuts and Jobs Act (the "2017 Tax Reform Act"), adopting broad U.S. corporate income tax reform will, among other things, reduce the U.S. corporate income tax rate, but will impose base-erosion prevention measures on earnings of non-U.S. subsidiaries of U.S. entities as well as the transition tax on mandatory deemed repatriation of accumulated non-U.S. earnings of U.S. controlled foreign corporations. There is no assurance that our actual income tax liability will not be materially different than what is reflected in our income tax provisions and accruals.

In addition, many countries are beginning to implement legislation and other guidance to align their international tax rules with the Organisation for Economic Co-operation and Development's Base Erosion and Profit Shifting recommendations and action plan that aim to standardize and modernize global corporate tax policy, including changes to cross-border tax, transfer pricing documentation rules, and nexus-based tax incentive practices. Because of the heightened scrutiny of corporate taxation policies, prior decisions by tax authorities regarding treatments and positions of corporate income taxes could be subject to enforcement activities, and legislative investigation and inquiry, which could also result in changes in tax policies or prior tax rulings. Any such changes in policies or rulings may also result in the taxes we previously paid being subject to change.

Due to the large scale of our international business activities, any substantial changes in international corporate tax policies, enforcement activities or legislative initiatives may materially adversely affect our business, the amount of taxes we are required to pay and our financial condition and results of operations generally.

We compete with life science, pharmaceutical and biotechnology companies who are capable of developing new approaches that could make our products and technology obsolete.

The market for therapeutic and commercial products is intensely competitive, rapidly evolving and subject to rapid technological change. We compete with several medium and small companies in each of our product categories as well as several large companies, including GE Healthcare, Danaher Corporation (Pall), Thermo Fisher Scientific Inc., MilliporeSigma and Sartorius. These competitors, as well as other life science, pharmaceutical and biotechnology companies may have greater financial, manufacturing, marketing, and research and development resources than we have, as well as stronger name recognition, longer operating histories and benefits derived from greater economies of scale. These factors, among others, may enable our competitors to market their products at lower prices or on terms more advantageous to customers than what we can offer. Competition may result in price reductions, reduced gross margins and loss of market share, any of which could have a material adverse effect on our business, financial condition and results of operations. Additionally, new approaches by these competitors may make our products and technologies obsolete or noncompetitive.

We may become subject to litigation, which could result in substantial costs and divert management's attention and resources from our business.

From time to time, we may become involved in litigation or other legal proceedings relating to claims arising from the ordinary course of business. Litigation is subject to inherent risks and uncertainties that may cause actual results to differ materially from our expectations. If we receive an adverse judgment in any litigation, we could be required to pay substantial damages. With or without merit, litigation can be complex, can extend for a protracted period of time, can be very expensive and the expense can be unpredictable. Litigation initiated by us could also result in counter-claims against us, which could increase the costs associated with the litigation and result in our payment of damages or other judgments against us. In addition, litigation, and any related publicity, may divert the efforts and attention of some of our management and key personnel, which could adversely affect our business.

We may be exposed to liabilities under the Foreign Corrupt Practices Act, and any determination that we violated the Foreign Corrupt Practices Act could have a material adverse effect on our business.

We are subject to the Foreign Corrupt Practice Act (the "FCPA") and other laws that prohibit improper payments or offers of payments to foreign governments and their officials and political parties by U.S. persons and issuers as defined by the statute for the purpose of obtaining or retaining business. We have operations and agreements with third parties and make sales in jurisdictions outside of the United States, which may experience corruption. Our activities in jurisdictions outside of the United States create the risk of unauthorized payments or offers of payments by one of our employees, consultants, sales agents or distributors, because these parties are not always subject to our control. These risks have increased following our recent acquisitions of overseas operations and facilities. It is our policy to implement safeguards to discourage these practices by our employees. However, our existing safeguards and any future improvements may prove to be less than effective, and the employees, consultants, sales agents or distributors of our Company may engage in conduct for which we might be held responsible. Violations of the FCPA may result in severe criminal or civil sanctions, and we may be subject to other liabilities, which could negatively affect our business, operating results and financial condition. In addition, the government may seek to hold us liable for successor liability FCPA violations committed by any companies in which we invest or that we acquire.

Our stock price could be volatile, which could cause shareholders to lose part or all of their investment.

The market price of our common stock, like that of the common stock of many other companies with similar market capitalizations, is highly volatile. In addition, the stock market has experienced extreme price and volume fluctuations. This volatility has significantly affected the market prices of securities of many life sciences, biotechnology and pharmaceutical companies for reasons frequently unrelated to or disproportionate to the operating performance of the specific companies. These broad market fluctuations may adversely affect the market price of our common stock.

Anti-takeover provisions in our charter documents, certain of our contracts with third parties, and under Delaware law could make an acquisition of us, even one that may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our certificate of incorporation and by-laws may delay or prevent an acquisition of us or a change in our management. These provisions include the ability of our board of directors to issue preferred stock without stockholder approval. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders owning in excess of 15% of our outstanding voting stock to merge or combine with us. Although we believe these provisions collectively provide for an opportunity to obtain greater value for stockholders by requiring potential acquirers to negotiate with our board of directors, they would apply even if an offer rejected by our board were considered beneficial by some stockholders. Additionally, certain of our contracts with third parties allow for termination upon specified change of control transactions. Anti-takeover provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management, and anti-takeover or change of control contract termination rights may frustrate or prevent any attempts by a third party to acquire or attempt to acquire the Company.

Changes in accounting standards and subjective assumptions, estimates, and judgments by management related to complex accounting matters could significantly affect our financial results or financial condition.

Generally accepted accounting principles and related accounting pronouncements, implementation guidelines, and interpretations with regard to a wide range of matters that are relevant to our business, such as revenue recognition, asset impairment and fair value determinations, inventories, business combinations and intangible asset valuations, leases, and litigation, are highly complex and involve many subjective assumptions, estimates, and judgments. Changes in these rules or their interpretation or changes in underlying assumptions, estimates, or judgments could significantly change our reported or expected financial performance or financial condition.

Our results of operations could be negatively affected by potential fluctuations in foreign currency exchange rates.

We conduct a large portion of our business in international markets. For the fiscal year ended December 31, 2018, 28% of our revenues and 15% of our costs and expenses were denominated in foreign currencies, primarily the Swedish Krona, the British pound sterling, and the Euro. We are exposed to the risk of an increase or decrease in the value of the foreign currencies relative to the U.S. Dollar, which could increase the value of our expenses and decrease the value of our revenue when measured in U.S. Dollars. As a result, our results of operation may be influenced by the effects of future exchange rate fluctuations and such effects may have an adverse impact on our common stock price.

Our ability to use net operating loss and tax credit carryforwards and certain built-in losses to reduce future tax payments is limited by provisions of the Internal Revenue Code, and it is possible that certain transactions or a combination of certain transactions may result in material additional limitations on our ability to use our net operating loss and tax credit carryforwards.

Section 382 and 383 of the Internal Revenue Code of 1986, as amended, contain rules that limit the ability of a company that undergoes an ownership change, which is generally any change in ownership of more than 50% of its stock over a three-year period, to utilize its net operating loss and tax credit carryforwards and certain built-in losses recognized in years after the ownership change. These rules generally operate by focusing on ownership changes involving stockholders owning directly or indirectly 5% or more of the stock of a company and any change in ownership arising from a new issuance of stock by the company. Generally, if an ownership change occurs, the yearly taxable income limitation on the use of net operating loss and tax credit carryforwards and certain built-in losses is equal to the product of the applicable long-term, tax-exempt rate and the value of the company's stock immediately before the ownership change. We may be unable to offset our taxable income with losses, or our tax liability with credits, before such losses and credits expire and therefore would incur larger federal income tax liability. While our Section 382 analysis completed during 2018 did not show any current exposure, future transactions or combinations of future transactions may result in a change in control under Section 382 in the future.

If we fail to maintain an effective system of internal controls, we may not be able to accurately report financial results or prevent fraud. If we identify a material weakness in our internal control over financial reporting, our ability to meet our reporting obligations and the trading price of our stock could be negatively affected.

Effective internal controls are necessary to provide reliable financial reports and to assist in the effective prevention of fraud. Any inability to provide reliable financial reports or prevent fraud could harm our business. We regularly review and update our internal controls, disclosure controls and procedures, and corporate governance policies. In addition, we are required under the Sarbanes-Oxley Act of 2002 to report annually on our internal control over financial reporting. Any system of internal controls, however well designed and operated, is based in part on certain assumptions and can provide only reasonable, not absolute, assurances that the objectives of the system are met. If we, or our independent registered public accounting firm, determine that our internal controls over financial reporting are not effective, discover areas that need improvement in the future or discover a material weakness, these shortcomings could have an adverse effect on our business and financial results, and the price of our common stock could be negatively affected. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. Accordingly, a material weakness increases the risk that the financial information we report contains material errors.

If we cannot conclude that we have effective internal control over our financial reporting, or if our independent registered public accounting firm is unable to provide an unqualified opinion regarding the effectiveness of our internal control over financial reporting, investors could lose confidence in the reliability of our financial statements, which could lead to a decline in our stock price. Failure to comply with reporting requirements could also subject us to sanctions and/or investigations by the SEC, The Nasdaq Stock Market or other regulatory authorities. We have previously implemented several significant ERP modules and expect to implement additional ERP modules in the future. The implementation of the ERP system represents a change in our internal control over financial reporting. Although we continue to monitor and assess our internal controls in the new ERP system environment as changes are made and new modules are implemented, and we have taken additional steps to modify and enhance the design and effectiveness of our internal control over financial reporting, there is a risk that deficiencies may occur that could constitute significant deficiencies or in the aggregate a material weakness.

If we fail to remedy any deficiencies or maintain the adequacy of our internal controls, we could be subject to regulatory scrutiny, civil or criminal penalties or shareholder litigation. In addition, failure to maintain adequate internal controls could result in financial statements that do not accurately reflect our operating results or financial condition.

Natural disasters, geopolitical unrest, war, terrorism, public health issues or other catastrophic events could disrupt the supply, delivery or demand of products, which could negatively affect our operations and performance.

We are subject to the risk of disruption by earthquakes, floods and other natural disasters, fire, power shortages, geopolitical unrest, war, terrorist attacks and other hostile acts, public health issues, epidemics or pandemics and other events beyond our control and the control of the third parties on which we depend. Any of these catastrophic events, whether in the United States or abroad, may have a strong negative impact on the global economy, our employees, facilities, partners, suppliers, distributors or customers, and could decrease demand for our products, create delays and inefficiencies in our supply chain and make it difficult or impossible for us to deliver products to our customers. A catastrophic event that results in the destruction or disruption of our data centers or our critical business or information technology systems would severely affect our ability to conduct normal business operations and, as a result, our operating results would be adversely affected.

Changes in laws and regulations governing the privacy and protection of data and personal information could adversely affect our business.

We are subject to data privacy and protection laws and regulations that apply to the collection, transmission, storage and use of proprietary information and personally-identifying information, which among other things, impose certain requirements relating to the privacy, security and transmission of certain individually identifiable information. In addition, numerous other federal and state laws, including state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, govern the collection, use, disclosure and security of personal information.

Various foreign countries also have, or are developing, laws governing the collection, use, disclosure, security, and cross-border transmission of personal information. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing amount of focus on privacy and data protection issues with the potential to affect our business. For example, privacy requirements in the European Union (“EU”) govern the transfer of personal information from the European Economic Area to the United States. While we continue to address the implications of changes to the EU data privacy regulations, the area remains an evolving landscape with new regulations coming into effect and continued legal challenges and our efforts to comply with the evolving data protection rules may be unsuccessful. Failure to comply with laws regarding data protection would expose us to risk of enforcement actions taken by data protection authorities in the EU and the potential for significant penalties if we are found to be non-compliant. Similarly, failure to comply with federal and state laws in the United States regarding privacy and security of personal information could expose us to penalties under such laws. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our business.

Our internal computer systems, or those of our customers, collaborators or other contractors, may be subject to cyber-attacks or security breaches, which could result in a material disruption of our product development programs.

Despite the implementation of security measures, our internal computer systems and those of our customers, collaborators and other contractors are vulnerable to damage from computer viruses and unauthorized access. Cyber-attacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyber-attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. Cyber-attacks also could include phishing attempts or e-mail fraud to cause payments or information to be transmitted to an unintended recipient. A material cyber-attack or security breach could cause interruptions in our operations and could result in a material disruption of our business operations, damage to our reputation or a loss of revenues.

In the ordinary course of our business, we collect and store sensitive data, including, among other things, personally identifiable information about our employees, intellectual property, and proprietary business information. Any cyber-attack or security breach that leads to unauthorized access, use or disclosure of personal or proprietary information could harm our reputation, cause us not to comply with federal and/or state breach notification laws and foreign law equivalents and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information. In addition, we could be subject to risks caused by misappropriation, misuse, leakage, falsification or intentional or accidental release or loss of information maintained in the information systems and networks of our company and our vendors, including personal information of our employees, and company and vendor confidential data. In addition, outside parties may attempt to penetrate our systems or those of our vendors or fraudulently induce our personnel or the personnel of our vendors to disclose sensitive information in order to gain access to our data and/or systems. Like other companies, we have on occasion experienced, and will continue to experience, threats to our data and systems, including malicious codes and viruses, phishing, business email compromise attacks, or other cyber-attacks. The number and complexity of these threats continue to increase over time. If a material breach of our information technology systems or those of our vendors occurs, the market perception of the effectiveness of our security measures could be harmed and our reputation and credibility could be damaged.

We could be required to expend significant amounts of money and other resources to respond to these threats or breaches and to repair or replace information systems or networks, and could suffer financial loss or the loss of valuable confidential information. In addition, we could be subject to regulatory actions and/or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations, including claims for misuse or inappropriate disclosure of data, as well as unfair or deceptive practices. Although we develop and maintain systems and controls designed to prevent these events from occurring, and we have a process to identify and mitigate threats, the development and maintenance of these systems, controls and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly sophisticated. Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely and there can be no assurance that any measures we take will prevent cyber-attacks or security breaches that could adversely affect our business.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

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ITEM 6. EXHIBITS

(a) Exhibits

Exhibit Number	Document Description
31.1 +	Rule 13a-14(a)/15d-14(a) Certification.
31.2 +	Rule 13a-14(a)/15d-14(a) Certification.
32.1*	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101+	The following materials from Repligen Corporation on Form 10-Q for the quarterly period ended March 31, 2019, formatted in Extensible Business Reporting Language (xBRL): (i) Consolidated Statements of Comprehensive Income, (ii) Consolidated Balance Sheets, (iii) Consolidated Statements of Stockholders' Equity, (iv) Consolidated Statements of Cash Flows, and (v) Notes to Consolidated Financial Statements, tagged as blocks of text.

\+ Filed herewith.
* Furnished herewith.

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SIGNATURES

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

REPLIGEN CORPORATION

Date: May 9, 2019 By: /S/ TONY J. HUNT

Tony J. Hunt
President and Chief Executive Officer
(Principal executive officer)
Repligen Corporation

Date: May 9, 2019 By: /S/ JON SNODGRES

Jon Snodgres
Chief Financial Officer
(Principal financial officer)
Repligen Corporation

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Section 2: EX-31.1 (EX-31.1)

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO RULE 13a-14(a) / RULE 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

I, Tony J. Hunt, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Repligen Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

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

Date: May 9, 2019

/s/ TONY J. HUNT

Tony J. Hunt
President and Chief Executive Officer
(Principal executive officer)

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Section 3: EX-31.2 (EX-31.2)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO RULE 13a-14(a) / RULE 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

I, Jon Snodgres, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Repligen Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

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

Date: May 9, 2019

/s/ JON SNODGRES

Jon Snodgres
Chief Financial Officer
(Principal financial officer)

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Section 4: EX-32.1 (EX-32.1)

Exhibit 32.1*

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Repligen Corporation (the "Company") on Form 10-Q for the period ending March 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officers of the Company hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to my knowledge, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 9, 2019 By: /S/ TONY J. HUNT

Tony J. Hunt
Chief Executive Officer and President
(Principal executive officer)

Date: May 9, 2019 By: /S/ JON SNODGRES

Jon Snodgres
Chief Financial Officer
(Principal financial officer)

* This certification shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liability of that section, nor shall it be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934.

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