REPLIGEN CORP
Form 10-K
March 01, 2019
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2018

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)**

Registrant s telephone number, including area code: (781) 250-0111

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

Title of Each Class	**Name of Exchange on Which Registered**
Common Stock, $0.01 Par Value Per Share	**The NASDAQ Stock Market LLC**

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No .

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No .

Indicate by checkmark 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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or

information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting 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. Yes No .

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates as of June 29, 2018, the last business day of the registrant s most recently completed second fiscal quarter, was $1,569,493,598.

The number of shares of the registrant s common stock outstanding as of February 22, 2019 was 43,921,488.

Documents Incorporated By Reference

The registrant intends to file a proxy statement pursuant to Regulation 14A within 120 days of the end of the fiscal year ended December 31, 2018. Portions of such proxy statement are incorporated by reference into Part III of this Annual Report on Form 10-K.

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (Form 10-K) 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 Form 10-K do not constitute guarantees of future performance. Investors are cautioned that express or implied statements in this Form 10-K that are not strictly historical statements, including, without limitation, statements regarding current or future financial performance, potential impairment of future earnings, management s strategy, plans and objectives for future operations or acquisitions, product development and sales, research and development, selling, general and administrative expenditures, intellectual property and adequacy of capital resources and financing plans constitute 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, the risks identified under the caption Risk Factors and other risks detailed in this Form 10-K and our other filings with the Securities and Exchange Commission. We assume no obligation to update any forward-looking information contained in this Form 10-K, except as required by law.

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PART I

ITEM 1. BUSINESS

The following discussion of our business contains forward-looking statements that involve risks and uncertainties. When used in this report, the words intend, anticipate, believe, estimate, plan and expect and similar expressions as they relate to us are included to identify forward-looking statements. Our actual results could differ materially from those anticipated in these forward-looking statements and are a result of certain factors, including those set forth under Risk Factors and elsewhere in this Annual Report on Form 10-K.

References throughout this Annual Report on Form 10-K to Repligen , we , us , our , or the Company refer to Repligen Corporation and its subsidiaries, taken as a whole, unless the context otherwise indicates.

Overview

Repligen 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 to 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.

We currently operate as one bioprocessing business, with a comprehensive suite of products to serve both upstream and downstream processes in biologic drug manufacturing. Building on over 35 years of industry expertise, we have developed a broad and diversified product portfolio that reflects our commitment to build a best-in-class bioprocessing technology company with a world-class direct sales and commercial organization.

We are committed to capitalizing on growth opportunities and maximizing the value of our product platform through both organic growth initiatives (internal innovation and commercial leverage) and targeted acquisitions.

Our Products

Our bioprocessing business is comprised of three main product lines Chromatography, Filtration and Proteins.

Direct-to-Customer Products (Chromatography and Filtration)

Since 2012, we have significantly expanded our direct-to-customer presence through our Chromatography and Filtration product lines, which include differentiated products and systems. We have diversified and grown our direct-to-customer product offering through internal innovation and through disciplined, accretive acquisitions of assets or businesses that leverage existing product lines and/or expand our customer and geographic scope.

To support our sales goals for our direct-to-consumer products, we have invested in our commercial organization. Our commercial and research and development teams work to effectively launch new products and applications, as well as build new markets for acquired technologies that increase flexibility and convenience while streamlining

biomanufacturing workflow for our customers. In addition, to meet increased demand for our products, we continue to invest in increasing the volume and scale of manufacturing at our facilities in the United States, Sweden and Germany.

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Chromatography

Our Chromatography product line includes a number of products used in the downstream purification and quality control of biological drugs. The main driver of growth in this portfolio is our lab and process-scale OPUS® pre-packed chromatography (PPC) column line.

Our other products include chromatography resins (such as CaptivA®) used in a small number of commercial drug processes and ELISA test kits used by quality control departments to detect and measure the presence of leached Protein A and/or growth factor in the final product.

OPUS®

Our Chromatography product line features 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 the PPC market. The customization and ready-to-use nature of our OPUS columns makes them ideal for purification of antibodies, recombinant proteins and vaccines. Biomanufacturers value the time savings, labor and utility cost savings, product consistency and the plug and play convenience of OPUS.

We launched our first production-scale OPUS columns in 2012 and have since added larger diameter options such as OPUS 45 and OPUS 60. Early in 2018, we introduced OPUS 80 R, the largest available PPC on the market, for use in late-stage clinical or select commercial purification processes. We have also introduced next-generation features such as a resin recovery port on our larger columns. This allows our customers to reuse the recovered resin in other applications. The unpacking port feature was made available in the first quarter of 2017 on our largest production-scale OPUS columns.

Through our acquisition of Atoll GmbH in 2016, we established a customer-facing center in Europe and expanded our portfolio to include our smaller-scale columns, named OPUS PD, that are used in high-throughput process development screening, viral validation studies and scale down validation of chromatography processes. We maintain a broad and customizable PPC product line to meet our customers diverse needs.

Other Chromatography

Also included in our Chromatography portfolio are ELISA kits, which are analytical test kits to detect the presence of proteins and growth factors, and chromatography resins, including our CaptivA® brand. In addition, following our acquisition of Spectrum in 2017, we sell Spectra/Chrom® liquid chromatography products as part of our Chromatography product line.

Filtration

XCell ATF

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. We first established our Filtration product line through our acquisition of XCell Alternating Tangential Flow (ATF) assets from Refine Technology (Refine) in 2014. XCell ATF systems are used primarily in upstream perfusion, or continuous manufacturing , processes.

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XCell ATF is 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. XCell ATF was designed to both increase the density of cells in a bioreactor and extend the production run. By continuously removing waste products from the fermenter, the XCell ATF System routinely increases cell densities to 2- or 3-times the levels achieved by standard batch fermentation. As a result, product yield is increased, which improves facility utilization and can reduce the size of a bioreactor required to manufacture a given volume of biologic drug product. This is important to biomanufacturers who seek to maximize output from their existing facilities. XCell ATF Systems are suitable for use in laboratory and scale-up all the way to production bioreactors as large as 2,000 liters.

Through internal innovation, we developed and in 2016 launched single-use formats of the original stainless steel XCell ATF device to address increasing industry demand for plug-and-play technology. The XCell ATF device is now available to customers in both its original configuration (steel housing and replaceable filters) in all sizes (2, 4, 6 and 10), and/or as a single-use device (disposable housing/filter combination) in most sizes (2, 6, and 10). The availability of XCell ATF in a single-use format eliminates the pre-use workflow associated with autoclaving, leading to an 80% reduction in implementation time. The single-use format also enables our customers to accelerate evaluations of the product with a lower initial overall cost of ownership. Based on strong demand, we have continued to expand the single-use XCell ATF offering.

In September 2018, we entered into a collaboration agreement with industry leader Sartorius Stedim Biotech (SSB) to integrate our XCell ATF controller technology into SSB s BIOSTAT® STR large-scale, single-use bioreactors, to create novel perfusion-enabled bioreactors.

SIUS Tangential Flow Filters (TangenX)

In December 2016, we acquired TangenX Technology Corporation (TangenX), balancing our upstream XCell ATF offering with a downstream portfolio of flat-sheet tangential flow filters (TFF) and cassettes used in downstream biologic drug purification and formulation processes. The TangenX portfolio includes our single-use SIUS TFF brand, providing customers with a high-performance, low-cost alternative to reusable TFF cassettes.

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. SIUS is an innovative single-use TFF line of cassettes and hardware for lab-scale through large-scale biopharmaceutical manufacturing. Single-use SIUS TFF cassettes with enclosed flat sheet membranes are designed to provide a high performing membrane at significantly lower product and labor costs than reusable TFF products. Each disposable cassette is delivered pre-sanitized, integrity tested and ready to be equilibrated and used for tangential flow diafiltration and ultrafiltration processing. Use of SIUS TFF cassettes eliminates non-value added steps of cleaning and flushing required in reusable TFF products. The cassettes are interchangeable with filter hardware from multiple manufacturers, simplifying customer trial and adoption of SIUS products.

KrosFlo®, ProConnex® (Spectrum Life Sciences LLC)

We acquired Spectrum Life Sciences LLC (Spectrum) and its subsidiaries in August 2017 to strengthen our filtration business with the addition of a leading portfolio of hollow-fiber (HF) filters and modules, single-use flow path connectors and TFF filtration systems. Spectrum products are used in bench-top through commercial-scale processes, primarily for the filtration, isolation, purification and concentration of biologics and diagnostic products. Our Spectrum filtration products offer both standard and customized solutions to bioprocessing customers, with particular strength in consumable and single-use offerings.

With the addition of Spectrum, we now in-house manufacture hollow-fiber filters that can be used in our XCell ATF system. In addition, we increased our direct sales presence in Europe and Asia, and we diversified our end markets beyond monoclonal antibodies to include vaccines, recombinant protein and gene therapies.

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Our Spectrum filtration brands include the KrosFlo® line of hollow-fiber cartridges and TFF systems, the Spectra/Por® portfolio of laboratory and process dialysis products and Pro-Connex® single-use hollow-fiber Module-Bag-Tubing sets.

In 2018, we introduced our KONDUiT device to automate concentration and buffer exchange to be used in conjunction with our hollow fiber or flat sheet TFF filtration products.

OEM Products (Proteins)

Our OEM products are represented by our Protein A affinity ligands, which are a critical component of Protein A chromatography resins used in downstream purification, and cell culture growth factor products, which are a key component of cell culture media used upstream to increase cell density in a bioreactor and improve product yield.

Protein A/Ligands

We are a leading provider of Protein A affinity 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 monoclonal antibody based drugs on the market or in development. We manufacture multiple forms of Protein A ligands under long-term supply agreements with major life sciences companies including GE Healthcare, MilliporeSigma and Purolite Life Sciences (Purolite), who in turn sell their Protein A chromatography resins to end users (mAb manufacturers). We have two manufacturing sites supporting overall global demand for our Protein A ligands: one in Lund, Sweden and another in Waltham, Massachusetts.

Protein A chromatography resins are considered the industry standard for purification of antibody-based therapeutics due to the ability of the Protein A ligand to very selectively bind to or capture antibodies from crude protein mixtures. Protein A resins are packed into the first chromatography column of typically three columns used in a mAb purification process. As a result of Protein A s high affinity for antibodies, the mAb product is highly purified and concentrated within this first capture step before moving to polishing steps.

In June 2018, we entered into an agreement with Navigo Proteins GmbH (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, 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 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 product line.

Growth Factors

Most biopharmaceuticals are produced through an upstream mammalian cell fermentation process. In order to stimulate increased cell growth and maximize overall yield from a bioreactor, manufacturers often add growth factors, such as insulin, to their cell culture fermentation media. As part of the Novozymes Acquisition in 2011, we gained several cell culture growth factor additives. Among those products is LONG®R3 IGF-1, our insulin-like growth factor that has been shown to be up to 100 times more biologically potent than insulin (the industry standard), thereby increasing recombinant protein production in cell culture fermentation applications. LONG R3 IGF-1 is sold through a distribution partnership with MilliporeSigma.

Corporate Information

We are a Delaware corporation with global headquarters in Waltham, Massachusetts. We were incorporated in 1981 and became a publicly traded company in 1986. Our common stock is listed on The Nasdaq Global Market

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under the symbol RGEN . We have over 540 employees and operate globally with offices and manufacturing sites located at multiple locations in the United States, Europe and Asia. Our principal executive offices are located at 41 Seyon Street, Waltham, Massachusetts 02453, our website is www.repligen.com and our telephone number is (781) 250-0111.

Our Market Opportunity

The global biologics drug market was estimated to be over $200 billion in 2017. This market includes therapeutic antibodies, recombinant proteins and vaccines. Antibody-based biologics alone accounted for over $115 billion of global biopharma revenue and represented a majority of the top 10 best-selling drugs across the pharmaceutical industry in 2017. Industry sources project the biologics market to grow at a rate of 8%-10% annually over the next five years, driven by strength in the mAb class of biologics, as evidenced by the rate of new approvals, expanded labels for marketed antibodies and the emergence of biosimilar versions of originator mAbs.

In 2018, 13 mAbs (a record 11 originator mAbs and two biosimilars) were approved by the U.S. Food and Drug Administration (FDA) to treat a diverse range of diseases. Between 2016 and 2018, 36 mAbs were approved by the FDA, representing over 40% of all approved mAbs since the first therapeutic antibody was brought to market in 1986. There are currently more than 80 mAbs on the market and more than 400 in various stages of clinical development addressing a wide range of medical conditions including asthma, migraines and Alzheimer s disease.

In addition to investments in the discovery and development of novel biologic drugs, there has been substantial investment in follow-on products (biosimilars) by generic and specialty pharmaceutical as well as large biopharmaceutical companies. Development of follow-on products has accelerated as the first major mAbs have come off patent in the European Union and United States. Due to the high cost of biologic drugs, many countries in the developing and emerging markets have been aggressively investing in biomanufacturing capabilities to supply lower cost biosimilars for the local markets. For both originator and follow-on biologics manufacturing, Repligen products are well-positioned to enable greater manufacturing flexibility, production yields and lower costs through improved process efficiencies.

Many of the products we manufacture are in the early stages of their adoption cycle, and together with the expansion of our commercial organization and strategic acquisitions, have contributed to product revenue growth from $47.5 million in 2013, to $193.9 million in 2018. While all product lines have grown over this period, our diversification strategy has resulted in a significant increase in direct product sales as a percent of total product revenue, from 17% in 2012. By 2018, 72% of total bioprocessing revenue was attributable to direct product sales; 47% from our Filtration product line, 23% from our Chromatography product line and a small percentage from other sources including sales of hospital products that we obtained through our acquisition of Spectrum.

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 applications that must be approved by regulators, such as the FDA, and the European Medicines Agency (EMA), 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.

The Biologics Manufacturing Process

Manufacturing biologic drugs requires three fundamental steps. First, upstream manufacturing involves the production of the biologic by living cells that are grown in a bioreactor under controlled conditions. Methods of production vary

with the industry standard being fed-batch, where nutrients (media) are added to a bioreactor to

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stimulate cell growth and productivity and then followed by a harvest step. The industry is increasingly adopting the perfusion (or continuous) method of production, which circulates nutrients into the bioreactor, while simultaneously harvesting the biologic drug product. Some manufacturers are embracing a hybrid approach combining both fed-batch and perfusion methods. The cells being grown in a bioreactor are engineered to produce the biologic drugs of interest. These tiny cell factories are highly sensitive to the conditions under which they grow, including the composition of the cell culture media and the growth factors used to stimulate increased cell growth and protein production, or titre. In the second downstream step, the biologic made upstream must be separated and purified, typically through various filtration and chromatography steps. Finally, the purified biologic drug is concentrated and formulated and then quality controlled and packaged into its final injectable form.

Biologics are generally high value therapies. Given the inherent complexities of the process and the final drug product, we have observed that manufacturers are seeking and investing in innovative technologies that address pressure points in the production process in order to improve yields. Manufacturers are also seeking technologies that reduce costs as the biologic drug moves through clinical stages and into commercial processes by adopting single-use technologies as well as other products that yield increased flexibility and efficiency.

Our Strategy

We are focused on the development, production and commercialization of differentiated, technology-leading solutions or products that address specific pressure points in the biologics manufacturing process and deliver substantial value to our customers. Our products are designed to increase our customers product yield, and we are committed to supporting our customers with strong customer service and applications expertise.

We intend to build on our recent history of developing market-leading solutions and delivering strong financial performance through the following strategies:

Continued innovation. We plan to capitalize on our internal technological expertise to develop products that address unmet needs in upstream and downstream bioprocessing. We intend to invest further in our core Proteins product lines while developing platform and derivative products to support our Filtration and Chromatography product lines.

Platforming our products. A key strategy for accelerating market adoption of our products is delivery of enabling technologies that become the standard, or platform, technology in markets where we compete. We focus our efforts on winning early-stage technology evaluations through direct interaction with the key biomanufacturing decision makers in process development labs. This strategy is designed to establish early adoption of our enabling technologies at key accounts, with opportunity for customers to scale up as the molecule advances to later stages of development and potential commercialization. We believe this approach can accelerate the implementation of our products as platform products, thereby strengthening our competitive advantage and contributing to long-term growth.

Targeted acquisitions. We intend to continue to selectively pursue acquisitions of innovative technologies and products. We intend to leverage our balance sheet to acquire technologies and products that improve our overall financial performance by improving our competitiveness in filtration or chromatography or moving us into adjacent markets with common commercial call points.

Geographical expansion. We intend to expand our global commercial presence by continuing to selectively build out our global sales, marketing, field applications and services infrastructure.

Operational efficiency. We seek to expand operating margins through capacity utilization and process optimization strategies designed to increase our manufacturing yields. We plan to invest in systems to support our global operations, optimizing resources across our global footprint to maximize productivity.

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Research and Development

Our research activities are focused on developing new high-value bioprocessing products. Specifically, we plan to focus these efforts on expanding our product portfolio and applications for our OPUS PPC columns, XCell ATF systems, SIUS TFF, KrosFlo®, TFF systems and other products, and developing next generation Protein A ligands.

Sales and Marketing

Our sales and marketing strategy supports our objective of strengthening our position as a leading provider of products and services, addressing upstream, downstream and quality control needs of bioprocessing customers in the biopharmaceutical industry.

Direct-to-Customer Team

To support our sales goals for our direct-to-consumer products, we have invested in our commercial organization. Since 2014, we have significantly expanded our global commercial organization, to form a 103-person commercial team as of December 31, 2018. This includes 54 people in field positions (direct sales, field applications and field service), and 49 people with internal positions (marketing, product management and customer service). This expansion also includes the team of 26 highly experienced field personnel that we added with our acquisition of Spectrum in 2017. With the acquisition, we have greatly expanded our direct sales team in Asia, where we also work effectively with key distributors to serve our expanding customer base.

As part of the Spectrum integration process, we transitioned to a new sales model in 2018, whereby all sales staff now represent all Repligen products across our Chromatography and Filtration portfolios. Our bioprocess account managers are supported in each region by bioprocess sales specialists with expertise in either Filtration or Chromatography and by technically trained field applications specialists and field service providers, who can work closely with customers on product demonstrations, implementation and support. We believe that this model helps drive further adoption at our key accounts and also open up new sales opportunities within each region.

OEM Agreements

For our Proteins product line, we are committed to being a partner of choice for our customers with distributor and supply agreements in place with large life sciences companies such as GE Healthcare, MilliporeSigma and Purolite. The GE Healthcare Protein A supply agreement relating to our Lund, Sweden facility runs, pursuant to its terms, through 2019 with an option for earlier termination on six months advance notice. The GE Healthcare Protein A supply agreement relating to our Waltham, Massachusetts facility runs, pursuant to its terms, through 2021. Our Protein A supply agreement with MilliporeSigma runs, pursuant to its terms, through 2023, and in 2018 we amended our Protein A supply agreement with Purolite that runs, pursuant to its terms, to August 2026 with an option for renewal through 2028. Our dual manufacturing capability provides strong business continuity and reduces overall supply risk for our OEM customers.

Significant Customers and Geographic Reporting

Customers for our bioprocessing products include major life science companies, contract manufacturing organizations, biopharmaceutical companies, diagnostics companies and laboratory researchers.

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

	For the Years Ended December 31,		
	2018	2017	2016
Revenue by customers geographic locations:			
North America	48%	43%	39%
Europe	40%	46%	54%
APAC	12%	11%	7%
Other	0%	0%	0%
Total revenue	100%	100%	100%

GE Healthcare, our largest bioprocessing customer, accounted for 15%, 21% and 29% of total revenues in the years ended December 31, 2018, 2017 and 2016, respectively. MilliporeSigma, our second largest bioprocessing customer, accounted for 15%, 18% and 28% of total revenues in the years ended December 31, 2018, 2017 and 2016, respectively.

Employees

As of December 31, 2018, we had 548 employees. Of those employees, 54 were engaged in engineering and research and development, 325 in manufacturing, 103 in sales and marketing and 66 in administrative functions. Each of our employees has signed a confidentiality agreement. None of our U.S. employees are covered by collective bargaining agreements. We have one collective bargaining agreement with two unions that covers our 62 employees in Sweden, comprising approximately 11% of our total workforce. We renewed these collective bargaining agreements during 2017, and the new collective bargaining agreements expire on March 31, 2020. We consider our employee relations to be satisfactory.

Intellectual Property

We are committed to protecting our intellectual property through a combination of patent, copyright, trade secret and trademark laws, as well as confidentiality agreements. As further described below, we 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.

Chromatography

For our Chromatography product line, we have a base of intellectual property that comes from our acquisitions of Atoll GmbH in 2016, and certain assets acquired from BioFlash Partners in 2010. Our issued patents cover certain unique methods and features of our OPUS pre-packed columns, including methods of making and loading these chromatography columns as well as the column structure. We continually seek to improve upon this technology and have multiple new patent filings including those covering gamma irradiation sterilization, packing methods, and methods of removing air using specialized tubing and valve systems.

Filtration

For our Filtration product line, we are leveraging our acquisitions of third-party filtration patented technology of Refine, with a focus on ATF technology, TangenX, with a focus on tangential flow flat sheet cassette technology, and Spectrum, with a focus on tangential flow hollow fiber technology. We continually seek to improve upon these technologies and have multiple new patent filings including those covering pumps and controllers, methods of harvesting, single-use products, and filters. Our patent for alternating tangential flow and associated methods to use such a device in perfusion, acquired from Refine, expires in 2020, and we are proactively developing technology in an effort to mitigate any effects resulting from the expiration of this patent.

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We currently have 44 patents granted (which expire over the next 20 years) and 85 patents pending in countries including Australia, Canada, China, France, Germany, India, Japan, Korea, Sweden, United Kingdom and the United States.

Our policy is to require each of our employees, consultants, business partners, potential collaborators and major customers to execute confidentiality agreements upon the commencement of an employment, consulting, business relationship, or product related audit with us. These agreements provide that all confidential information developed or made known to the other party during the course of the relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees and consultants, the agreements generally provide that all inventions conceived by the individual in the course of rendering services to Repligen shall be our exclusive property and must be assigned to Repligen.

Protein A

We currently hold a patent for Nucleic Acids Encoding Recombinant Protein A, which claims an isolated nucleic acid molecule that encodes a Protein A molecule with an amino acid sequence identical to that of the natural Protein A, which has long been commercialized for bioprocessing applications. This patent will remain in effect until June 2028. We also have two pending patents covering affinity ligands through our collaboration with Navigo GmbH.

Trademarks

We vigilantly protect our products and services branding by maintaining trademark registrations globally for the Repligen trademark and our key product brands. We have a comprehensive branding policy that includes trademark usage guidelines to ensure Repligen trademarks are used in a manner that provides the maximum protection.

We prioritize our housemark trademarks, (i.e., Repligen, Spectrum and TangenX), and ensure they are sufficiently protected and registered in key countries or regions globally, such as the United States, Canada, Europe and China. We also have product trademarks, including OPUS, XCell ATF, KrosFlo, SIUS, Pro-Connex, Spectra/Por and NGL-Impact A, that provide valuable company recognition and goodwill with its customers.

Our ability to compete effectively in the marketplace is dependent in part on our ability to protect our intellectual property rights, which includes protecting the trademarks we use in connection with our products and services. We rely on several registered and unregistered trademarks to protect our brand.

Licensing Agreements

We have entered into multiple licensing and collaboration relationships with third-party business partners in an effort to fully exploit our technology and advance our bioprocessing business strategy.

Competition

Our bioprocessing products compete on the basis of quality, performance, cost effectiveness, and application suitability with numerous established technologies. Additional products using new technologies that may be competitive with our products may also be introduced. Many of the companies selling or developing competitive products, which in some cases include GE Healthcare and MilliporeSigma, our two largest customers, have greater financial and human resources, research and development, manufacturing and marketing experience than we do. They may undertake their own development of products that are substantially similar to or compete with

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our products and they may succeed in developing products that are more effective or less costly than any that we may develop. These competitors may also prove to be more successful in their production, marketing and commercialization activities. We cannot be certain that the research, development and commercialization efforts of our competitors will not render any of our existing or potential products obsolete.

Manufacturing

We manufacture seven commercial forms of Protein A, including native Protein A for life sciences companies, including GE Healthcare, MilliporeSigma and Purolite, under long-term supply agreements which expire between 2019 and 2023. Native Protein A is manufactured in Lund, Sweden, while the recombinant forms are manufactured in both Waltham, Massachusetts and Lund, Sweden. We currently manufacture our growth factor products in Lund, Sweden. Our OPUS chromatography columns and XCell ATF System products are manufactured in Waltham, Massachusetts. Our OPUS PD columns are manufactured in Ravensburg, Germany, and our SIUS TFF products were manufactured in Shrewsbury, Massachusetts until December 31, 2018 before manufacturing of the SIUS TFF products shifted to our new facility in Marlborough, Massachusetts. Our KrosFlo, Spectra/Pro and Pro-Connex lines of products are manufactured in Rancho Dominguez, California. Our operating room products are manufactured in Irving, Texas, and our Spectra/Chrom products are manufactured in Houston, Texas.

We utilize our own facilities in Waltham, Massachusetts and Lund, Sweden as well as third-party contract manufacturing organizations to carry out certain fermentation and recovery operations, while the purification, immobilization, packaging and quality control testing of our bioprocessing products are conducted at our facilities. Our facilities located in Waltham, Massachusetts; Lund, Sweden; Ravensburg, Germany; and Rancho Dominguez, California are ISO 9001:2015 certified and maintain formal quality systems to maintain process control, traceability, and product conformance. Additionally, our facility in Irving, Texas is ISO 13485:2012 certified. We practice continuous improvement initiatives based on routine internal audits as well as external feedback and audits performed by our partners and customers. In addition, we maintain a business continuity management system which focuses on key areas such as contingency planning, security stocks and off-site storage of raw materials and finished goods to ensure continuous supply of our products.

Available Information

We maintain a website with the address www.repligen.com. We are not including the information contained on our website as a part of, or incorporating it by reference into, this Annual Report on Form 10-K. We make available free of charge through our website our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, and amendments to these reports, as soon as reasonably practicable after we electronically file such materials with, or furnish such materials to, the Securities and Exchange Commission. Our Code of Business Conduct and Ethics is also available free of charge through our website.

Our filings with the Securities and Exchange Commission may be accessed through the Securities and Exchange Commission s Electronic Data Gathering, Analysis and Retrieval (EDGAR) system at www.sec.gov.

ITEM 1A. RISK FACTORS

Investors should carefully consider the risk factors described below before making an investment decision.

If any of the events described in the following risk factors occur, our business, financial condition or results of operations could be materially harmed. In that case the trading price of our common stock could decline, and

investors may lose all or part of their investment. Additional risks and uncertainties that we are unaware of or that we currently deem immaterial may also become important factors that affect Repligen.

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This Annual Report on Form 10-K contains forward looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including the risks faced by us described below and elsewhere in this Annual Report on Form 10-K.

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 collaboration 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, and expect to continue to depend 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 other 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 (the Lund Agreement and Waltham Agreement, respectively). The Lund Agreement runs pursuant to its terms, through

2019 and the Waltham Agreement runs, pursuant to its terms, through 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.

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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.

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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 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;

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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

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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.

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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

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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.

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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

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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 period-to-period comparisons of our results of operations are not 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.

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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.

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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,

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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

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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.

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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, imposes 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.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

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ITEM 2. PROPERTIES

Our material office and manufacturing leases are detailed below:

Location	Square Feet	Principal Use	Lease Expiration
Waltham, Massachusetts	75,594	Corporate headquarters, manufacturing, research and development, marketing and administrative offices	May 31, 2023
Rancho Dominguez, California	68,908	Manufacturing, research and development, marketing and administrative operations	July 15, 2020[(1)]
Marlborough, Massachusetts	63,761	Manufacturing operations	November 30, 2028
Lund, Sweden	45,381	Manufacturing and administrative operations	December 31, 2021

(1) In 2018, we expanded our facility in Rancho Dominguez, California by approximately 15,000 square feet. The lease for the expanded portion of the facility expires on November 30, 2025.

During the year ended December 31, 2018, we incurred total rental costs for all facilities of $4.4 million.

ITEM 3. 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 4. MINE SAFETY DISCLOSURES

Not applicable.

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PART II

ITEM 5. MARKET FOR REGISTRANT S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Stockholders and Dividends

As of February 22, 2019, there were 353 stockholders of record of our common stock. We have not paid any dividends since our inception and do not intend to pay any dividends on our common stock in the foreseeable future. We anticipate that we will retain all earnings, if any, to support our operations. Any future determination as to the payment of dividends will be at the sole discretion of our Board of Directors and will depend on our financial condition, results of operations, capital requirements and other factors our Board of Directors deems relevant.

Equity Compensation Plan Information

The following table sets forth information as of December 31, 2018 regarding shares of common stock that may be issued under the Company s equity compensation plans, consisting of the Second Amended and Restated 2001 Repligen Corporation Stock Plan, the Amended and Restated 2012 Stock Option and Incentive Plan and the 2018 Stock Option and Incentive Plan.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	1,703,639[1]	$ 27.54[2]	2,874,751

(1) Includes 998,226 shares of common stock issuable upon the exercise of outstanding options and 705,413 shares of common stock issuable upon the vesting of restricted stock units (RSUs). No shares of restricted stock are outstanding.

(2) Since RSUs do not have any exercise price, such units are not included in the weighted average exercise price calculation.

Issuer Purchases of Equity Securities

In June 2008, the Board of Directors authorized a program to repurchase up to 1.25 million shares of our common stock to be repurchased at the discretion of management from time to time in the open market or through privately negotiated transactions. The repurchase program has no set expiration date and may be suspended or discontinued at any time. We did not repurchase any shares of common stock during the year ended December 31, 2018. In prior

years, we repurchased a total of 592,827 shares, leaving 657,173 shares remaining under this authorization.

The graph below matches Repligen Corporation s cumulative 5-year total shareholder return on common stock with the cumulative total returns of the NASDAQ Composite index, the NASDAQ Pharmaceutical index, and the NASDAQ Biotechnology index. The graph tracks the performance of a $100 investment in our common stock and in each index (with the reinvestment of all dividends) from December 31, 2013 to December 31, 2018.

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COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN*

Among Repligen Corporation, the NASDAQ Composite Index,

the NASDAQ Pharmaceutical Index and the NASDAQ Biotechnology Index

*$100 invested on 12/31/13 in stock or index, including reinvestment of dividends.

Fiscal year ending December 31.

The information contained in the performance graph shall not be deemed to be soliciting material or to be filed with the Securities and Exchange Commission, and such information shall not be incorporated by reference into any future filing under the Securities Act of 1933, as amended (the Securities Act) or the Securities Exchange Act of 1934, as amended (the Exchange Act), except to the extent that Repligen specifically incorporates it by reference into such filing.

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ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA

The following selected consolidated financial data are derived from the audited financial statements of Repligen. The selected financial data set forth below should be read in conjunction with our financial statements and the related notes thereto and Management s Discussion and Analysis of Financial Condition and Results of Operations included elsewhere in this Annual Report, and in our Annual Reports on Form 10-K for the years ended December 31, 2018, 2017, 2016, 2015 and 2014.

	For the Years Ended December 31,				
	2018 [1]	2017[2]	2016	2015[3]	2014
	(Amounts in thousands, except per share data)				
Revenue:					
Product revenue	$ 193,891	$ 141,089	$ 104,441	$ 83,537	$ 60,431
Royalty and other revenue	141	147	100		3,117
Total revenue	194,032	141,236	104,541	83,537	63,548
Operating costs and expenses:					
Cost of product revenue	86,531	67,050	47,117	35,251	28,022
Research and development	15,821	8,672	7,355	5,740	5,609
Selling, general and administrative	65,692	51,509	30,853	24,699	17,154
Contingent consideration fair value adjustments			3,242	4,083	2,072
Total operating costs and expenses	168,044	127,231	88,567	69,773	52,857
Income from operations	25,988	14,005	15,974	13,764	10,691
Other expenses, net	(4,552)	(6,757)	(4,282)	(341)	447
Income before income taxes	21,436	7,248	11,692	13,423	11,138
Income tax provision (benefit)	4,819	(21,105)	11	4,078	2,968
Net income	$ 16,617	$ 28,353	$ 11,681	$ 9,345	$ 8,170
Earnings per share:					
Basic	$ 0.38	$ 0.74	$ 0.35	$ 0.28	$ 0.25
Diluted	$ 0.37	$ 0.72	$ 0.34	$ 0.28	$ 0.25
Weighted average shares outstanding:					
Basic	43,767	38,234	33,573	32,882	32,498
Diluted	45,471	39,150	34,099	33,577	33,264

	As of December 31,				
	2018	2017	2016	2015	2014
	(Amounts in thousands)				

Cash and marketable securities[4]	$ 193,822	$ 173,759	$ 141,780	$ 73,407	$ 62,003
Working capital	145,897	217,571	163,078	84,471	70,264
Total assets	774,621	743,519	288,913	146,237	128,293
Long-term obligations	29,211	126,760	99,074	4,708	5,879
Accumulated deficit	(15,568)	(31,508)	(59,861)	(71,542)	(80,887)
Total stockholders equity	615,568	591,548	168,764	122,748	111,732

(1) Includes the full year impact of the acquisition of Spectrum Lifesciences, LLC on August 1, 2017
(2) Includes the full year impact of the acquisition of Atoll GmbH on April 1, 2016 and the acquisition of TangenX Corporation on December 14, 2016.
(3) Includes the full year impact of the acquisition of Refine Technology on June 2, 2014.
(4) Excludes restricted cash of $0.5 million as of December 31, 2016, 2015 and 2014 and $0.2 million as of December 31, 2013 related to the lease arrangement on our headquarters.

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ITEM 7. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Repligen and its subsidiaries, collectively doing business as Repligen Corporation (Repligen , we , our , or the Company) is a leading provider of advanced bioprocessing technology 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, 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 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 (more permanent) glass columns used in downstream purification processes. By designing OPUS as an 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 pre-packed 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 (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 in 2016 launched 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. Spectrum 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 monoclonal antibody (mAb) based drugs on the market or in development that our customers sell to end users (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.

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Critical Accounting Policies and Estimates

While our significant accounting policies are more fully described in the notes to our consolidated financial statements, we have identified the policies and estimates below as being critical to our business operations and the understanding of our results of operations. The impact of and any associated risks related to these policies on our business operations are discussed throughout Management s Discussion and Analysis of Financial Condition, including in the Results of Operations section, where such policies affect our reported and expected financial results.

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. Revenue is measured as the amount of consideration the Company expects to receive in exchange for transferring products or services to a customer (transaction price). To the extent the transaction price includes variable consideration, the Company estimates the amount of variable consideration that should be included in the transaction price utilizing the expected value method or the most likely amount method, depending on the facts and circumstances relative to the contract. Variable consideration is included in the transaction price if, in the Company s judgment, it is probable that a significant future reversal of cumulative revenue under the contract will not occur. Estimates of variable consideration and determination of whether to include estimated amounts in the transaction price are based largely on an assessment of the Company s anticipated performance and all information (historical, current and forecasted) that is reasonably available. Sales, value add, and other taxes collected on behalf of third parties are excluded from revenue.

When determining the transaction price of a contract, an adjustment is made if payment from a customer occurs either significantly before or significantly after performance, resulting in a significant financing component. Applying the practical expedient in paragraph 606-10-32-18, the Company does not assess whether a significant financing component exists if the period between when the Company performs its obligations under the contract and when the customer pays is one year or less. None of the Company s contracts contained a significant financing component as of December 31, 2018.

Contracts with customers may contain multiple performance obligations. For such arrangements, the transaction price is allocated to each performance obligation based on the estimated relative standalone selling prices of the promised products or services underlying each performance obligation. The Company determines standalone selling prices based on the price at which the performance obligation is sold separately. If the standalone selling price is not observable through past transactions, the Company estimates the standalone selling price taking into account available information such as market conditions and internally approved pricing guidelines related to the performance obligations.

The Company recognizes product revenue under the terms of each customer agreement upon transfer of control to the customer, which occurs at a point in time.

Inventories

We value inventory at cost or, if lower, net realizable value, using the first-in, first-out method. We review our inventory at least quarterly and record a provision for excess and obsolete inventory based on our estimates of expected sales volume, production capacity and expiration dates of raw materials, work-in-process and finished products. Expected sales volumes are determined based on supply forecasts provided by key customers for the next

three to 12 months. We write down inventory that has become obsolete, inventory that has a cost basis in excess of its expected net realizable value, and inventory in excess of expected requirements to cost of product revenue. Manufacturing of bioprocessing finished goods is done to order and tested for quality specifications prior to shipment.

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A change in the estimated timing or amount of demand for our products could result in additional provisions for excess inventory quantities on hand. Any significant unanticipated changes in demand or unexpected quality failures could have a significant impact on the value of inventory and reported operating results. During all periods presented in the accompanying consolidated financial statements, there have been no material adjustments related to a revised estimate of inventory valuations.

Business combinations

Amounts paid for acquisitions are allocated to the assets acquired and liabilities assumed, if any, based on their fair values at the dates of acquisition. The fair value of identifiable intangible assets is based on detailed valuations that use information and assumptions determined by management. Any excess of purchase price over the fair value of the net tangible and intangible assets acquired is allocated to goodwill. The fair value of contingent consideration includes estimates and judgments made by management regarding the probability that future contingent payments will be made, the extent of royalties to be earned in excess of the defined minimum royalties, etc. Management updates these estimates and the related fair value of contingent consideration at each reporting period based on the estimated probability of achieving the earnout targets and applying a discount rate that captures the risk associated with the expected contingent payments. To the extent our estimates change in the future regarding the likelihood of achieving these targets we may need to record material adjustments to our accrued contingent consideration. Changes in the fair value of contingent consideration are recorded in our consolidated statement of operations and comprehensive income.

We use the income approach to determine the fair value of certain identifiable intangible assets including customer relationships and developed technology. This approach determines fair value by estimating after-tax cash flows attributable to these assets over their respective useful lives and then discounting these after-tax cash flows back to a present value. We base our assumptions on estimates of future cash flows, expected growth rates, expected trends in technology, etc. We base the discount rates used to arrive at a present value as of the date of acquisition on the time value of money and certain industry-specific risk factors. We believe the estimated purchased customer relationships, developed technologies, trademark / tradename, patents, and in process research and development amounts so determined represent the fair value at the date of acquisition and do not exceed the amount a third party would pay for the assets.

Intangible assets and goodwill

Intangible assets

We amortize our intangible assets that have finite lives using the straight-line method. Amortization is recorded over the estimated useful lives ranging from 2 to 20 years. We review our intangible assets subject to amortization to determine if any adverse conditions exist or a change in circumstances has occurred that would indicate impairment or a change in the remaining useful life. Further, we also review our indefinite-lived intangible assets not subject to amortization to determine if any adverse conditions exist or a change in circumstances occurred that would indicate an impairment. If the carrying value of an asset exceeds its estimated undiscounted cash flows, we will write-down the carrying value of the intangible asset to its fair value in the period identified. In assessing fair value, we must make assumptions regarding estimated future cash flows and discount rates. If these estimates or related assumptions change in the future, we may be required to record impairment charges. We generally calculate fair value as the present value of estimated future cash flows to be generated by the asset using a risk-adjusted discount rate. If the estimate of an intangible asset s remaining useful life is changed, we will amortize the remaining carrying value of the intangible asset prospectively over the revised remaining useful life.

Goodwill

We test goodwill for impairment on an annual basis and between annual tests if events and circumstances indicate it is more likely than not that the fair value of a reporting unit is less than its carrying value. Events that

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would indicate impairment and trigger an interim impairment assessment include, but are not limited, to current economic and market conditions, including a decline in market capitalization, a significant adverse change in legal factors, business climate or operational performance of the business, and an adverse action or assessment by a regulator. Our annual impairment test date is the last day of our fiscal year, December 31st. While we currently operate as one operating segment, we perform our annual impairment test over each of the Company s two reporting units and concluded that goodwill was not impaired.

Accrued liabilities

We estimate accrued liabilities by identifying services performed on our behalf, estimating the level of service performed and determining the associated cost incurred for such service as of each balance sheet date. For example, we would accrue for professional and consulting fees incurred with law firms, audit and accounting service providers and other third-party consultants. These expenses are determined by either requesting those service providers to estimate unbilled services at each reporting date for services incurred or tracking costs incurred by service providers under fixed fee arrangements.

We have processes in place to estimate the appropriate amounts to record for accrued liabilities, which principally involve the applicable personnel reviewing the services provided. In the event that we do not identify certain costs that have begun to be incurred or we under or over-estimate the level of services performed or the costs of such services, the reported expenses for that period may be too low or too high. The date on which certain services commence, the level of services performed on or before a given date, and the cost of such services often require the exercise of judgment. We make these judgments based upon the facts and circumstances known at the date of the financial statements.

A change in the estimated cost or volume of services provided could result in additional accrued liabilities. Any significant unanticipated changes in such estimates could have a significant impact on our accrued liabilities and reported operating results. There have been no material adjustments to our accrued liabilities in any of the periods presented in the accompanying consolidated financial statements.

Stock-based compensation

We use the Black-Scholes option pricing model to calculate the fair value of share-based awards on the grant date.

The expected term of options granted represents the period of time for which the options are expected to be outstanding and is derived from our historical stock option exercise experience and option expiration data. For purposes of estimating the expected term, we have aggregated all individual option awards into one group, as we do not expect substantial differences in exercise behavior among our employees. The expected volatility is a measure of the amount by which our stock price is expected to fluctuate during the expected term of options granted. We determined the expected volatility based upon the historical volatility of our common stock over a period commensurate with the option s expected term. The risk-free interest rate is the implied yield available on U.S. Treasury zero-coupon issues with a remaining term equal to the option s expected term on the grant date. We have never declared or paid any cash dividends on any of our capital stock and do not expect to do so in the foreseeable future. Accordingly, we use an expected dividend yield of zero to calculate the grant-date fair value of a stock option.

We recognize compensation expense on awards that vest based on service conditions on a straight-line basis over the requisite service period based upon the number of options that are ultimately expected to vest, and accordingly, such compensation expense has been adjusted by an amount of estimated forfeitures. We recognize compensation expense on awards that vest based on performance conditions based on our assessment of the probability that the performance

condition will be achieved over the service period. Forfeitures represent only the unvested portion of a surrendered option. Forfeitures are estimated at the time of grant and revised, if necessary,

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in subsequent periods if actual forfeitures differ from those estimates. Based on an analysis of historical data, we have calculated an 8% annual forfeiture rate for non-executive level employees, a 3% annual forfeiture rate for executive level employees, and a 0% forfeiture rate for non-employee members of the Board of Directors, which we believe are reasonable assumptions to estimate forfeitures. However, the estimation of forfeitures requires significant judgment and, to the extent actual results or updated estimates differ from our current estimates, such amounts will be recorded as a cumulative adjustment in the period estimates are revised.

For the years ended December 31, 2018, 2017 and 2016, we recorded stock-based compensation expense of $10.2 million, $6.7 million and $4.6 million, respectively, for share-based awards granted under all of the Company s stock plans.

As of December 31, 2018, there was $27.1 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 4.53 years. We expect 1,195,236 unvested options and RSUs to vest over the next five years.

Income taxes

Deferred taxes are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect in the years in which the differences are expected to reverse. Valuation allowances are provided, if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. We account for uncertain tax positions using a more-likely-than-not threshold for recognizing and resolving uncertain tax positions. The evaluation of uncertain tax positions is based on factors including, but not limited to, changes in tax law, the measurement of tax positions taken or expected to be taken in tax returns, the effective settlement of matters subject to audit, new audit activity and changes in facts or circumstances related to a tax position. We evaluate our tax position on a quarterly basis. We also accrue for potential interest and penalties related to unrecognized tax benefits in income tax expense.

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 years 2018, 2017, and 2016 were comprised of the following:

	For the Years Ended December 31,			2018 vs. 2017		2017 vs. 2016	
	2018	2017	2016	$ Change	% Change	$ Change	% Change
	(Amounts in thousands, except for percentage data)						
Revenue:							
Product	$ 193,891	$ 141,089	$ 104,441	$ 52,802	37.4%	$ 36,648	35.1%
Royalty and other	141	147	100	(6)	(4.1%)	47	47.0%
Total revenue	$ 194,032	$ 141,236	$ 104,541	$ 52,796	37.4%	$ 36,695	35.1%

Product revenues

Since 2016, we have been increasingly focused on selling our products directly to customers in the pharmaceutical industry and to our its contract manufacturers. These direct sales have increased to approximately 72% of our product revenue during 2018. 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.

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Product revenues were comprised of the following:

	For the Years Ended December 31,		
	2018	2017[1]	2016[2,3]
	(Amounts in thousands)		
Chromatography products	$ 45,326	$ 36,309	$ 29,520
Filtration products	90,586	49,050	19,774
Protein products	54,375	53,969	54,716
Other	3,604	1,761	431
Total product revenue	$ 193,891	$ 141,089	$ 104,441

(1) 2017 revenue for filtration, chromatography and other products includes revenue related to Spectrum from August 1, 2017 through December 31, 2017.
(2) 2016 revenue for filtration products includes revenue related to TangenX from December 14, 2016 through December 31, 2016.
(3) 2016 revenue for chromatography products includes revenue related to Atoll from April 1, 2016 through December 31, 2016.

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, KrosFlo filtration products 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 our operating room products to hospitals as well as freight revenue.

For 2018, product revenue increased by $52.8 million, or 37%, as compared to 2017. The increase is due to the continued adoption of our products by our key bioprocessing customers and a full year of revenues derived from our acquisition of Spectrum in August 2017. 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.

For 2017, product revenues increased by $36.6 million, or 35%, as compared to 2016. The increase in product revenues is due largely to increased volumes in our Filtration and Chromatography products, full year of revenue generated from Atoll and TangenX in 2017, and revenues of $19.4 million generated from the acquisition of Spectrum in 2017. We sell our various bioprocessing products at different price points. The mix of products sold varies and impacts the fluctuations in total product revenue and cost of product revenues from period to period.

Royalty revenues

Royalty revenues in 2018 and 2017 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.

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Costs and operating expenses

Total costs and operating expenses for years 2018, 2017 and 2016 were comprised of the following:

	For the Years Ended December 31,			2018 vs. 2017		2017 vs. 2016	
	2018	2017	2016	$ Change	% Change	$ Change	% Change
	(Amounts in thousands, except for percentage data)						
Cost of product revenue	$ 86,531	$ 67,050	$ 47,117	$ 19,481	29.1%	$ 19,933	42.3%
Research and development	15,821	8,672	7,355	7,149	82.4%	1,317	17.9%
Selling, general and administrative	65,692	51,509	30,853	14,183	27.5%	20,656	66.9%
Contingent consideration fair value adjustments			3,242		N/A	(3,242)	(100.0%)
Total costs and operating expenses	$ 168,044	$ 127,231	$ 88,567	$ 40,813	32.1%	$ 38,664	43.7%

Cost of product revenue

For 2018, cost of product revenue increased $19.5 million, or 29%, as compared to 2017 due primarily to the increase in product revenue mentioned above. Gross margins may fluctuate in future quarters based on expected production volume and product mix. For 2017, cost of product revenue increased $19.9 million, or 42% as compared to 2016. This increase is primarily due to the increase in product revenues noted above, the sale of higher cost Spectrum finished goods inventory due to step up to fair value upon acquisition, and costs related to continuing investments in our operations to support future growth.

Gross margins were 55%, 53%, and 55% for 2018, 2017 and 2016, respectively. During 2018, gross margins increased compared to 2017 primarily due to higher product revenue. During 2017, gross margins declined slightly compared to 2016 due to product mix, the sale of higher cost Spectrum finished good inventory due to step up to fair value upon acquisition and continuing investments in operations to support future growth.

Research and development expenses

During 2018, 2017 and 2016, research and development expenses were related to bioprocessing products which included 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.

For 2018, research and development expenses increased by $7.1 million, or 82%, as compared to 2017. This increase is primarily driven by investments made during 2018 to expand our proteins product offerings through our development agreement with Navigo Proteins GmbH (Navigo). Additionally, the increase is related to product development activities acquired as part of the Spectrum acquisition and increased activity in our various bioprocessing development projects.

For 2017, research and development expenses increased by $1.3 million, or 18% as compared to 2016. This increase is related to the increased expenditures related to the continued development of our single-use XCell ATF products and other new products in development, as well as expenses incurred by Spectrum since acquisition.

We expect our research and development expenses in the year ending December 31, 2019 to increase in order to support new product development.

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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.

For 2018, SG&A costs increased by $14.2 million, or 28%, as compared to 2017. The increase is due to selling and administrative activities incurred following the Spectrum acquisition, as well as the continued buildout of our administrative infrastructure to support expected future growth and continued expansion of our customer-facing activities to drive sales of our bioprocessing products.

For 2017, SG&A costs increased by $20.7 million, or 67%, as compared to 2016. This increase is primarily due to costs related to our acquisition of Spectrum, the continuing buildout of our administrative infrastructure to support future growth, the continuing expansion of our customer-facing activities to drive sales of our bioprocessing products, a full year of costs related to Atoll and TangenX and costs incurred by Spectrum since acquisition.

Contingent consideration

In 2016, we recorded contingent consideration expense related primarily to our acquisitions of Refine and Atoll. Contingent consideration related to the Refine Acquisition in 2016 is based on actual 2016 XCell ATF sales and any receipts related to the resolution, withdrawal or settlement of certain patent disputes with a third party to be paid to the former shareholders of Refine. Contingent consideration related to Atoll is based on actual 2016 sales growth compared to 2015 sales. The decrease is attributable to recording Refine contingent consideration fair value adjustments related to projected 2015 and 2016 XCell ATF sales in the previous year, while in 2016 we only recorded fair value adjustments related to 2016 sales. This decrease is partially offset by contingent consideration expense related to our acquisition of Atoll. Because the contingent consideration periods related to our acquisitions of BioFlash, Refine and Atoll all concluded in 2016, we did not incur any contingent consideration expense in 2017.

Other expenses, net

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

	For the Years Ended December 31,			2018 vs. 2017		2017 vs. 2016	
	2018	2017	2016	$ Change	% Change	$ Change	% Change
	(Amounts in thousands, except for percentage data)						
Investment income	$ 1,895	$ 371	$ 346	$ 1,524	410.8%	$ 25	7.2%
Interest expense	(6,709)	(6,441)	(3,768)	(268)	4.2%	(2,673)	70.9%
Other expenses	262	(687)	(860)	949	(138.1%)	173	(20.1%)
Total other expense, net	$ (4,552)	$ (6,757)	$ (4,282)	$ 2,205	(32.6%)	$ (2,475)	57.8%

Investment income

Investment income includes income earned on invested cash balances. The increase of $1.5 million for 2018, as compared to 2017 was attributable to higher average invested cash balances and higher interest rates on such invested cash balances. The increase of approximately $25,000, or 7%, for 2017 was primarily due to higher interest rates

during 2017 compared to 2016. 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 $0.3 million in 2018, as compared to 2017 due to the

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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. The increase of $2.7 million in 2017, as compared to 2016 was due to incurring a full year of interest expense on the Notes in 2017.

Other expenses

Changes in other expense in 2018, compared to the corresponding periods in the prior year are 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.

Provision (benefit) for income taxes

Income tax provision (benefit) for the years ended December 31, 2018, 2017 and 2016 was as follows:

	For the Years Ended December 31,			2018 vs. 2017		2017 vs. 2016	
	2018	2017	2016	$ Change	% Change	$ Change	% Change
	(Amounts in thousands, except for percentage data)						
Income tax provision (benefit)	$ 4,819	$ (21,105)	$ 11	$ 25,924	>(100%)	$ (21,116)	>(100%)
Effective tax rate	22.5%	(291.2%)	0.1%				

For the year ended December 31, 2018, we recorded an income tax provision of $4.8 million. The effective tax rate was 22.5% in 2018 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 Tax Cuts and Jobs Act (the 2017 Tax Act) enacted in December 2017.

For the year ended December 31, 2017, we recorded an income tax benefit of ($21.1) million. This income tax benefit was composed of current income tax provision of $3.6 million, offset by ($24.7) million deferred tax benefit. The 2017 tax provision of $3.6 million primarily relates to a foreign tax provision of $3.3 million. Our deferred tax benefit of ($24.7) million is primarily due to a reduction of the valuation allowance on our deferred tax assets in the amount of $12.2 million from the sale of certain intellectual property to Repligen Sweden AB during 2017 and taxable temporary differences generated from the Spectrum acquisition. Additionally, the Company recorded a deferred tax benefit of $12.8 million resulting from a reduction of the U.S. federal income tax on the Company s net U.S. deferred tax liabilities stemming from new U.S. federal tax legislation passed in December 2017.

Non-GAAP Financial Measures

We provide non-GAAP adjusted income from operations, non-GAAP adjusted net income and adjusted EBITDA as supplemental measures to GAAP measures regarding our operating performance. These financial measures exclude the impact of certain acquisition related items and, therefore, have not been calculated in accordance with GAAP. A detailed explanation and a reconciliation of each non-GAAP financial measures to its most comparable GAAP financial measures are described 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, inventory step-up charges, intangible

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amortization and contingent consideration expenses 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 years ended December 31, 2018 and 2017:

	For the Years Ended December 31,	
	2018	2017
	(Amounts in thousands)	
GAAP income from operations	$ 25,988	$ 14,005
Non-GAAP adjustments to income from operations:		
Acquisition and integration costs	2,928	7,519
Inventory step-up charges		3,816
Intangible amortization	10,518	6,215
Non-GAAP adjusted income from operations	$ 39,434	$ 31,555

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, inventory step-up charges, contingent consideration expenses, intangible amortization and related tax effects, non-cash interest expense, the partial release of the valuation allowance on our deferred tax assets and the net impact of tax reform legislation booked through our consolidated statements of comprehensive income. The following is a reconciliation of net income in accordance with GAAP to non-GAAP adjusted net income for the years ended December 31, 2018 and 2017:

	For the Years Ended December 31,			
	2018		2017	
	Amount	Fully Diluted Earnings per Share	Amount	Fully Diluted Earnings per Share
	(Amounts in thousands, except per share data)			
GAAP net income	$ 16,617	$ 0.37	$ 28,353	$ 0.72
Non-GAAP adjustments to net income:				
Acquisition and integration costs	2,928	0.06	7,519	0.19
Inventory step-up charges			3,816	0.10
Intangible amortization	10,518	0.23	6,215	0.16
Non-cash interest expense	4,248	0.09	3,977	0.10
Tax effect of intangible amortization and acquisition costs	(979)	(0.02)	(882)	(0.02)
Release of valuation allowance on deferred tax assets			(12,236)	(0.31)
Net impact of tax reform legislation			(9,586)	(0.24)
Non-GAAP adjusted net income	$ 33,332	$ 0.73	$ 27,176	$ 0.69

Note that earnings per share amounts may not add due to rounding.

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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 years ended December 31, 2018 and 2017:

	For the Years Ended December 31,	
	2018	2017
	(Amounts in thousands)	
GAAP net income	$ 16,617	$ 28,353
Non-GAAP EBITDA adjustments to net income:		
Investment income	(1,895)	(371)
Interest expense	6,709	6,441
Tax provision	4,819	(21,105)
Depreciation	5,213	4,237
Amortization	10,565	6,215
EBITDA	42,028	23,770
Other non-GAAP adjustments:		
Acquisition and integration costs	2,928	7,519
Inventory step-up charges		3,816
Adjusted EBITDA	$ 44,956	$ 35,105

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 December 31, 2018, we had cash and cash equivalents of $193.8 million compared to cash, cash equivalents and marketable securities of $173.8 million at December 31, 2017. A deposit for our leased office in Waltham, Massachusetts of $0.5 million was classified as restricted cash and was not included in cash and marketable securities totals for December 31, 2016. There were no restrictions on cash for December 31, 2018 and 2017.

In July 2017, we completed a public offering in which 2,807,017 shares of our common stock were sold to the public at a price of $42.75 per share. The underwriters were granted an option, which they exercised in full, to purchase an additional 421,052 shares of our common stock. The total proceeds from this offering, net of underwriting discounts, commissions and other offering expenses, totaled $129.3 million.

On August 1, 2017, we completed our acquisition of Spectrum for $112.8 million in cash (net of cash received) and 6,153,995 unregistered shares of the Company s common stock.

During the fourth quarter of 2018, 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 first quarter of 2019. The Notes have a face value of $115.0 million and a carrying value of $103.5 million and are classified as current liabilities on the Company s consolidated balance sheet as of December 31, 2018. 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.

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Cash flows

	For the Years Ended December 31,			FY18 vs FY17	FY17 vs FY16
	2018	2017	2016	$ Change	$ Change
	(Amounts in thousands)				
Operating activities	$ 32,770	$ 17,451	$ 7,521	$ 15,319	$ 9,930
Investing activities	(14,037)	(98,696)	(49,194)	84,659	(49,502)
Financing activities	3,407	129,945	112,113	(126,538)	17,832
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(2,077)	2,376	(2,299)	(4,453)	4,675
Net increase in cash, cash equivalents and restricted cash	$ 20,063	$ 51,076	$ 68,141	$ (31,013)	$ (17,065)

Operating activities

For 2018, our operating activities provided cash of $32.8 million reflecting net income of $16.6 million and non-cash charges totaling $30.3 million primarily related to depreciation, amortization, non-cash interest expense, deferred tax expense and stock-based compensation charges. An increase in receivables consumed $8.7 million of cash and was primarily driven by the 37% year-to-date increase in revenues. An increase in inventory levels to accommodate future revenue growth consumed $4.0 million of cash, payment of accrued liabilities consumed $1.4 million of cash and an increase in other assets used $1.8 million. This utilization of cash is partially offset by $2.3 million of cash provided by an increase in accounts payable due to the timing of payments to vendors. The remaining cash flow used in operations resulted from net unfavorable changes in various other working capital accounts.

For 2017, our operating activities provided cash of $17.5 million, reflecting net income of $28.4 million offset by net non-cash charges totaling $3.4 million comprised mainly of depreciation, amortization, stock-based compensation charges and deferred tax benefits. Increases in accounts receivable consumed $6.9 million of cash, which is based on timing of revenues billed to and payments from customers. Decreases in accounts payable and accrued liabilities consumed $1.2 million of cash due to timing of payments to vendors.

For 2016, our operating activities provided cash of $7.5 million reflecting net income of $11.7 million and non-cash charges totaling $11.3 million comprised mainly of depreciation, amortization, stock-based compensation charges, deferred tax benefits and the revaluation of contingent consideration. Increases in accounts receivable and inventories consumed $9.4 million of cash. Decreases in accounts payable and accrued liabilities consumed $5.8 million of cash.

Investing activities

Our investing activities consumed $14.0 million of cash, including $12.8 million for capital expenditures. Of those expenditures, $2.1 million represented capitalized costs related to our internal-use software. In addition, a capitalized payment for developed technology of $1.3 million was paid to Navigo in 2018 to assist in expanding our proteins product offerings through a development agreement.

For 2017, our investing activities consumed $98.7 million of cash. We used $112.8 million in cash (net of cash received) for our acquisition of Spectrum. Fixed asset additions consumed $5.5 million, as we continued to increase

our manufacturing capacity. Net redemptions of marketable securities provided $19.6 million of cash in 2017.

For 2016, our investing activities consumed $49.2 million of cash. We used $8.8 million in cash (net of cash received) for our acquisition of Atoll and $35.8 million (net of cash received) for our acquisition of TangenX. Fixed asset additions consumed $4.3 million, as we increased the manufacturing capacity of our facilities in the United States and Sweden. Net purchases of marketable securities consumed $0.3 million of cash in 2016.

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Financing activities

In 2018, our financing activities provided $3.4 million of cash. We received proceeds of $3.4 million from stock option exercises, partially offset by cash outlays of $11,000 related to the partial conversion of the Notes in the first quarter of 2018.

In July 2017, we received net proceeds of $129.3 million from the issuance of common stock. In May 2016, we received net proceeds of $111.1 million from the issuance of our senior convertible notes. Exercises of stock options provided cash receipts of $2.4 million and $1.8 million in 2017 and 2016, respectively. Cash payments to Atoll and Refine in 2017 totaled $5.1 million, of which $1.7 million related to the fair value of these liabilities as of the respective acquisition dates and is included as part of financing activities. Cash payments to Refine and BioFlash in 2016 totaled $4.1 million, of which $0.8 million related to the fair value of these liabilities as of the respective acquisition dates and is included as part of financing activities. The remaining amounts are included as an offset to our cash provided by operating activities.

Off-balance Sheet Arrangements

We do not have any special purpose entities or off-balance sheet financing arrangements.

Contractual Obligations

As of December 31, 2018, we had the following fixed obligations and commitments:

	Total	Less than one year	One to three years	Three to five years	Over five years
			(Amounts in thousands)		
Convertible senior notes	$ 114,989	$ 114,989	$	$	$
Operating lease obligations	18,034	4,021	6,862	3,529	3,622
Purchase obligations[(1)]	29,043	29,043			
Total	$ 162,066	$ 148,053	$ 6,862	$ 3,529	$ 3,622

(1) Primarily represents purchase orders for the procurement of raw material for manufacturing.

The table excludes a liability for uncertain tax positions totaling $2.9 million since we cannot currently make a reliable estimate of the period in which the liability will be payable, if ever. Please see Note 7, *Income Taxes,* to our consolidated financial statements for more information.

Capital Requirements

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;

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. We expect operating expenses

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in the year ending December 31, 2019 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.

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.

Foreign Earnings

As of December 31, 2018, the Company has accumulated undistributed earnings generated by our foreign subsidiaries of approximately $72.4 million. Because $58.0 million of such earnings have previously been subject to the one-time transition tax on foreign earnings required by the 2017 Tax Act, any additional taxes due with respect to such earnings or the excess of the amount for financial reporting over the tax basis of our foreign investments would generally be limited to foreign and state taxes. At December 31, 2018, we have not provided for taxes on outside basis differences of our foreign subsidiaries, as we have the ability and intent to indefinitely reinvest the undistributed earnings of our foreign subsidiaries, and there are no needs for such earnings in the United States that would contradict our plan to indefinitely reinvest.

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.

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ITEM 7A. 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 December 31, 2018. As a result, a hypothetical 100 basis point increase in interest rates would have no effect on our cash position as of December 31, 2018.

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.

Although a majority of our contracts are denominated in U.S. dollars, 28% and 23% of total revenues during 2018 and 2017, respectively, were denominated in foreign currencies while 15% and 24% of our costs and expenses during 2018 and 2017, respectively, were denominated in foreign currencies, primarily operating expenses associated with cost of revenue, sales and marketing and general and administrative. In addition, 24% and 18% of our consolidated tangible assets were subject to foreign currency exchange fluctuations as of each of December 31, 2018 and 2017, respectively, while 6% and 8% of our consolidated liabilities were exposed to foreign currency exchange fluctuations as of each of December 31, 2018 and 2017, respectively.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Financial statements and supplementary data required by Item 8 are set forth at the pages indicated in Item 15(a) below and are incorporated herein by reference.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

None.

ITEM 9A. CONTROLS AND PROCEDURES

(a) Disclosure Controls and Procedures.

The Company s management, with the participation of our principal executive officer and 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 and as required by paragraph (b) of Rules 13a-15 or 15d-15 under the Exchange Act) as of the end of the period covered by this report. Based on such evaluation, our 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 at the reasonable assurance level.

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(b) Report of Management on Internal Control Over Financial Reporting.

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act as a process designed by, or under the supervision of, the Company s principal executive and principal financial officers and effected by the Company s Board of Directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles and includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company;

- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and

- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company s assets that could have a material effect on the financial statements.

Management assessed the effectiveness of the Company s internal control over financial reporting as of December 31, 2018. In making this assessment, management used the criteria established in *Internal Control Integrated Framework*, issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (COSO).

Subject to the foregoing, based on this assessment, our management concluded that, as of December 31, 2018, our internal control over financial reporting is effective based on those criteria. Ernst & Young LLP, the independent registered public accounting firm that audited our financial statements included in this Annual Report on Form 10-K, has issued an attestation report on our internal control over financial reporting as of December 31, 2018.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

(c) Attestation Report of the Independent Registered Public Accounting Firm.

Our independent registered public accounting firm that audited the financial statements included in this annual report has issued an attestation report on our internal controls over financial reporting. This report appears below.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of Repligen Corporation:

Opinion on Internal Control over Financial Reporting

We have audited Repligen Corporation s internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Repligen Corporation (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2018 and 2017, the related consolidated statements of operations and comprehensive income, stockholders equity and cash flows for each of the three years in the period ended December 31, 2018, and the related notes and our report dated March 1, 2019 expressed an unqualified opinion thereon.

Basis for Opinion

The Company s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Report of Management on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company s internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company s internal control over financial reporting is a process designed 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. A company s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

Boston, Massachusetts

March 1, 2019

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(d) Changes in Internal Control Over Financial Reporting

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 December 31, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

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PART III

Pursuant to General Instructions G to Form 10-K, the information required for Part III, Items 10, 11, 12, 13 and 14, is incorporated herein by reference from the Company s proxy statement for the 2018 Annual Meeting of Stockholders.

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PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

The following documents are filed as part of this Annual Report on Form 10-K:

(a) (1) *Financial Statements*:

The financial statements required by this item are submitted in a separate section beginning on page 53 of this Report, as follows:

(a) (2) *Financial Statement Schedules*:

None.

(a) (3) *Exhibits*:

The Exhibits which are filed as part of this Annual Report or which are incorporated by reference are set forth in the Exhibit Index hereto.

EXHIBIT INDEX

Exhibit Number	Document Description
2.1	Agreement and Plan of Merger and Reorganization, dated June 22, 2017, by and among Repligen Corporation, Top Hat, Inc., Swing Time, LLC, Spectrum, Inc., and Roy T. Eddleman (filed as Exhibit 2.1 to Repligen Corporation s Current Report on Form 8-K filed on June 23, 2017 and incorporated herein by reference).
3.1	Restated Certificate of Incorporation dated June 30, 1992, as amended September 17, 1999 and May 16, 2014 (filed as Exhibit 3.1 to Repligen Corporation s Quarterly Report on Form 10-Q for the quarter ended September 30, 1999 and incorporated herein by reference).
3.2	Second Amended and Restated Bylaws (filed as Exhibit 3.1 to Repligen Corporation s Current Report on Form 8-K filed on May 23, 2017 and incorporated herein by reference).

4.1	Specimen Stock Certificate (filed as Exhibit 4.1 to Repligen Corporation s Annual Report on Form 10-K for the year ended March 31, 2002 and incorporated herein by reference).
4.2	Base Indenture, dated as of May 24, 2016, by and between Repligen Corporation and Wilmington Trust, National Association (filed as Exhibit 4.1 to Repligen Corporation s Current Report on 8-K filed on May 24, 2016 and incorporated herein by reference).
4.3	First Supplemental Indenture, dated as of May 24, 2016, by and between Repligen Corporation and Wilmington Trust, National Association (filed as Exhibit 4.2 to Repligen Corporation s Current Report on 8-K filed on May 24, 2016 and incorporated herein by reference).

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Exhibit Number	Document Description
4.4	Form of 2.125% Convertible Senior Note due 2021 (included in Exhibit 4.3).
4.5	Second Supplemental Indenture, dated as of October 31, 2018, to Indenture for Senior Debt Securities, dated May 24, 2016, by and between Repligen Corporation and Wilmington Trust Association (filed as Exhibit 4.1 to Repligen Corporation s Quarterly Report on Form 10-Q for the quarter ended October 31, 2018 and incorporated herein by reference).
4.6	Stockholder Agreement, dated June 22, 2017, by and between Repligen Corporation and Roy T. Eddleman (filed as Exhibit 10.1 to Repligen Corporation s Current Report on Form 8-K filed on June 23, 2017 and incorporate herein by reference).
10.1*	Repligen Executive Incentive Compensation Plan (filed as Exhibit 10.1 to Repligen Corporation s Current Report on form 8-K filed on December 14, 2005 and incorporated herein by reference).
10.2*	Second Amended and Restated 2001 Repligen Corporation Stock Plan (filed as Exhibit 10.1 to Repligen Corporation s Current Report on Form 8-K filed on September 18, 2008 and incorporated herein by reference).
10.3.1*	Amended and Restated 2001 Repligen Corporation Stock Option Plan, Form of Incentive Stock Option Agreement (filed as Exhibit 10.14 to Repligen Corporation s Annual Report on Form 10-K for the year ended March 31, 2005 and incorporated herein by reference).
10.3.2*	Amended and Restated 2001 Repligen Corporation Stock Plan, Form of Restricted Stock Agreement (filed as Exhibit 10.1 to Repligen Corporation s Current Report on Form 8-K filed on January 9, 2006 and incorporated herein by reference).
10.4+	Lease Between Repligen Corporation as Tenant and West Seyon LLC as Landlord, 35 Seyon Street, Waltham, MA (as amended to date).
10.5#	Strategic Supplier Alliance Agreement dated January 28, 2010 by and between Repligen Corporation and GE Healthcare Bio-Sciences AB) (as amended to date) (filed as Exhibit 10.1 to Repligen Corporation s Quarterly Report on Form 10-Q for the quarter ended March 31, 2016 and incorporated herein by reference).
10.6#	Strategic Supplier Alliance Agreement Contract Manufacturing, by and between GE Healthcare Bio-Sciences AB and Repligen Sweden AB (as successor-in-interest to Novozymes Biopharma Sweden AB), dated as of July 7, 2011 (as amended to date) (filed as Exhibit 10.2 to Repligen Corporation s Quarterly Report on Form 10-Q for the quarter ended March 31, 2016 and incorporated herein by reference).
10.7	Lease Between Repligen Sweden AB (as successor-in-interest to Novozymes Biopharma Sweden AB) as Tenant and i-parken i Lund AB as Landlord, St. Lars Vag 47, 220 09 Lund, Sweden (filed as Exhibit 10.18 to Repligen Corporation s Transition Report on Form 10-K for the year ended December 31, 2011 and incorporated herein by reference).
10.8*	Repligen Corporation Amended and Restated 2012 Stock Option and Incentive Plan (filed as Exhibit 99.1 to Repligen Corporation s Form S-8 filed on June 2, 2014 and incorporated herein by reference).
10.9*	Repligen Corporation Non-Employee Directors Deferred Compensation Plan. (filed as Exhibit 10.16 to Repligen Corporation s Annual Report on Form 10-K for the year ended December 31, 2014 and incorporated by reference).

10.10*	Letter Agreement, dated as of June 10, 2014, by and between Repligen Corporation and Jon K. Snodgres (filed as Exhibit 10.1 to Repligen Corporation s Current Report on Form 8-K filed on July 15, 2014 and incorporated herein by reference).
10.11*	Employment Agreement, dated as of February 26, 2015, by and between Repligen Corporation and Tony J. Hunt (filed as Exhibit 10.1 to Repligen Corporation s Current Report on Form 8-K/A filed on March 2, 2015 and incorporated herein by reference).

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Exhibit Number	Document Description
10.12*	Repligen Corporation Amended and Restated Non-Employee Directors Compensation Policy (filed as Exhibit 10.3 to Repligen Corporation s Quarterly Report on Form 10-Q for the quarter ended March 31, 2018 and incorporated herein by reference).
10.13	Form of Indemnification Agreement (filed as Exhibit 10.1 to Repligen Corporation s Current Report on Form 8-K filed on May 12, 2016 and incorporated herein by reference).
10.14*	Transitional Services and Separation Agreement, dated as of November 20, 2017, by and between Repligen Corporation and Howard Benjamin (filed as Exhibit 10.1 to Repligen Corporation s Current Report on Form 8-K filed on November 22, 2017 and incorporated herein by reference).
10.15	Lease Agreement, dated February 6, 2018, by and between Repligen Corporation and U.S. REIF 111 Locke Drive Massachusetts, LLC (filed as Exhibit 10.1 to Repligen Corporation s Current Report on Form 8-K filed on February 8, 2018 and incorporated herein by reference).
10.16*	2018 Repligen Corporation Stock Option and Incentive Plan (filed as Exhibit 10.1 to Repligen Corporation s Quarterly Report on Form 10-Q for the quarter ended June 30, 2018 and incorporated herein by reference).
10.17*+	Letter Agreement, dated as of September 3, 2016 by and between Repligen Corporation and Ralf Kuriyel.
10.18#	Amendment No. 4 to Strategic Supplier Alliance Agreement, dated February 20, 2018, by and between Repligen Sweden AB and GE Healthcare Bio-Sciences AB (filed as Exhibit 10.2 to Repligen Corporation s Quarterly Report on Form 10-Q for the quarter ended March 31, 2018 and incorporated herein by reference).
21.1+	Subsidiaries of the Registrant.
23.1+	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm.
24.1+	Power of Attorney (included on signature page).
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-K for the year ended December 31, 2018, formatted in Extensive Business Reporting Language (XBRL): (i) Consolidated Statements of Operations and Comprehensive Income, (ii) Consolidated Balance Sheets, (iii) Consolidated Statement of Stockholders Equity, (iv) Consolidated Statements of Cash Flows, and (v) Notes to Consolidated Financial Statements, tagged as blocks of text.

Confidential treatment obtained as to certain portions.
* Management contract or compensatory plan or arrangement.
+ Filed herewith.
The exhibits listed above are not contained in the copy of the Annual Report on Form 10-K distributed to stockholders. Upon the request of any stockholder entitled to vote at the 2019 annual meeting, the Registrant will

furnish that person without charge a copy of any exhibits listed above. Requests should be addressed to Repligen Corporation, 41 Seyon Street, Waltham, MA 02453.

ITEM 16. 10-K SUMMARY

We may voluntarily include a summary of information required by Form 10-K under this Item 16. We have elected not to include such summary information.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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: March 1, 2019

By: /s/ TONY J. HUNT
Tony J. Hunt

President and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby makes, constitutes and appoints Tony J. Hunt and Jon K. Snodgres with full power to act without the other, his true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities to sign any or all amendments to this Form 10-K, and to file the same with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agents of any of them, or any substitute or substitutes, lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ TONY J. HUNT **Tony J. Hunt**	President, Chief Executive Officer and Director (Principal executive officer)	March 1, 2019
/s/ JON K. SNODGRES **Jon K. Snodgres**	Chief Financial Officer (Principal financial and accounting officer)	March 1, 2019
/s/ KAREN DAWES **Karen Dawes**	Chairperson of the Board	March 1, 2019
/s/ NICOLAS M. BARTHELEMY **Nicolas M. Barthelemy**	Director	March 1, 2019

/s/ GLENN L. COOPER	Director	March 1, 2019
Glenn L. Cooper, M.D.		
/s/ JOHN G. COX	Director	March 1, 2019
John G. Cox		
/s/ GLENN P. MUIR	Director	March 1, 2019
Glenn P. Muir		
/s/ THOMAS F. RYAN, JR.	Director	March 1, 2019
Thomas F. Ryan, Jr.		

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INDEX TO FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of Repligen Corporation:

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Repligen Corporation (the Company) as of December 31, 2018 and 2017, and the related consolidated statements of operations and comprehensive income, stockholders equity and cash flows for each of the three years in the period ended December 31, 2018, and the related notes (collectively referred to as the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company s internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control-Integrated Framework issued by the Committee of the Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated March 1, 2019 expressed an unqualified opinion thereon.

Basis for Opinion

These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on the Company s financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the US federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures include examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company s auditor since 2002

Boston, Massachusetts

March 1, 2019

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REPLIGEN CORPORATION

CONSOLIDATED BALANCE SHEETS

(Amounts in thousands, except share data)

	December 31, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 193,822	$ 173,759
Accounts receivables, less reserve for doubtful accounts of $227 and $58 at December 31, 2018 and December 31, 2017, respectively	33,015	27,585
Royalties and other receivables	136	153
Unbilled receivables	2,602	
Inventories, net	42,263	39,004
Prepaid expenses and other current assets &nb		