REPLIGEN CORP
Form 10-K
March 14, 2014
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2013

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 x.

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 x.

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 x No ¨.

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes x 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. x

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 and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ¨	Accelerated filer x	Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates as of June 28, 2013, the last business day of the registrant s most recently completed second fiscal quarter, was $262,149,000.

The number of shares of the registrant s common stock outstanding as of February 12, 2014 was 31,935,541.

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, 2013. Portions of such proxy statement are incorporated by reference into Part III of this Annual Report on Form 10-K.

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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.

Overview

Repligen Corporation (Repligen, the Company or we) is a life sciences company that develops, manufactures and markets high-value, consumable bioprocessing products for life sciences and biopharmaceutical companies worldwide. We are a world-leading manufacturer of both native and recombinant forms of Protein A, critical reagents used in biomanufacturing to purify monoclonal antibodies, a type of biologic drug. We also supply several growth factor products used to increase cell culture productivity during the bioproduction process. In the expanding area of flexible biomanufacturing technologies, we have developed and currently market a series of OPUS® (Open-Platform, User-Specified) chromatography columns for use in clinical-scale manufacturing. These pre-packed, plug-and-play columns are uniquely customizable to our customers media and size requirements. We generally manufacture and sell Protein A and growth factors to life sciences companies under long-term supply agreements and sell our chromatography columns, as well as media and quality test kits, directly to biopharmaceutical companies or contract manufacturing organizations. We refer to these activities as our bioprocessing business.

On December 20, 2011, we significantly increased the size of our bioprocessing business through a strategic acquisition. We acquired certain assets and assumed certain liabilities of Novozymes Biopharma Sweden, AB (Novozymes) in Lund, Sweden, including the manufacture and supply of cell culture ingredients for use in industrial cell culture, stem and therapeutic cell culture as well as Protein A affinity ligands for use in biopharmaceutical manufacturing (the Novozymes Biopharma Business and the acquisition of the Novozymes Biopharma Business, the Novozymes Acquisition) for a total purchase price of 20,310,000 Euros (~$26,400,000). As a result of the Novozymes Acquisition, we doubled the size of our bioprocessing business.

We have out-licensed certain intellectual property to Bristol-Myers Squibb Company, or Bristol, from which we received royalties on Bristol s net sales in the United States through 2013 of their product Orencia®. On April 7, 2008, we entered into a settlement agreement with Bristol in connection with a patent infringement lawsuit that we filed against Bristol. Under the terms of the settlement agreement, Bristol was obligated to pay us royalties on its U.S. net sales of Orencia® for any clinical indication at a rate of 1.8% for the first $500,000,000 of annual sales, 2.0% for the next $500,000,000 of annual sales and 4% of annual sales in excess of $1 billion. Under the terms of the agreement, we will not receive any future royalties on Bristol s sales of Orencia® made after December 31, 2013. We expect that the loss of these royalty payments will materially and adversely affect our revenue and operating results.

Historically, Repligen also conducted activities aimed at developing proprietary therapeutic drug candidates, often with a potential of entering into a collaboration with a larger commercial stage pharmaceutical or biotechnology company in respect of these programs. As part of our strategic decision in 2012 to focus our efforts on our core bioprocessing business, we reduced our efforts on our clinical development programs and increased our efforts to find collaboration partners to pursue the development and, if successful, the commercialization of these drug programs. The current status of our therapeutic drug development portfolio is:

On December 28, 2012, we out-licensed our spinal muscular atrophy program, or SMA program, led by RG3039, a small molecule drug candidate in clinical development for SMA, to Pfizer Inc., or Pfizer.

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Pursuant to the license agreement, Pfizer assumed the majority of the costs associated with completing the required clinical trials for this program as well as obtaining U.S. Food and Drug Administration (FDA) approval of the respective new drug application (NDA). Under the license agreement, we were obligated to conduct additional activities in support of this program, which included completing the second cohort of the initial Phase I trial for RG3039 and supporting the transition of the program to Pfizer. We completed this second cohort during the quarter ended March 31, 2013 and substantially all of our remaining clinical obligations during the quarter ended June 30, 2013. As of September 30, 2013, we had completed all of our obligations under the license agreement.

On January 21, 2014, we out-licensed our histone deacetylase inhibitor (HDACi) portfolio, which includes the Friedreich s ataxia program, to BioMarin Pharmaceuticals Inc., or BioMarin. Under the terms of the agreement, Repligen received an upfront payment of $2 million in January 2014 from BioMarin and we have the potential to receive up to $160 million in future milestone payments for the development, regulatory approval and commercial sale of portfolio compounds included in the agreement. In addition, Repligen is eligible to receive royalties on sales of qualified products developed.

Our clinical development portfolio also includes RG1068, a synthetic human hormone developed as a novel imaging agent for the improved detection of pancreatic duct abnormalities in combination with magnetic resonance imaging in patients with pancreatitis and potentially other pancreatic diseases. We submitted an NDA to the FDA and a marketing authorization application to the European Medicines Agency in the first quarter of 2012. In the second quarter of 2012, we received a complete response letter from the FDA, indicating the need for additional clinical efficacy and safety trial data. We have also received from the FDA the requirements for an additional registration study. We believe this information may be a factor in the decision by third-parties that may wish to pursue a development or commercialization agreement with us for RG1068. We expect that any additional development activities in the future will be supported by sponsors or other third parties.

Corporate Background

We were incorporated in May 1981, under the laws of the State of Delaware. Our principal executive offices are located at 41 Seyon Street, Waltham, Massachusetts 02453 and our telephone number is (781) 250-0111. We conduct manufacturing in Waltham and at our facility in Lund, Sweden.

Change in Fiscal Year

In 2011 we changed our fiscal year end from March 31 to December 31. This Annual Report on Form 10-K reports our financial results for the twelve-month period ending on December 31, 2013. This report also includes our financial results for the twelve-month period ending on December 31, 2012, and the nine-month periods ending on December 31, 2011 and December 31, 2010.

Currently Marketed Products

We currently sell various commercial bioprocessing products based on Protein A and growth factors, as well as a line of pre-packed chromatography columns and quality test kits, which are used in the production of monoclonal antibodies and other biopharmaceutical products.

Our Products for the Manufacturing of Biologic Drugs

Repligen is a leading developer and manufacturer of certain consumable bioprocessing products used in the production of monoclonal antibodies and other biologic drugs. The Company manufactures multiple forms of Protein A ligand, a critical component of Protein A media that is used in the downstream purification process for monoclonal antibodies, on behalf of several major life sciences companies. We also manufacture and sell growth

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factors, used to increase cell growth and productivity during upstream fermentation, and chromatography products. Our chromatography products include OPUS pre-packed columns for biologics purification, proprietary Protein A media and quality test kits. These products are sold to life sciences companies, contract manufacturing organizations and biopharmaceutical companies for use in the biologic drug production. Demand for our bioprocessing products has grown in concert with the expanding global market for biologics, particularly monoclonal antibodies, and also as a result of new product offerings through our acquisition of the Novozymes Biopharma business in December 2011.

In 2012, the global biologics market was valued at approximately $175 billion and is expected to grow at a rate in the high single digits annually. Market research indicates that the monoclonal antibody segment comprised over 40% of the overall biologics market in 2012 and is growing more rapidly than the overall market. Six of the ten worldwide best-selling drugs in 2012 were monoclonal antibodies, including blockbuster products such as Enbrel® and Remicade® for the treatment of rheumatoid arthritis and other inflammatory disorders, Rituxan® for non-Hodgkin s lymphoma and Herceptin® for the treatment of breast cancer. There are more than 35 approved monoclonal antibody products and over 350 product candidates currently in clinical development, most of which are manufactured using Protein A.

Repligen has been a leading manufacturer of Protein A for over fifteen years and manufactures multiple forms of Protein A for major life sciences companies including GE Healthcare and EMD Millipore under long-term supply agreements which extend to dates between 2016 and 2021. To be useful in the monoclonal antibody manufacturing process, Protein A is chemically bound to proprietary microscopic beads that are manufactured by life sciences companies, such as those mentioned above. These beads provide the rigid support required to use Protein A ligands. The combination of Protein A ligands bound to the beads is known as Protein A chromatographic media, which is packed by end-users into cylindrical columns and used to purify monoclonal antibodies. For example, after a fermentation process that produces monoclonal antibodies, the broth containing the monoclonal of interest, as well as numerous fermentation by-products and contaminants, is pumped through a column filled with Protein A chromatographic media. The Protein A media selectively binds to or captures the monoclonal antibody. Protein A has a high affinity for the monoclonal antibody and as a result, the antibody remains bound to the Protein A media while impurities flow through the column and are discarded. Once the impurities are removed, a change in pH conditions releases the purified antibody from the Protein A media. As a result, the monoclonal antibody product is highly purified and concentrated from a single purification step. Further purification steps are usually necessary to increase purity to a level greater than 98%. Over the past three years, the majority of our product sales have been sales of Protein A products.

Most biopharmaceuticals are produced through mammalian cell fermentation. In order to spur increased cell growth, manufacturers add growth factors and nutrients to the fermentor. As part of the Novozymes Acquisition, the Company acquired four cell culture growth factor products. Among those products is LONG®R3 IGF-I, a growth factor that is more biologically potent than insulin, and that has been shown to significantly increase recombinant protein production in fermentation applications. LONG®R3 IGF-I is currently used in the manufacture of several commercial biopharmaceutical products and is sold under a distribution agreement with Sigma-Aldrich Corporation (Sigma) which extends to 2021. Sigma has distribution rights for industrial cell culture applications while Repligen sells the product for use in stem cell and other cell-based therapies. In addition, we acquired long epidermal growth factor (LONG®EGF) and transforming growth factor alpha (LONG®TGF-a) supplements for serum-free or low serum culture in cell-based therapy applications, as well as recombinant transferrin (rTransferrin) which has been developed as an iron supplement for cell culture. There may be applications for these growth factors in stem cell and other cell-based therapies.

We also sell a number of products used in purification and quality control applications to contract manufacturers and biopharmaceutical companies. These products include: OPUS pre-packed, disposable chromatography columns, proprietary Protein A chromatography media and quality test kits. Our pre-packed chromatography columns are sold in a variety of sizes with the customer s choice of media. This product line s smaller sizes consist of proprietary technology that we acquired from BioFlash Partners, LLC (BioFlash) in

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January 2010 while the larger sizes encompass products and technology that we developed as a result of our internal research and development efforts. The OPUS brand stands for Open Platform, User Specified. OPUS columns have the potential to improve manufacturing efficiencies and lower costs by reducing labor and time spent on column packing, validation, set-up and cleaning. In addition, because OPUS columns are plug-and-play we believe they offer customers significantly greater manufacturing efficiency and flexibility when used with other flexible, disposable technologies. In early 2012, we introduced new, process-scale OPUS chromatography columns with diameters of 20cm and 30cm. These new products are well suited for the production of a broad range of clinical trial material and niche commercial products such as orphan biologics.

Our proprietary Protein A chromatography media is used by contract manufacturers and biopharmaceutical companies in a variety of applications, including in the purification of some currently marketed biotherapeutics. Customers use our Protein A and Growth Factor ELISA test kits to ensure that there are minimal levels of residual Protein A and growth factor, respectively, in the final bulk drug product.

Research and Development

Historically, our research activities have been focused on both the development of proprietary therapeutic drug candidates and the development of new and improved bioprocessing products. As part of our strategic decision in 2012 to focus the Company s efforts on our core bioprocessing business, we reduced our research efforts on our clinical development programs and increased our efforts to find collaboration partners to finish their development and, if successful, commercialize these therapeutic drug candidates. We intend to focus the majority of our future research and development efforts on developing new bioprocessing products. Specifically, we plan to focus these efforts on our growth factor and chromatography product offerings because we believe those markets may offer a higher rate of growth than the bulk Protein A market. As a result, we expect research and development expenses to decrease slightly in 2014 as compared to 2013.

HDAC Agreement with BioMarin

On January 21, 2014, we out-licensed our HDACi portfolio, which includes the Friedreich s ataxia program, to BioMarin Pharmaceuticals Inc. Friedreich s ataxia is an inherited disease that causes progressive damage to the nervous system resulting in symptoms ranging from impaired walking and speech problems to heart disease. Under the terms of the agreement, Repligen received an upfront payment of $2 million in January 2014 from BioMarin and we have the potential to receive up to $160 million in future milestone payments for the development, regulatory approval and commercial sale of portfolio compounds included in the agreement. In addition, Repligen is eligible to receive royalties on sales of qualified products developed.

SMA Agreement with Pfizer

On December 28, 2012, we entered into an exclusive worldwide licensing agreement (the License Agreement) with Pfizer to advance the SMA program, which is led by RG3039 and also includes backup compounds and enabling technologies. Under the terms of the License Agreement, we received $5 million from Pfizer as an upfront payment on January 22, 2013 and a $1 million milestone payment on September 4, 2013. We are entitled to receive up to $64 million in potential future milestone payments, a portion of which may be owed to third parties. These potential payments are approximately equally divided between milestones related to clinical development and initial commercial sales in specific geographies. In addition, we are entitled to receive royalties on any future sales of RG3039 or any SMA compounds developed under the License Agreement. The License Agreement also provides for tiered and increasing royalty rates which begin in the high single-digits for RG-3039 or lesser amounts for any backup compounds developed under the License Agreement. Our receipt of these royalties is subject to an obligation under an existing in-license agreement and other customary offsets and deductions. Royalties are payable, on a country-by-country basis, for a duration based upon the later of (a) expiration of the licensed patent(s) or (b) a predetermined time after the first commercial sale of the first such product in such country.

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Pursuant to this License Agreement, Pfizer has assumed full responsibility for the SMA program moving forward, including the conduct of the clinical trials necessary for any product approvals. Pfizer may terminate the license agreement at any time for convenience.

Orencia® (CTLA4-Ig) Royalties

CTLA4 is a key regulator of the activity of the immune system. CTLA4 turns off the immune system after it has successfully cleared a bacterial or viral infection by blocking the activation of T-cells, the immune cells responsible for initiating an immune response. In the 1990 s, our collaborators at the University of Michigan and the U.S. Navy demonstrated in animal models that a fusion protein consisting of fragments of CTLA4 and an antibody (CTLA4-Ig) could be used to treat certain autoimmune diseases. This research finding resulted in the granting of U.S. patent No. 6,685,941 (the 941 Patent) covering the treatment of certain autoimmune disorders including rheumatoid arthritis with CTLA4-Ig. CTLA4-Ig s mechanism of action is different from the current therapies for autoimmune disease or organ transplant rejection, thus, it may provide a treatment for patients who are refractory to existing therapies.

In December 2005, the FDA approved Bristol s application to market CTLA4-Ig, under the brand name Orencia®, for treatment of rheumatoid arthritis. In January 2006, Repligen and the University of Michigan jointly filed a lawsuit against Bristol in the United States District Court for the Eastern District of Texas for infringement of the 941 Patent. In April 2008, Repligen and the University of Michigan entered into a settlement agreement with Bristol pursuant to which, Bristol made an initial payment of $5 million to us and agreed to pay us royalties on the U.S. net sales of Orencia® for any clinical indication at a rate of 1.8% for the first $500 million of annual sales, 2.0% for the next $500 million and 4.0% of annual sales in excess of $1 billion for each year from January 1, 2008 until December 31, 2013. These royalty payments have ceased.

The 941 Patent is owned by the University of Michigan and exclusively licensed to Repligen. In consideration of this exclusive license, Repligen agreed to pay the University of Michigan 15% of all royalty income received from Bristol, after deducting legal expenses. There are no annual or other fees associated with this agreement. As of December 31, 2013, we have paid approximately $10,065,000 to the University of Michigan under this agreement.

Sales and Marketing

We sell our bioprocessing products through our direct sales force, to partners such as GE Healthcare, EMD Millipore, Sigma Aldrich and to distributors in certain foreign markets.

Segment and Geographic Areas

We have one reportable segment. Segment and geographical information is contained in Note 2, the notes to our consolidated financial statements.

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. For the fiscal years ended December 31, 2013 and 2012, the nine-month fiscal year ended December 31, 2011 and the nine-month period ended December 31, 2010, total revenues from sales to customers in the United States were approximately 51%, 46%, 48%, and 48%, respectively, of total revenues. During the same periods, total revenues generated through sales to customers in Sweden were 35%, 42%, 44% and 45%, respectively, of total revenues. During the same periods, total revenues generated through sales to customers in the United Kingdom were 12%, 9%, 3% and 4%, respectively, of total revenues. For the fiscal years ended December 31, 2013 and 2012, the nine-month fiscal year ended December 31, 2011 and the nine-month period ended December 31, 2010, royalty

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revenue from Bristol represented 27%, 24%, 37% and 37% of total revenues, respectively. Our largest bioprocessing customer accounted for 35%, 42%, 44% and 45% of total revenues in the fiscal years ended December 31, 2013 and 2012, the nine-month fiscal year ended December 31, 2011 and the nine-month period ended December 31, 2010, respectively.

Employees

As of February 17, 2014, we had 116 employees. Of those employees, 94 were engaged in research, development and manufacturing and 22 were in administrative and marketing functions. Each of our employees has signed a confidentiality agreement. None of our U.S. employees are covered by collective bargaining agreements. We have two collective bargaining agreements that cover our 58 employees in Sweden, comprising approximately 50% of our total workforce. The current collective bargaining agreements expire on March 1, 2016. The Company considers its employee relations to be satisfactory.

Patents, Licenses and Proprietary Rights

Repligen considers patents to be an important element in the protection of our competitive and proprietary position and actively, and selectively, pursues patent protection in the United States and in major countries abroad. As further described below, Repligen owns or has exclusive rights to a number of U.S. patents and U.S. pending patent applications as well as corresponding foreign patents and patent applications. The expiration of key patents owned or licensed by us or the failure of patents to issue on pending patent applications could create increased competition, with potential adverse effects on our business prospects.

Other forms of market protection, including trade secrets and know-how, are also considered important elements of our proprietary strategy. Our policy is to require each of our employees, consultants, business partners 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.

Protein A

We have developed proprietary technology, trade secrets, and know-how relating to the manufacture of recombinant Protein A at a scale and quality standard which is consistent with the requirements of the biopharmaceutical industry. In addition, in April 2010, we were granted U.S. Patent No. 7,691,608 B2, Nucleic Acids Encoding Recombinant Protein A, which claims a recombinant gene that encodes a Protein A molecule with an amino acid sequence identical to that of the natural Protein A molecule, which has long been commercialized for bioprocessing applications. This U.S. patent, with the term extension that was granted, will remain in effect until 2028. Foreign equivalents of this patent are being prosecuted outside of the United States.

OPUS

In January 2012, Repligen filed a provisional patent application with the U.S. Patent and Trademark Office (USPTO) which covers certain unique features of our OPUS pre-packed columns. Pending claims that relate to these unique features cover the ease and flexibility of column packing, bed height and cleaning that is improved over existing column designs. In January 2013, we filed an international patent cooperation treaty (PCT) application as well as a utility application with the USPTO on the basis of the provisional application.

CTLA4-Ig

The 941 patent, covering the use of CTLA4-Ig to treat specific autoimmune disorders including rheumatoid arthritis and multiple sclerosis was issued in February 2004. The patent is assigned to the University of Michigan

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and the U.S. Navy and is exclusively licensed to Repligen. In April 2008, Repligen granted Bristol an exclusive sublicense to this patent, pursuant to which Bristol paid us royalties on its U.S. net sales of its rheumatoid arthritis drug, Orencia® through December 31, 2013. These royalty payments have ceased.

Spinal Muscular Atrophy

In 2009, Repligen entered into an exclusive license agreement with a non-profit organization, FSMA, for worldwide rights to patent applications related to compositions and methods for the treatment of spinal muscular atrophy. FSMA had funded the development of these compounds and identified a novel enzyme target (DcpS) that these compounds inhibit. In 2011, we were granted U.S. Patent Nos. 7,888,366 and 7,985,755, both entitled 2,4 Diaminoquinazolines for Spinal Muscular Atrophy, with allowed composition claims that cover both the genus and the species of the chemical structures of the lead clinical candidates. Pursuant to the License Agreement, we licensed all of our intellectual property related to SMA to Pfizer and Pfizer has assumed responsibility for maintaining existing intellectual property and prosecuting new intellectual property relating to this program.

Histone Deacetylase Inhibitors

Repligen has entered into an exclusive license agreement with The Scripps Research Institute for worldwide rights to a patent application claiming compounds and methods for treating Friedreich s ataxia with inhibitors of histone deacetylase. We have extended this original work and filed additional patent applications which claim both methods and compositions for treating Friedreich s ataxia. We licensed all of our intellectual property related to HDAC to BioMarin and BioMarin has assumed responsibility for maintaining existing intellectual property and prosecuting new intellectual property relating to this program.

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 have greater financial and human resources, research and development, manufacturing and marketing experience than we do. 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 forms of commercial scale Protein A including native Protein A for life sciences companies including GE Healthcare and EMD Millipore under long-term supply agreements which expire between 2016 and 2021. Native Protein A is manufactured in Sweden, while the recombinant forms are manufactured in both Waltham and Sweden. We currently manufacture our growth factor products in Sweden and assemble and pack our OPUS chromatography columns in Waltham.

We generally purchase raw materials from more than one commercially established company and believe that the necessary raw materials are currently commercially available in sufficient quantities necessary to meet market demand. We utilize our own facilities in Waltham and 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 U.S. facility, located in Waltham, Massachusetts and our Sweden facility, located in Lund, are both ISO 9001 certified and maintain formal quality systems to maintain process control, traceability, and product conformance. Our Sweden facility, located in Lund, is also cGMP certified. We practice continuous

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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.

In addition, the public may read and copy any materials that we file with the Securities and Exchange Commission at the Securities and Exchange Commission s Public Reference Room at 100 F Street, NE, Washington, D.C. 20549. The public may obtain information on the operation of the Public Reference Room by calling the Securities and Exchange Commission at 1-800-SEC-0330. Also, 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.

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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.

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 competitors or other companies may at any time develop additional products that compete with our products. If an existing or future competitor 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.

We depend on, and expect to continue to depend on, a limited number of customers for a high percentage of our revenues.

As a result, the loss of, or a significant reduction in orders from, any of these customers 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, our revenue could decline, and our operating results may not meet market expectations. In addition, if those customers order our products, but fail to pay on time or at all, our liquidity and operating results could be materially and adversely affected.

As we evolve from a company involved in research and development to a company with a strategic focus on our bioprocessing business, we may encounter difficulties in expanding our operations successfully.

In connection with the Company s decision to focus our efforts on the growth of our core bioprocessing business, we will continue to seek development and commercialization partnerships for our remaining portfolio

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of therapeutic and diagnostic assets. Our future financial performance will depend, in part, on our ability to successfully negotiate and consummate these partnerships. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from monetizing our clinical stage assets. There is also no guarantee that we will successfully expand our bioprocessing business as a result of this change in strategic focus and the Company s financial performance will likely suffer if we are unable to do so.

If intangible assets that we recorded in connection with the Novozymes Acquisition become impaired, we could have to take significant charges against earnings.

In connection with the accounting for the Novozymes Acquisition, we recorded a significant amount of intangible assets, including developed technology and customer relationships relating to the growth factor products. Under U.S. GAAP, we must assess, at least annually and potentially more frequently, whether the value of intangible assets has been impaired. Intangible assets will be assessed for impairment in the event of an impairment indicator. Any reduction or impairment of the value of intangible assets 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 increased dramatically since the consummation of the Novozymes Acquisition.

Our operations and sales outside of the United States have increased and may continue to increase as a result of the Novozymes Acquisition. Risks related to these increased foreign operations include:

- changes in general economic and political conditions in countries where we operate, particularly as a result of ongoing economic instability within the European Union;
- being subject to complex and restrictive employment and labor laws and regulations, as well as union and works council restrictions;
- fluctuations in foreign currency exchange rates;
- 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.

Our business success depends in part on our ability to anticipate and effectively manage these and other risks to which our exposure has increased following the Novozymes Acquisition. We cannot assure you that these and other related factors will not materially adversely affect our international operations or business as a whole since the consummation of the Novozymes Acquisition.

We may be unable to manage efficiently having become a larger and more geographically diverse organization since the consummation of the Novozymes Acquisition.

Since the acquisition of the Novozymes Biopharma Business, we have faced challenges inherent in efficiently managing 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.

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The environmental risks of our business have increased dramatically since the Novozymes Acquisition.

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 and have increased since we completed the acquisition of the Novozymes Biopharma Business. Any violations, even if inadvertent or accidental, of current or future environmental, 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.

In addition to the Novozymes Acquisition and 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;
- lack of synergies or the inability to realize expected synergies and cost-savings;
- difficulties in managing geographically dispersed operations;
- underperformance of any acquired technology, product, or business relative to our expectations and the price we paid;
- negative near-term impacts on financial results after an acquisition, including acquisition-related earnings charges;
- the potential loss of key employees, customers, and strategic partners of acquired companies;
- claims by terminated employees and shareholders of acquired companies or other third parties related to the transaction;
- the assumption or incurrence of additional debt obligations or expenses, or use of substantial portions of our cash;
- the issuance of equity securities to finance or as consideration for any acquisitions would dilute the ownership of our stockholders;
- the issuance of equity securities to finance or as consideration for any acquisitions may not be an option of 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; and

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.

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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.

Our royalty agreement with Bristol-Myers Squibb on sales of Orencia expired on December 31, 2013.

Our royalty agreement with Bristol provided for us to receive payments from Bristol based on their net sales of their Orencia® product in the United States through December 31, 2013. As a result, we no longer receive royalty payments under this agreement as of December 31, 2013. If we are unable to replace these royalty payments with an alternative source of revenue and related income, our operating results will decline and, as a result, we may experience a decline in the price of our common stock.

We have limited sales and marketing capabilities.

We have a small sales force and, historically, we have generated most of our revenues through sales of bioprocessing products to a limited number of life sciences companies, such as GE Healthcare, EMD Millipore, Sigma-Aldrich, Life Technologies and through other individual distributors. However, we expect a significant amount of our future revenue growth to come from bioprocessing products that we sell directly to end-users such as biopharmaceutical companies and contract manufacturing organizations. This may 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 patent and trade secret protection for our products and processes when available in order to protect them 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:

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

We cannot be sure that any patent applications relating to our products that we will file in the future or that any currently pending applications will issue on a timely basis, if ever. Since patent applications in the United States filed prior to November 2000 are maintained in secrecy until patents issue and since publication of discoveries in the scientific or patent literature often lag behind actual discoveries, 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.

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

In some cases, litigation or other proceedings may be necessary to assert claims of infringement, to enforce patents issued to us or our licensors, to protect trade secrets, know-how or other intellectual property rights we own or to determine the scope and validity of the proprietary rights of third parties. Such litigation could result in substantial cost to us and diversion of our resources. An adverse outcome in any such litigation or proceeding could have a material adverse effect on our business, financial condition and results of operations.

If our competitors prepare and file patent applications in the United States that claim technology also claimed by us, we may be required to participate in interference proceedings declared by the U.S. Patent and Trademark Office to determine priority of invention, which would result in substantial costs to us.

Since some of our U.S. patents covering recombinant Protein A have expired, 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 recombinant Protein A in the U.S. 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

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other party and be held liable for significant damages. The failure to obtain any required license on commercially acceptable terms or at all may harm our business, results of operations, financial condition, cash flow and future prospects.

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

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

In connection with the Company s decision to focus its efforts on the growth of its core bioprocessing business, we will seek development and commercialization partnerships for our remaining portfolio of clinical stage assets. Any disputes with such partners, such as Pfizer or BioMarin, 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, such as a larger size version of our OPUS disposable chromatography products which we began selling in 2012. The commercial success of these new products as well as the products acquired in the Novozymes Acquisition 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.

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

Our success depends on the market s confidence that we can provide reliable, high-quality bioprocessing products. We believe that customers in our target markets are likely to be particularly sensitive to product defects and errors. Our reputation and the public image of our products and technologies may be impaired if our products fail to perform as expected. Although our products are tested prior to shipment, defects or errors could nonetheless occur in our products. Furthermore, the Protein A that we manufacture is subsequently incorporated into products that are sold by other life sciences companies and we have no control over the manufacture and production of those products.

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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 c