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

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

For the fiscal year ended December 31, 2015

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: 001-36721

Coherus BioSciences, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**27-3615821**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

333 Twin Dolphin Drive, Suite 600
Redwood City, California 94065
(650) 649 - 3530
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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

Title of Each Class	**Name of Each Exchange on Which Registered**
Common Stock, $0.0001 par value per share	**The NASDAQ Stock Market, Inc.**

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 check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period than 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 and posted on its corporate Web site, 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 ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the 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 definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act (check one):

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

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

The aggregate market value of the registrant's common stock, held by non-affiliates of the registrant as of June 30, 2015 (which is the last business day of registrant's most recently completed second fiscal quarter) based upon the closing market price of such stock on the NASDAQ Global Market on that date, was approximately $783.5 million. For purposes of this disclosure, shares of common stock held by each officer and director have been excluded in that such persons may be deemed to be "affiliates" as that term is defined under the Rules and Regulations of the Securities Exchange Act of 1934. This determination of affiliate status is not necessarily conclusive.

The number of shares of registrant's common stock issued and outstanding as of January 31, 2016 was 39,103,426.

DOCUMENTS INCORPORATED BY REFERENCE

Part III incorporates by reference certain information from the registrant's definitive proxy statement for the 2016 Annual Meeting of Stockholders.

COHERUS BIOSCIENCES, INC.
ANNUAL REPORT ON FORM 10-K
TABLE OF CONTENTS

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This 2015 Annual Report on Form 10-K contains forward-looking statements that involve risks and uncertainties. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this Annual Report on Form 10-K are forward-looking statements. In some cases, you can identify forward-looking statements by words such as "aim," "anticipate," "assume," "believe," "contemplate," "continue," "could," "due," "estimate," "expect," "goal," "intend," "may," "objective," "plan," "predict," "potential," "seek," "should," "target," "will," "would" and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- the timing and the success of the design of the clinical trials and planned clinical trials of CHS-1701 (our pegfilgrastim (Neulasta®) biosimilar candidate); CHS-0214 (our etanercept (Enbrel®) biosimilar candidate); and CHS-1420 (our adalimumab (Humira®) biosimilar candidate);
- whether the results of our trials will be sufficient to support domestic or global regulatory approvals for CHS-1701, CHS-0214 and CHS-1420;
- our ability to obtain and maintain regulatory approval of CHS-1701, CHS-0214 and CHS-1420 or our future product candidates;
- our expectations regarding the potential market size and the size of the patient populations for our product candidates, if approved for commercial use;
- our expectation that our existing capital resources together with funding we expect to receive under our license agreements with Daiichi Sankyo Company, Limited and Baxalta Incorporated, Baxalta US Inc., and Baxalta GmbH, together Baxalta, will be sufficient to fund our operations for at least the next 12 months;
- The implementation of strategic plans for our business and product plans;
- the initiation, timing, progress and results of future preclinical and clinical studies and our research and development programs;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates;
- our expectations regarding the scope or enforceability of third party intellectual property rights, or the applicability of such rights to our product candidates;
- our ability to maintain and establish collaborations or obtain additional funding;
- our reliance on third-party contract manufacturers to supply our product candidates for us;
- our reliance on third-party contract research organizations to conduct clinical trials of our product candidates;
- the benefits of the use of CHS-1701, CHS-0214 and CHS-1420;
- the rate and degree of market acceptance of CHS-1701, CHS-0214 and CHS-1420 or any future product candidates;
- our expectations regarding government and third-party payor coverage and reimbursement;
- our ability to manufacture CHS-1701, CHS-0214 and CHS-1420 in conformity with regulatory requirements and to scale up manufacturing capacity of these products for commercial supply;
- our ability to compete with companies currently producing the reference products, including Neulasta, Enbrel and Humira and other products in our pipeline that are in preclinical stages of development;
- our financial performance; and
- developments and projections relating to our competitors and our industry.

Any forward-looking statements in this Annual Report on Form 10-K reflect our current views with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under Part I, Item 1A. Risk Factors and discussed elsewhere in this Annual Report on Form 10-K. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

This Annual Report on Form 10-K also contains estimates, projections and other information concerning our industry, our business, and the markets for certain diseases, including data regarding the estimated size of those markets, and the incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources.

PART I

Item 1. *Business*

Overview

We are a late-stage clinical biologics platform company focused on the global biosimilar market. Biosimilars are an emerging class of protein-based therapeutics with high similarity to approved originator products on the basis of various physicochemical and structural properties, as well as in terms of safety, purity and potency. Our goal is to become a global leader in the biosimilar market by leveraging our team's collective expertise in key areas such as process science, analytical characterization, protein production and clinical-regulatory development. Since our founding in 2010, we have advanced three product candidates into Phase 3 or Biologics License Application (BLA), enabling clinical development and entered into partnerships with two global pharmaceutical companies and one strategic biologics manufacturer.

Our business is organized around therapeutic franchises:

1) Oncology biosimilar candidates pegfilgrastim (Neulasta), in late clinical-stage, and bevacizumab (Avastin®), in preclinical-stage;

2) Immunology (Anti-TNF) biosimilar candidates, etanercept (Enbrel) and adalimumab (Humira), which are both in late clinical-stage;

3) Ophthalmology biosimilar candidate ranibizumab (Lucentis®) in preclinical stage; and

4) Multiple sclerosis small molecule therapeutic candidate, CHS-131 (formerly INT-131), in Phase 2 proof-of-concept trial.

Oncology Biosimilars

Our long-acting granulocyte colony-stimulating factor (G-CSF) product candidate, CHS-1701, is a pegfilgrastim (Neulasta) biosimilar. G-CSF stimulates production of granulocytes (a type of white blood cell) in order to promote the body's ability to fight infections. In March 2015, we initiated a pivotal pharmacokinetic and pharmacodynamic (PK/PD) study for CHS-1701 in the United States to support the planned filing of a BLA in the United States, which we reported in October 2015. This study met its primary PD endpoints of absolute neutrophil count (ANC). In terms of PK parameters, the study also met bioequivalence for C_{max}. The Area Under the Curve (AUC) portion of the PK results did not meet bioequivalence due to the presence of a low, anomalous PK profile in the first treatment period Neulasta group. Although this PK/PD study is acceptable to support filing the BLA, we initiated a follow-on PK/PD study in February 2016, which we anticipate will read-out in the end of the first half of 2016. We initiated an immunogenicity study in healthy volunteers pursuant to this BLA in May 2015 and reported in February 2016 that CHS-1701 met its immunogenicity endpoints in that study. We continue to believe it may be possible to advance CHS-1701 to a 351(k) (biosimilar) approval application without a collaboration or licensing partner in the United States.

We are developing master cell banks for several new biosimilar candidates of biologic therapeutics in oncology. As we intend to commercialize CHS-1701 in the United States, we anticipate being able to commercialize other candidates in that territory as well. We will seek to find a commercial partner for all oncology biosimilars outside the United States.

Anti-TNF Biosimilars

Our clinical-stage pipeline consists of two anti-Tumor Necrosis Factors, or anti-TNFs. TNF is a substance in the body that is involved in the inflammatory response. Our most clinically advanced anti-TNF product candidate, CHS-0214, is an etanercept (Enbrel) biosimilar candidate which we have partnered with Baxalta Incorporated, Baxalta US Inc., and Baxalta GmbH, or together, Baxalta, and Daiichi Sankyo Company, Limited, or Daiichi Sankyo, in key markets outside of the United States. We have completed two Phase 3 clinical trials with CHS-0214 in rheumatoid arthritis and psoriasis, which met their primary clinical endpoints in November 2015 and January 2016, respectively. Our second anti-TNF product candidate, CHS-1420, is an adalimumab (Humira) biosimilar candidate, and completed Phase 1 studies in August 2014. We initiated a Phase 3 clinical trial in psoriasis in August 2015 for CHS-1420 to support the planned filing of a marketing application in the United States in 2016 and in the European Union (EU) in 2017.

We are developing master cell banks for anti-TNF or anti-inflammatory biosimilar candidates. We intend to find commercialization partners for all of our anti-TNF or anti-inflammatory biosimilar candidates.

Overview of the Market Opportunity for Biosimilars

According to Evaluate Pharma, total annual revenues from the anti-tumor necrosis factor alpha, or anti-TNF-α, and pegfilgrastim-based originator products exceeded approximately $25 billion in 2014 in the sales territories targeted by our current clinical-stage pipeline. We intend to pursue a brand strategy for our biosimilar products that projects high similarity to the originator and positive differentiation to competing biosimilars, at a competitive price.

The global market opportunity for biosimilars is emerging as a result of several factors. First, through 2020, 30 “blockbuster” biologics, each with worldwide annual sales in excess of $1 billion, face loss of patent exclusivity in at least one major pharmaceutical market. These products achieved approximately $108 billion in aggregate worldwide sales in 2014. Second, regulatory agencies around the world have responded to these upcoming patent expirations by defining new biosimilar approval pathways. We believe these regulatory initiatives will help streamline the approval process across various international regulatory agencies and encourage growth of the overall biosimilar market. Third, implementation of more stringent cost containment practices on the part of governments and insurers has increased demand for high-quality biosimilars, which we believe will result in substantial market growth over time.

While the potential market opportunity is significant, biosimilar product development poses a number of scientific, regulatory and technical challenges that distinguish it from traditional, small-molecule generic product development. We believe our world-class team of biologic therapeutic developers and renowned scientists gives us the critical capabilities to successfully address the complexities underlying these challenges. Our team includes industry veterans with decades of experience in pioneering biologics companies, such as Amgen and Genentech, where they were responsible for leading, and in some cases establishing, these organizations’ core capabilities in process development, protein manufacturing and analytical research and development. We have also assembled a distinguished scientific advisory board of leading scientists who are acknowledged experts in their respective fields.

Our business model places our internal team at the center of a coordinated development effort in which our senior team of experts focuses on the highly-specialized, strategic and technical aspects of biosimilar development that are core to our business and difficult to replicate. For other aspects of our operations that require greater scale or more capital-intensive investments, we have established a network of highly-competent external organizations and strategic partnerships that we believe will provide the competitive scale required to address the global biosimilar market opportunity. For example, in December 2015, we entered into a strategic manufacturing agreement with KBI Biopharma, Inc. (KBI Biopharma) for long-term commercial manufacturing of CHS-1701. Many such collaborators are also our equity holders, which we believe results in a strategically aligned consortium designed to select, evaluate and develop biosimilar product candidates in an efficient, cost-effective manner. We believe these elements of our business model have helped us maintain a relatively modest cost structure while providing important fundamental advantages over larger companies. In addition, our dynamic organization allows us to respond to the rapidly evolving biosimilar landscape.

Our Strategy

Our goal is to become a leading global biosimilar company. The key elements of our strategy are to:

- ***Leverage our platform and internal expertise in process science, molecular biology and protein production, as well as our clinical, regulatory and commercial strategies, to screen and select biosimilar candidates.*** Our team possesses a deep understanding of the technical advancements that enable the development of biosimilars. We believe we are able to effectively select product candidates using a stringent process that factors in technical feasibility, size of originator products opportunity and market receptivity to biosimilars, as well as other criteria. With this comprehensive approach, we believe we are able to move quickly and in a capital efficient manner to advance product candidates into clinical trials with strong potential to be partnered and commercialized.
- ***Advance our lead programs through clinical development to secure approvals in major markets.*** We have developed a clinical-stage pipeline consisting of three product candidates. In June and July 2014, we initiated our first Phase 3 clinical trials, advancing CHS-0214 in rheumatoid arthritis and psoriasis, to support the planned filing of a marketing application in Europe and Japan in 2016. We initiated a Phase 3 clinical trial of CHS-1420 in psoriasis in August 2015, to support the planned filing of a marketing application in the United States in 2016 and the E.U. in 2017. For CHS-1701, we initiated a pivotal pharmacokinetic and pharmacodynamic study in March 2015 and an immunogenicity study in May 2015 to support filing of a BLA in the United States. As mentioned above, the PK/PD study met the bioequivalence endpoint for PD and C_{max}, but not for AUC due to an anomalous PK profile in the first period Neulasta group. The immunogenicity study met the primary endpoints. In February 2016, we have initiated a follow-on PK /PD study, which is expected to read-out late in the first half of 2016. We expect to file a BLA in the United States directly thereafter. We believe it is possible to advance CHS-1701 to a 351(k) (biosimilar) approval application without a collaboration or licensing partner. We attempt to adapt our clinical trials to meet the regulatory requirements of multiple jurisdictions, including the United States, Europe and Japan, such that one set of pivotal clinical trials may be sufficient for approval in all jurisdictions.
- ***Continue to advance our early-stage product pipeline.*** We will apply our team's expertise and our platform to identify and pursue multiple additional biosimilar product opportunities. In addition to our clinical-stage product portfolio, we have identified at least two potential product candidates (including CHS-5217, bevacizumab (Avastin) and CHS-3351, ranibizumab (Lucentis) biosimilar product candidates) that meet our stringent selection criteria, which have entered early development. Our goal is to advance at least one of these product candidates into clinical trials in 2016. We continue to evaluate other potential product development candidates to further expand our pipeline.
- ***Maximize the value of our portfolio and pipeline by retaining commercial rights to our products for our oncology biosimilar candidates in the United States and by partnering with leading pharmaceutical companies to commercialize our products in other therapeutic areas.*** We intend to retain U.S. rights to our oncology assets while licensing rights in exchange for upfront, cost sharing, milestone and royalty payments for our assets in other therapeutic areas. For example, we have partnered with Baxter and Daiichi Sankyo to commercialize CHS-0214 in key markets outside of the United States and we may seek a partner for CHS-1420 in 2016 in some or all territories. Such arrangements are intended to support the clinical studies required for regulatory approval of our product candidates and provide us with financial resources and enhanced commercial access.
- ***Attract and retain exceptionally capable team members who share our vision of bringing high quality, lower cost biologic therapeutics to patients.*** We value the experience that has been gained by our veteran team members over the course of decades in the biotechnology industry as essential for execution at all stages of biosimilar product development. Our level of technical expertise is also rare, difficult for others to replicate and a basis for screening those who would join our team. We intend to maintain the capabilities that will enable us to realize our vision of expanding patient access to high quality, lower cost biologic therapeutics globally.

Background on Biosimilars

Significant Market Opportunity

According to the IMS Institute for Healthcare Informatics, the 2014 global biologics market represented over approximately $200 billion in sales, with virtually the entire market composed of branded originator products. The next five years will see a surge in patent expirations for many commercially successful branded biologic products that will provide an unprecedented opportunity for cost containment through the introduction of biosimilars. For 30 major branded biologic products that face loss of patent exclusivity in at least one major market through 2020, aggregate global sales in 2014 were approximately $108 billion. We believe this wave of patent expirations will create one of the most significant opportunities for the biotechnology industry in the coming years. The following originator products (all of which are "blockbuster" biologics) are facing loss of patent exclusivity in at least one major market through 2020:

Actemra	Herceptin	Neupogen	Rebif
Advate	Humalog	Norditropin SimpleXx	Remicade
Avastin	Humira	NovoMix 30	Rituxan
Avonex	Kogenate	NovoRapid	Synagis
Botox	Lantus	Orencia	Tysabri
Enbrel	Levemir	Pediarix	Xolair
Epogen	Lucentis	Pegasys	
Erbitux	Neulasta	Procrit	

Escalating healthcare costs and healthcare reform have been major drivers for the advancement of the biosimilar market. Governments and insurers are in search of mechanisms to contain costs and expand patient access without sacrificing quality of care. Further, governments and private-payors are using an increasing and disproportionate amount of healthcare spending by governments and private payors is on biologic therapeutics. According to data from Express Scripts, approximately $4 out of every $10 spent on prescription drugs in 2014 in the United States is projected to be spent on specialty medications, mostly complex biologics that are only used by 2% of the population. Compounding the issue is the fact that biologic therapeutic costs are escalating at an increasingly unsustainable rate. IMS Institute for Healthcare Informatics also reported that the total spend increase for specialty biologic therapeutics in 2014 was as high as approximately 27%, depending on payor segment. Consequently, we believe there is tremendous cost pressure to bring high-quality, lower-priced biologic therapeutics to market. We further believe our products target payor segments having among the highest rates of spending and anticipated spending growth, including inflammation and cancer.

We expect the biosimilar marketplace to have several distinct characteristics as it develops. First, it is likely to become a branded market without significant participation by generic small molecule manufacturers, who are less likely to have the technical, regulatory and clinical expertise required to succeed in this market. Second, the biosimilar markets we expect to target are unlikely to default to interchangeability in the near to medium term, which means the prescription decision will not exclusively reside in the hands of pharmacists or payors but also in the hands of physicians, requiring commercialization efforts to drive sales. We believe that the biosimilar market adoption and penetration rates for each biosimilar will primarily be determined by four key factors: (1) patient criticality (the degree of severity in the patient's condition), (2) rapidity of feedback on the safety and efficacy of the drug based on the patient response, (3) the physician and patient share influence relative to the payor in the prescribing decision and (4) the prevalence of payor incentives to drive substitution. We believe there will be strong market adoption and penetration for G-CSF and anti-TNF biosimilars particularly due to low patient criticality and payor incentives. We believe that the expected participation of major pharmaceutical firms in the biosimilar markets that we are targeting indicates that there will be a relatively small number of biosimilar competitors, pricing stability and favorable market dynamics.

The Challenge of Biosimilar Product Development

Proteins consist of one or more long chains of amino acid residues and perform a vast array of functions within living organisms, including catalyzing metabolic reactions, replicating DNA, responding to stimuli and transporting molecules from one location to another. Such protein molecules differ from one another primarily in their sequence of amino acids, which results in folding of the protein into a specific three-dimensional structure that determines its activity.

Although the sequence of amino acids in a protein is consistently replicated, there are a number of changes that can occur following synthesis that create inherent variability. Chief among these is the glycosylation, or the attachment of sugars at certain amino acids. Most protein-based therapeutics, including all monoclonal antibodies, are glycosylated to some degree. Monoclonal antibodies are identical antibodies that have an affinity for the same antigen and are produced by a specific clone or cell line. The glycosylation of monoclonal antibodies and other protein-based therapeutics can be critical to half-life, efficacy and even safety of the therapeutic and is therefore a key consideration for biosimilarity. Defining and understanding the variability of an originator molecule in order to match its glycosylation profile requires significant skill in cell biology, protein purification and analytical protein chemistry. Furthermore, manufacturing proteins with reliable and consistent glycosylation profiles at scale is challenging and highly dependent on the skill of the cell biologist and process scientist.

Protein-based therapeutics are inherently heterogeneous and their structure is highly dependent on the production process and conditions. Products from one production facility can differ within an acceptable range from those produced in another facility. Similarly, physicochemical differences can also exist among different lots produced within a single facility. The physicochemical complexity and size of biologic therapeutics creates significant technical and scientific challenges in the context of their replication as biosimilar products. This is further exacerbated by the fact that some originator product's quality characteristics, such as glycosylation, have been shown to change or "drift" over time.

Accordingly, inherent variation is a fundamental consideration with respect to establishing biosimilarity to an originator product to support regulatory approval requirements. Since the product quality characteristics of originator molecules exist as a range of values rather than as an absolute, regulators have issued guidelines that require demonstration of biological similarity and functional equivalence. In contrast, small molecules are homogeneous and therefore relatively simple to replicate, obtain regulatory approval for and commercialize as generics. This simplicity of small molecules allows multiple market entrants and rapid price erosion upon loss of exclusivity. Thus, we believe the ultimate result of protein heterogeneity and complexity is a biosimilar market where only organizations with great technical skill can compete successfully and will do so in a market of relatively few participants and relatively stable prices.

Our Approach

Our Platform

The essential elements of our platform that distinguish our development approach include:

- ***Advanced proprietary analytics.*** Regulators require extensive and sophisticated analytics to demonstrate comparability with the originator molecule. Analytical techniques, such as mass spectrometry, which enable the measurement of the structure and elemental composition of individual molecules, are an essential tool in this process, and we have invested a substantial part of our capital budget in this area.
- ***Molecular tuning to achieve biosimilarity.*** After a protein is produced in a cell, a number of modifications to the protein can occur. These modifications can vary greatly depending on the type of cell that was selected to produce the protein and the process conditions used to generate the protein in the cell, as well as metabolic mechanisms and other considerations. One such modification, glycosylation, results when the cell that produces the protein adds sugar molecules to the backbone of the protein. For a highly glycosylated molecule such as Enbrel, accurately reproducing the glycosylation pattern of the originator protein is particularly critical as glycoform distribution profiles substantially impact pharmacokinetics and biologic activity. For instance, with CHS-0214, we were able to complete the molecular tuning in an extremely short period of time by conducting a number of critical steps in a parallel fashion, making adjustments to cell growth conditions and process conditions while conducting *in vivo* and *in vitro* testing simultaneously. The same parallel process has been applied to our other biosimilar product candidates. While the range of acceptability for pharmacokinetic equivalence is 80% to 125% with the target being at 100%, for CHS-0214, we achieved a geometric ratio of 98% indicating pharmacokinetic equivalence in the pivotal Phase 1 study. As used herein, the term "geometric ratio" denotes the comparison of a measured pharmacokinetic value observed for a first drug, to the same measured value observed for a different drug, where the geometric mean of each drug's measured values is used as the basis for the comparison. The geometric mean indicates the central tendency or typical value of a set of numbers. The use of a geometric mean "normalizes" the ranges being averaged, so that no range dominates the weighting, and a given percentage change in any numerical range has the same effect on the geometric mean. The geometric means ratio, or GMR, which is the ratio of a first geometric mean to a second geometric mean for a measured pharmacokinetic parameter, such as maximum concentration, or C_{max}, is commonly used to determine bioequivalence between drugs, such that a GMR value of 1 (or 100%) signifies that the two compared pharmacokinetic values are the same.

- ***Process science.*** Originators are required by regulators to manufacture under the same decades-old protocols in existence when their biologic therapeutics were first approved unless they invest in costly process change protocols and file appropriate amendments. In contrast, we are not constrained to replicate outdated processes and are free to design and develop systems that integrate state-of-the-art growth media, chromatography resins, filters and techniques to produce our products. We have demonstrated that our cutting-edge protein production processes are highly scalable, extremely robust and easily automated, resulting in consistent product quality, biosimilarity and yield.
- ***Intellectual Property.*** We believe our expertise and investment in the discovery of proprietary technologies, such as in the area of protein stabilization, enhances our ability to create intellectual property that can enable us to innovate around patent protected features of originator products. For example, stabilization of protein in solution (the ability to maintain a protein's three dimensional structure and biological activity) is an essential part of obtaining a commercially viable therapeutic. While originator companies have pursued a strategy of establishing intellectual property around certain patent protected formulations, we believe our investment in proprietary formulation technology allows us to differentiate our products in order to avoid such patent protected formulations, thereby enabling earlier market entry than otherwise would be possible. In particular, we note that the originator formulations for Humira and Enbrel are subject to unexpired patents that specify use of various formulation ingredients and properties. We have developed proprietary formulations for our Enbrel and Humira biosimilar products which do not require these features.
- ***Global regulatory strategy and clinical development.*** The global biosimilar regulatory environment is rapidly evolving and differs significantly from that of originator products. We and our global partners have met with competent authorities in the United States, Canada, the E.U. and Japan and have gained deep insight into regulatory rationale and the nuanced approach required to successfully navigate global requirements. To date, meetings with regulators have been held as follows:
    - *CHS-1701:* We met with U.S. regulators in 2012 and 2014 to discuss our overall development plan. In our meeting with the FDA in October, 2014, we informed the agency of our decision to transition from a 351(a) (novel biologic) approval pathway to a 351(k) (biosimilar) approval pathway. We have finalized our development plan for CHS-1701 and implemented these plans in 2015.
    - *CHS-0214:* We met with regulators in the United States and Japan in 2013 and in the E.U. in 2014. The subject of these meetings was our overall development plan and the amount of evidence needed to support marketing approval in each of these regions.
    - *CHS-1420:* We met with E.U. regulators in September 2014 and with U.S. FDA in the February 2015 to discuss our development plan and the amount of evidence needed to support our application to obtain approval for all of the indications in the originator label. We also received feedback from central E.U. regulators in the first quarter of 2015 on our development plans. We implemented these plans starting in August 2015 with the initiation of a global Phase 3 clinical study in psoriasis comparing CHS-1420 to Humira.

Five Key Steps to Biosimilar Drug Development

We apply our platform to five key steps of biosimilar development that are designed to provide the analytical, nonclinical and clinical basis to establish biosimilarity and support regulatory approvals of our product candidates. Regulators may approve a product label inclusive of all or a subset of the indications of the originator therapeutic based on the totality of the data. We have had meetings with regulators in the major regulated markets to discuss our three most advanced product candidates and the data required to support approval. The outcome of these discussions has informed our clinical designs, product development and regulatory strategies.

Step 1: Cell Line Development and Manufacturing

The amino acid sequence of the candidate biosimilar molecule must precisely match that of the originator. We have found that publicly available data can be unreliable in some instances. Therefore, we validate the amino acid sequence of all candidate biosimilar products prior to developing clones. While all clones are expected to produce proteins with the same primary sequence, it is essential to select clones which produce protein that most closely matches the glycosylation profile of the originator, since such product quality characteristics impact pharmacokinetics, or PK, and pharmacodynamics, or PD, properties as well as safety and efficacy of the molecule. A process to manufacture the desired product must be developed, scaled-up and implemented in a Good Manufacturing Practice, or GMP, facility in order to be used in human clinical trials.

Step 2: Analytical Characterization and In Vitro Comparability

Once a biosimilar product candidate has been manufactured, we use sophisticated analytical methods and equipment as well as highly trained analysts in order to detect, analyze and interpret the chemical and structural similarity between our biosimilar candidate and the originator product. We test for comparability of biologic activity using a battery of sensitive *in vitro* pharmacology assays that demonstrate binding characteristics, functionality and mechanism of action. These data may be predictive of clinically relevant differences in PK, PD, efficacy, safety and immunogenicity between our biosimilar candidate and the originator product.

Step 3: In Vivo Animal Comparability

Following demonstration of *in vitro* biosimilarity, we compare our biosimilar product candidate to the originator product in relevant animal models using the intended dosage form and route of administration prior to performing human clinical trials. As PK, PD and safety observations from these studies may be predictive of the human clinical trial experience, it is important to perform these studies in animals before proceeding to human clinical trials. Generally speaking, two studies are required in relevant animal models to provide sufficient nonclinical rationale to advance to a pivotal Phase 1 study.

Step 4: Pivotal Phase 1 Human Pharmacokinetic and Pharmacodynamic Study

An essential global regulatory requirement is the completion of a clinical study in a sufficient number of human subjects directly comparing the originator product and our biosimilar product candidate to establish PK / PD similarity. The U.S. and European regulatory agencies have established requirements for bioequivalence with respect to three prospectively defined parameters as follows:

- C_{max} : maximum measured serum concentration;
- AUC_{0-t} : area under the concentration-time curve from the first time point measured (0) to the last time point measured (t); and
- AUC_{0-inf} : area under the concentration-time curve from the first time point measured (0) extrapolated to infinity.

The area under the curve, or the AUC, is a measure of how much of a drug is in a patient's system over a given time period. In order to calculate the AUC, the concentration of the drug in blood serum or plasma is plotted over time starting at the time the drug is administered and ending when the last time point is collected (AUC_{0-t}) or when the serum or plasma concentration would be below the level of detection or zero (AUC_{0-inf}), and then the area under this curve is calculated. To be deemed bioequivalent, regulators require that, for each parameter, the ratio of the originator product and the biosimilar candidate fall within 80% and 125%, with the identical match being at 100%.

Step 5: Phase 3 Confirmatory Safety and Efficacy Clinical Trials

The final step to support approval is a single Phase 3 confirmatory safety and efficacy study in a therapeutic indication for which the originator product has been approved. The objective of this study is to demonstrate biosimilarity between the two molecules with respect to safety and efficacy. Subject to discussions with regulators and agreement on trial endpoints, we strive to demonstrate that our biosimilar products are as effective and safe as the originators. Trial endpoints include considerations such as the number of subjects, statistical significance, confidence intervals and accumulated safety database size.

Development Portfolio

The following table summarizes key information regarding our current product candidate pipeline:

Candidate	Originator Product	Originator Approved Indications	Status/Anticipated Milestones	Coherus Commercial Rights
Oncology Pipeline				
CHS-1701	pegfilgrastim (Neulasta)	Febrile neutropenia	• Phase 1 (351 (a)) completed • Completed pivotal PK/PD BLA-enabling study in October 2015 • Immunogenicity study read-out met primary endpoints in the first quarter of 2016 • Initiated follow-on PK/PD BLA-enabling study in the first quarter of 2016 • Expect to file 351 (k) BLA	Worldwide
CHS-5217	bevacizumab (Avastin)	Metastatic Colorectal Cancer, Non–Small Cell Lung Cancer, Metastatic Kidney Cancer, Advanced Cervical Cancer, Platinum-Resistant Ovarian Cancer, Recurrent Glioblastoma.	• Preclinical stage	Worldwide
Immunology (Anti-TNF) Pipeline				
CHS-0214	etanercept (Enbrel)	Ankylosing Spondylitis, Juvenile Idiopathic Arthritis, Psoriasis (PsO), Psoriatic Arthritis, Rheumatoid Arthritis (RA),	• Phase 3 clinical trials in PsO and in RA met primary efficacy endpoints in fourth quarter of 2015 and first quarter of 2016, respectively • Initiate two bridging Phase 1 studies in the first half of 2016 • File Market Authorization Application (MAA) in E.U. in 2016	US only[1]
CHS-1420	adalimumab (Humira)	Ankylosing Spondylitis Behçet's Disease Crohn's Disease Juvenile Idiopathic Arthritis Psoriasis (PsO) Psoriatic Arthritis Rheumatoid Arthritis (RA) Ulcerative Colitis	• Phase 1 study completed • Initiated Phase 3 clinical study in PsO in third quarter of 2015 • Initiated PK bioequivalence bridging studies in 2016 with Phase 3 drug material • File BLA in U.S. in the second half of 2016	Worldwide
Ophthalmology Pipeline				
CHS-3351	ranibizumab (Lucentis)	Neovascular (Wet) Age-related Macular Degeneration, Macular Edema Following, Retinal Vein Occlusion, Diabetic Macular Edema, Diabetic Retinopathy Ulcerative Colitis	• Preclinical stage	Worldwide
Ophthalmology Pipeline				
CHS-3351	ranibizumab (Lucentis)	Neovascular (Wet) Age-related Macular Degeneration Macular Edema Following Retinal Vein Occlusion Diabetic Macular Edema Diabetic Retinopathy	• Preclinical stage	Worldwide

1 The therapeutic protein in etanercept is subject to certain originator-controlled United States patents expiring in 2028 and 2029. Assuming these patents are valid and enforceable, and that we would be unable to obtain a license to them, we do not expect to commercialize CHS-0214 in the United States prior to their expiration.

Oncology Biosimilar Pipeline Opportunity

CHS-1701 (Our Pegfilgrastim (Neulasta) Biosimilar Candidate)

Granulocyte colony-stimulating factor, or G-CSF, is a protein produced in different cell types of the body that promotes the survival, proliferation and differentiation of certain white blood cells called neutrophils. G-CSF regulates the production of neutrophils within the bone marrow by stimulating neutrophil progenitor proliferation and differentiation, as well as activating certain immune functions in the body. Recombinant G-CSF therapies, such as filgrastim (Neupogen) and pegfilgrastim (Neulasta), are commonly used in the prevention of chemotherapy-induced neutropenia, which is characterized by an abnormally low level of neutrophils and other white blood cells that aid in the defense against infections. Secondary infections arising from chemotherapy-induced neutropenia are the most common dose-limiting toxicity of cancer therapy. Febrile neutropenia, a more severe form of neutropenia associated with fever and other signs of infection, occurs in as many as 25 to 40% of patients receiving common first-line chemotherapy regimens. The occurrence of febrile neutropenia often necessitates chemotherapy delays or dose reductions and may also lengthen the duration of hospital stays, increase monitoring, diagnostic and treatment costs and reduce the patient's quality of life. In light of this, G-CSF therapies are routinely used prophylactically to prevent febrile neutropenia resulting from chemotherapy and radiation treatments for cancer. Additionally, in the US, Neulasta is indicated for increasing survival in patients acutely exposed to myelosuppressive doses of radiation.

The worldwide G-CSF market is composed of short-acting G-CSFs, such as filgrastim, lenograstim and TBO-filgrastim, and extended duration PEGylated G-CSFs such as pegfilgrastim. The term "PEGylation" refers to the attachment of a polymer (polyethylene glycol, or PEG) to the G-CSF protein in order to improve its half-life, or the length of time the drug remains in the body. We selected pegfilgrastim (Neulasta) as the biosimilar development target for our biosimilar G-CSF product candidate, CHS-1701, for the following reasons:

- *Large market opportunity.* The combined opportunity for both short- and long-acting G-CSF therapies worldwide is estimated to be approximately $5 billion in 2017 and pegfilgrastim therapies are expected to capture over 70% of worldwide market revenues in the G-CSF class. It is estimated that the worldwide opportunity for Neulasta, the reference product for CHS-1701, will exceed $4.0 billion in 2017.
- *Receptivity to biosimilars.* We believe there is strong conviction among payors to drive biosimilar adoption in the G-CSF category. This is supported by the uptake of filgrastim biosimilars in the EU5 (Spain, Great Britain, France, Germany and Italy), which were initially launched in 2008 and achieved approximately 59% share of the accessible short-acting G-CSF market and approximately 80% of the reference product market by the end of 2014. These percentage shares are based on sales of all short-acting G-CSF products in the EU5 measured in treatment days (TD). The accessible short-acting G-CSF market is formed by Euprotin, Granocyte, Myelostim, Neutrogin, Neulasta (the reference product) and filgrastim biosimilars.
- *Timing of patent expiration.* We believe that the expiration of certain originator patents pertaining to pegfilgrastim (Neulasta) in major markets offers us a near-term opportunity to introduce biosimilar competitors in these markets. Specifically, we believe we would not be precluded by the originator's patents from introducing a pegfilgrastim (Neulasta) biosimilar candidate in the United States after October 2015 and in Europe after August 2017.

Product Overview

Pegfilgrastim (Neulasta), the reference product for CHS-1701, is a PEGylated form of the recombinant human G-CSF analog, filgrastim. Filgrastim produced from *E. coli* is not glycosylated. We have performed extensive analytical characterization of CHS-1701 and have determined that its basic and higher-order structures are similar to Neulasta. We have also performed *in vitro* characterization of the biological activity of CHS-1701. The biological effect of CHS-1701 on neutrophils was assessed by measuring the proliferation of NFS-60 cells that are commercially available hematopoietic cells (blood cells that give rise to other blood cells) of neutrophilic lineage expressing G-CSF receptors and have been used extensively for testing G-CSF products. The biological activity of CHS-1701 (proliferation of NFS-60 cells) is a consequence of its binding to G-CSF receptors expressed on NFS-60 cells, activation of this receptor and induction of the proliferation. In this assay, proliferation of NFS-60 cells is stimulated with varying concentrations of CHS-1701. Proliferation is then measured through the addition of the special dye that is transformed during cell proliferation and induces a luminescent signal directly proportional to the number of living cells. Luminescence is emission of light caused by chemical reactions. We determined that CHS-1701 stimulated the proliferation of the NFS-60 cells in a manner consistent with that observed with Neulasta.

Neulasta is approved in the United States and Europe and is indicated as a treatment to reduce the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anticancer drugs associated with a clinically significant incidence of febrile neutropenia.

Analysts project the worldwide market for Neulasta in 2017 will exceed $4.0 billion, of which approximately $3.2 billion would be in the United States. We have concluded that patent expiration in major markets offers a near-term opportunity to introduce biosimilar competitors in the United States after October 2015 and in Europe after February 2018.

Current Development Status and Data

Under the 351(a) (novel biologic) pathway, we have successfully advanced CHS-1701 through steps 1 through 4 of biosimilar drug development, including completion of a Phase 1 PK /PD study in healthy volunteers. This study was conducted under an Investigational New Drug application in the United States. In October 2014, we met with FDA to discuss our development plan for CHS-1701. We informed the agency of our decision to transition from a 351(a) (novel biologic) approval pathway to a 351(k) (biosimilar) pathway. In March 2015, we received written feedback from the FDA on our development plan for CHS-1701 and we initiated a pivotal pharmacokinetic and pharmacodynamic study for CHS-1701. This study met its primary PD endpoints. In terms of PK parameters, the study also met bioequivalence for C_{max}. The AUC portion of the PK results did not meet bioequivalence due to the presence of a low, anomalous PK profile in the first treatment period Neulasta group. Although this PK/PD study is acceptable to support filing the BLA, we initiated a follow-on PK/PD study in the first quarter of 2016, which we anticipate will be completed at the end of the first half of 2016. We expect to file a BLA directly thereafter the completion of the follow-on PK/PD study. In January 2016, we completed an immunogenicity study in healthy volunteers pursuant to this BLA, which met its primary endpoints.

Step 1: Cell Line Development and Manufacturing

As with our other product candidates, we confirmed that the amino acid sequence of CHS-1701 is identical to the originator molecule. CHS-1701 is manufactured in *E. coli* and PEGylation occurs as a subsequent step in the manufacturing process. For PEGylation of CHS-1701, we used the equivalent polyethylene glycol, or PEG, molecule as Neulasta and established that chemistry and site of attachment of the PEG molecule was the same. In December 2015, we entered into a strategic manufacturing agreement with KBI Biopharma for long-term commercial manufacturing of CHS-1701.

Step 2: Analytical Characterization and In Vitro Comparability

Filgrastim produced from *E. coli* is not glycosylated. We performed extensive analytical characterization of CHS-1701 and have determined its basic and higher-order structures are similar to Neulasta. We studied the *in vitro* activity of CHS-1701 in a luminescence assay measuring the proliferation of the murine myeloid leukemia cell line, NFS-60. CHS-1701 stimulated the proliferation of the NFS-60 cells in a concentration-dependent manner, consistent with the proliferation seen with Neulasta.

Step 3: In Vivo Animal Comparability

With CHS-1701, we have performed two preclinical pharmacology/toxicology studies: a two-week study in rats and a four-week study in monkeys. We performed a two-week rat study to characterize the toxicity and pharmacodynamics of CHS-1701 administered every four days for two weeks, with a recovery period of one week compared to Neulasta. Doses ranged from 0.1 to 1.0 mg/kg. There was no mortality during the study and no systemic signs of toxicity could be attributed to treatment. There were no differences in clinical observations between the control and treated animals. Dose-proportional increases in absolute neutrophil count, or ANC, and total white blood cell count were observed at all dose levels of CHS-1701. Clinical chemistry findings and mild to moderate splenic enlargement in the CHS-1701-treated animals were consistent with the pharmacological effects of treatment with Neulasta.

We designed a second pharmacology/toxicology study in animals to characterize PK and PD profiles as well as the potential for harmful antibody responses to CHS-1701 or other toxic effects, in order to compare these attributes observed for CHS-1701 with those we observed for Neulasta. We administered either CHS-1701 or Neulasta at dose levels of 0.075, 0.25 and 0.75 mg/kg once weekly for 4 weeks. We found that CHS-1701 performed in a manner similar to Neulasta in that it increased the production of white blood cells in the bone marrow and resulted in an increase in the amount of white blood cells in the blood, in the bone marrow and in lymphoid tissues such as spleen and thymus tissue. Moreover, we found no differences between CHS-1701 and Neulasta in terms of potentially harmful antibody responses or other toxicities, or in terms of PK and PD.

Step 4: Pivotal Phase 1 Human Pharmacokinetic and Pharmacodynamic Study

While under the 351(a) regulatory pathway, we conducted a Phase 1, randomized, double-blind, single-dose, two-period crossover study to assess the PK profile, safety and activity of a single subcutaneous 6 mg dose of CHS-1701 compared to Neulasta in 79 healthy human subjects between November 2012 and March 2013.

This Phase 1 study met its primary endpoint for purposes of enabling us to pursue a 351(a) (novel biologic) approval pathway, but did not establish bioequivalence necessary to support a 351(k) (biosimilar) pathway. In October 2014, we met with the FDA to

discuss our development plan for CHS-1701. We informed the agency of our decision to transition from a 351(a) (novel biologic) approval pathway to a 351(k) (biosimilar) approval pathway.

Step 5: Further Studies Supporting 351(k) BLA Regulatory Filing.

In March 2015, we received written feedback from the FDA on our development plan for CHS-1701 and we initiated a pivotal pharmacokinetic and pharmacodynamic study for CHS-1701 under the 351(k) (biosimilar) pathway in the United States which completed in October 2015. This study met its primary PD endpoints. In terms of PK parameters, the study also met bioequivalence for C_{max}. The AUC portion of the PK results did not meet bioequivalence due to the presence of a low, anomalous PK profile in the first treatment period Neulasta group. Although this PK/PD study could support the BLA, we initiated a follow-on PK/PD study in the first quarter of 2016, which we anticipate will read-out at the end of the first half of 2016. In May 2015, we initiated an immunogenicity study in healthy volunteers pursuant to this BLA, which completed in January 2016 and met its primary endpoints. We expect to file the US BLA directly thereafter the completion of the follow-on PK/PD study. We anticipate seeking further advice in the EU to determine timing for a MAA.

CHS-5217 (Our Bevacizumab (Avastin) Biosimilar Candidate)

Bevacizumab is a recombinant humanized monoclonal antibody that blocks angiogenesis by inhibiting vascular endothelial growth factor A (VEGF-A). VEGF-A is a protein that stimulates angiogenesis, which is the formation of blood vessels. In turn, the formation of new blood vessels may contribute to promote the growth of certain solid tissues, including solid tumors. Bevacizumab was first approved in 2004 by the FDA for combination use with standard chemotherapy for metastatic colon cancer. It has since been approved for use in certain lung cancers, renal cancers, ovarian cancers and glioblastoma.

Bevacizumab achieved approximately $7 billion in worldwide sales in 2014. We selected bevacizumab (Avastin) as the biosimilar development target for our biosimilar, CHS-5217, for the following reasons:

- *Large market opportunity.* The combined opportunity for bevacizumab worldwide is estimated to remain near $7 billion in 2017, and forecasted to decrease to $6.4 billion in 2020, when biosimilar candidates of bevacizumab may be introduced to the market.
- *Channel synergy.* We anticipate marketing CHS-5217 to many of the payers, hospitals and clinics that could contract for CHS-1701, our pegfilgrastim (Neulasta) biosimilar candidate, and would aim to leverage a common sales force and commercial strategy for the oncology therapeutic area.
- *Timing of patent expiration.* As part of a second wave of biosimilar candidates, we believe we would not be precluded by the originator's patents from introducing a bevacizumab (Avastin) biosimilar candidate in the United States after July 2019.

Current Development Status and Data

Step 1: Cell Line Development and Manufacturing

We have identified the amino acid sequence of CHS-5217 and confirmed that it is identical to the reference product, Avastin. We established Master Cell Banks, or MCBs, and produced toxicology materials in the third quarter of 2015. We are currently transferring the manufacturing process to a US contract manufacturing organization, or CMO, for clinical trial supply.

Step 2: Analytical Characterization and In Vitro Comparability

We demonstrated CHS-5217 similarity to Avastin with respect to key physicochemical properties that impact PK / PD, safety and efficacy using a broad spectrum of analytical methods. Through *in vitro* ligand and receptor binding studies, we have shown CHS-5217 to have highly similar pharmacological activity to Avastin.

Step 3: In Vivo Animal Comparability

We compared CHS-5217 to Avastin in a repeat dose study evaluating toxicity in cynomolgus monkeys and no appreciable differences were identified.

Immunology (Anti-TNF) Pipeline Opportunity

Tumor necrosis factor, or TNF, belongs to a family of soluble protein mediators, or cytokines, that play an important role in disease progression across a number of inflammatory and chronic conditions, including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's Disease, psoriasis and ulcerative colitis. Cytokines, such as TNF, are substances produced by cells in the body that can cause a biological effect on other cells in the body. TNF is generally understood as the "master regulator" of the body's immune response and is the key initiator of immune-mediated inflammation in multiple organ systems. Several biologic agents have been developed that inhibit the inflammatory activity of TNF in the context of these diseases, which are collectively referred to as the anti-TNF class of therapeutics. Anti-TNF products with significant global sales include adalimumab (Humira), etanercept (Enbrel), infliximab (Remicade), golimumab (Simponi) and certolizumab pegol injection (Cimzia). These products share a common mechanism of action in that they inhibit TNF, but differ in their dosing schedules as well as the indications for which they are approved. Collectively, these treatments represent a significant revenue opportunity, with projected global sales in excess of $37 billion in 2017.

Our anti-TNF biosimilar product candidates, CHS-0214 and CHS-1420, are based on Enbrel and Humira, respectively. We selected these originator products as biosimilar development targets for the following principal reasons:

- *Large market opportunity.* Global sales of Enbrel and Humira are projected to exceed $24 billion in 2017, representing over 60% of combined estimated global sales in the anti-TNF monoclonal antibody and TNF inhibitor markets in 2017. Approximately $21 billion of this estimated market is in territories in which we or our partners currently intend to commercialize our anti-TNF products. In addition, among the top ten selling drugs in its pharmacological class, Humira is also approved for the largest number of inflammatory indications worldwide.
- *Receptivity to biosimilars.* Because anti-TNF agents are typically used to treat diseases where there is low risk of imminent mortality, we believe physicians and payors will be inclined to support adoption of biosimilar anti-TNF agents that allow for rapid confirmation of safety and efficacy for the individual patient. We believe that physicians recognize the payor will be a key influencer in driving the adoption of biosimilar anti-TNF agents.
- *Technical barriers to entry.* There are numerous challenges in the development of biosimilars to these reference products related to quality characteristics such as glycosylation that we believe our specialized expertise in protein chemistry and process science will allow us to overcome.
- *Timing of patent expiration.* The expiration of certain originator patents pertaining to etanercept (Enbrel) and adalimumab (Humira) in major markets offers us a near-term opportunity to introduce biosimilar competitors in these markets. Specifically, we believe we would not be precluded by the originator's patents from introducing an etanercept (Enbrel) biosimilar candidate in Europe after August 2015 or in Japan after September 2015. In the case of adalimumab (Humira), we do not believe originator patents would preclude us from introducing a biosimilar in the United States after December 2016, in Europe after October 2018 and in Japan after August 2018 (for rheumatoid arthritis) or May 2020 (for psoriasis).

CHS-0214 (Our Etanercept (Enbrel) Biosimilar Candidate)

Product Overview

Etanercept (Enbrel), the reference product for CHS-0214, is a complex fusion protein that combines the protein for tumor necrosis factor receptor 2, or TNFR-2, to another protein (called IgG1 Fc) which enables the fusion protein to attach to cells in the body. The TNFR-2 portion of the fusion protein binds to soluble and cell bound tumor necrosis factors alpha and beta, or TNF-α and TNF-β, respectively, and inhibits TNF-α and TNF-β from binding to cell surface proteins that recognize them. Autoimmune diseases are caused by an overactive immune response. Etanercept (Enbrel) treats these diseases by inhibiting TNF-α, thus inhibiting the inflammatory cytokine cascade, which is a sequence of events in the body, caused by cytokines, leading to inflammation in a tissue or organ.

Enbrel has been approved by the European Medicines Agency, or EMA, and the U.S. Food and Drug Administration, or FDA, for the treatment of the following indications:

- rheumatoid arthritis;
- juvenile idiopathic arthritis;
- psoriatic arthritis;
- ankylosing spondylitis; and
- psoriasis.

Enbrel has been approved by the Japanese Pharmaceutical and Medical Devices Agency, or PMDA, for the treatment of the following indications only when conventional therapies are not sufficiently effective:

- rheumatoid arthritis; and
- juvenile idiopathic arthritis.

In 2017, sales of Enbrel are projected to exceed approximately $8 billion worldwide. Because patents in the United States, assuming validity and enforceability, provide market exclusivity for the etanercept (Enbrel) originator molecule until 2029, we focused our CHS-0214 regulatory program on Europe and Japan, but harmonized as needed for potential FDA approval. We have licensed CHS-0214 to Daiichi Sankyo in Japan and to Baxter in territories outside of Japan, the United States and certain Caribbean and Latin American countries. We have licensed CHS-0214 to Orox for certain Caribbean and Latin American countries. According to Evaluate Pharma, in 2017 sales of Enbrel in Europe, Japan and other territories outside the United States are projected to be approximately $3.2 billion.

Current Development Status and Data

We have successfully advanced CHS-0214 through steps 1 through 5 of biosimilar drug development. Our pivotal Phase 1 human PK / PD study was conducted in the United States. We are currently evaluating CHS-0214 in two randomized Phase 3 clinical trials, which met their primary endpoints. The Phase 3 clinical trial in rheumatoid arthritis enrolled subjects in the following countries: United States, Belarus, Ukraine, Spain, Italy, France, Germany, Hungary, Israel, Japan, Poland, Russia, South Africa and the United Kingdom. The Phase 3 clinical trial in psoriasis enrolled subjects in the following countries: United States, Canada, Australia, Germany, Israel, Poland, Russia, South Africa and the United Kingdom. We have filed an IND application or equivalent request for approval in all of the countries where we are performing studies. We expect the European marketing application for CHS-0214 to be filed with the EMA in the second half of 2016. If approved, we believe we will be able to extrapolate the data from our trials in rheumatoid arthritis and psoriasis to gain approval for CHS-0214 in all the indications included in the label for Enbrel.

Step 1: Cell Line Development and Manufacturing

We have identified the amino acid sequence of CHS-0214 and confirmed that it is identical to the reference product, Enbrel. We established Master Cell Banks, or MCBs, and Working Cell Banks, or WCBs, and produced toxicology materials in the third quarter of 2012 and Phase 1 study materials at a U.S. contract manufacturing organization, or CMO. We then transferred the manufacturing process to a European CMO for Phase 3 clinical trial supply and subsequent commercialization.

Step 2: Analytical Characterization and In Vitro Comparability

We demonstrated CHS-0214 similarity to Enbrel with respect to key physicochemical properties that determine PK / PD, safety and efficacy using a broad spectrum of analytical methods. Through *in vitro* receptor binding studies, including Fc receptors, complement (C1q) and Fc-mediated functional activities (i.e., antibody-dependent cell-mediated cytotoxicity, or ADCC, and complement-dependent cytotoxicity, or CDC), we have shown CHS-0214 to have highly similar pharmacological activity to Enbrel. ADCC and CDC refer to biological mechanisms of immune system defense which facilitate the body's ability to use its immune system to target and destroy a given target cell. Comparing the effects of CHS-0214 and Enbrel on these mechanisms provides us a basis for determining how similar CHS-0214 is to Enbrel in terms of pharmacological activity.

Step 3: In Vivo Animal Comparability

We compared CHS-0214 to Enbrel in a single-dose PK study and a 28-day study in evaluating toxicity and PK in cynomolgus monkeys and no appreciable differences were identified.

Step 4: Pivotal Phase 1 Human Pharmacokinetic and Pharmacodynamic Study

We announced the Phase 1 PK similarity trial results for CHS-0214 in October 2013. This study was a single dose cross-over study conducted in 60 healthy adult human volunteers to evaluate the PK and safety of CHS-0214 compared to Enbrel. CHS-0214 met the primary endpoint of clinical PK similarity to Enbrel with the study demonstrating a 98% correlation between CHS-0214 and Enbrel.

We also collected safety data in all subjects and both CHS-0214 and Enbrel were well tolerated. Treatment emergent adverse events were similar for each treatment and treatment period, and there were no unusual or unexpected or serious adverse events related to either product. There were no clinically meaningful differences in other safety parameters observed during this study.

Due to the change in the manufacturing location from the United States to the E.U., we conducted an additional PK similarity trial comparing CHS-0214 to a lot of Enbrel manufactured in Europe, which met its primary endpoint in April 2015. The design of this trial was a single-dose, cross-over study similar to the one described above. We initiated a PK similarity trial comparing EU Enbrel to CHS-0214 produced under a new process and we plan to initiate a PK similarity trial comparing CHS-0214 produced under a new process and CHS-0214 under a former process and used in the two Phase 3 trials.

Step 5: Phase 3 Confirmatory Safety and Efficacy Clinical Trials

We announced the dosing of the first patient in a Phase 3 rheumatoid arthritis clinical trial in June 2014, and subsequently initiated a separate Phase 3 clinical trial in psoriasis in July 2014. The design of each Phase 3 clinical trial reflects guidance from regulatory agencies regarding key study parameters. Our intent is to complete both Phase 3 clinical trials in parallel in May 2016 and to file a Marketing Authorization Application, or MAA, for CHS-0214 with the EMA in the second half of 2016.

The Phase 3 clinical trial in rheumatoid arthritis is on-going and is designed as a double blind, multi-center, parallel group study in which patients with DMARD (disease-modifying antirheumatic drug)-refractory active rheumatoid arthritis were put on a stable dose of methotrexate. This trial enrolled 647 subjects who were randomized 1:1 to CHS-0214 50 mg or Enbrel 50 mg, administered subcutaneously weekly over a period of 24 weeks and, in January 2016, met its primary efficacy endpoint of ACR 20 (20% improvement according to American College of Rheumatology Criteria) scores at 24 weeks, the same primary endpoint that was used in the Enbrel registration trial for rheumatoid arthritis. Following the initial 24-week double-blind period, all patients were moved to a CHS-0214 treatment for a period of 6 months. The trial is expected to complete dosing in April 2016.

The Phase 3 clinical trial in psoriasis is on-going and is designed as a double-blind, parallel group, multi-center study in patients with active psoriasis. This trial enrolled 521 patients who were randomized 1:1 to CHS-0214 or Enbrel, 50 mg administered subcutaneously twice weekly for the first 12 weeks, switching to once weekly and continuing in the same treatment arms for an additional 40 weeks, which included four weeks of follow-up. In November 2015, this trial met its primary efficacy endpoint of mean percent change in Psoriasis Area and Severity Index, or PASI from baseline and the proportion of subjects achieving a 75% improvement in the PASI from baseline (PASI-75), scores at 12 weeks.

In July 2015, we initiated an open-label, safety extension study (OLSES) evaluating the longer-term safety and durability of response of subjects who completed 48 weeks of evaluations in the confirmatory safety and efficacy Phase 3 studies evaluating CHS-0214 in patients with rheumatoid arthritis and psoriasis. We expect enrolling up to 400 subjects in this study.

CHS-1420 (Our Adalimumab (Humira) Biosimilar Candidate)

Product Overview

Adalimumab (Humira), which is the reference, or originator, product for CHS-1420, is a monoclonal antibody that can bind to a substance in the body known as tumor necrosis factor, or TNF, thereby inhibiting the known effect of this substance as a potent mediator of inflammation. Humira thus provides a therapeutic benefit for treatment of various inflammatory diseases characterized by increased production of TNF in the body. However, it is also known that Humira can bind to receptors on white blood cells which may lessen the ability of the body's immune system to fight infections.

Humira has been approved by the EMA and the FDA for the treatment of the following indications only when conventional therapies are not sufficiently effective:

- rheumatoid arthritis;
- juvenile idiopathic arthritis;
- psoriatic arthritis;
- ankylosing spondylitis;
- Crohn's disease;
- ulcerative colitis; and
- psoriasis.

Humira has been approved by the PMDA for the treatment of the following indications only when conventional therapies are not sufficiently effective:

- rheumatoid arthritis;
- psoriatic arthritis;
- psoriasis; and
- Behçet's disease.

Worldwide sales of Humira are projected to exceed $15 billion in 2017, with about $11.4 billion in the United States and $4.5 billion in Europe, the two primary regions in which we plan to focus our commercialization efforts. CHS-1420 will target a large global anti-TNF market, including but not limited to the worldwide market for the originator product, Humira. According to Evaluate Pharma, in 2017, sales of Humira worldwide and of Enbrel in the United States are projected to exceed $20 billion.

Current Development Status and Data

We have successfully advanced CHS-1420 through steps 1 through 4 of biosimilar drug development, and we have completed a pivotal Phase 1 PK / PD study comparing CHS-1420 to Humira in healthy volunteers. This Phase 1 PK study met the primary endpoint and demonstrated bioequivalence for all prospectively defined endpoints and was conducted under an IND application in the United States. We initiated a Phase 3 clinical trial in psoriasis in August 2015 to support the planned filing of a marketing application in the United States in the second half of 2016 and the E.U. in 2017. We initiated a Phase 1 PK bridging study comparing our Phase 3 material to U.S. manufactured Humira in the first quarter of 2016 and plan to initiate a study bridging to E.U. manufactured Humira in mid-2016. We reached concurrence with regulatory authorities the United States and Europe with the objective of designing a harmonized global Phase 3 program to support registration in these territories. If approved, we believe we will be able to extrapolate the data from our trial in psoriasis to gain approval for CHS-1420 in all the indications included in the label for Humira.

Step 1: Cell Line Development and Manufacturing

As with all our molecules, we matched the amino acid sequence of CHS-1420 to the originator molecule (Humira) prior to development and demonstrated it to be identical. We established MCBs and WCBs and transferred the manufacturing process to a U.S. CMO for manufacturing of Phase 1 study and Phase 3 clinical trial supplies.

Step 2: Analytical Characterization and In Vitro Comparability

We accomplished characterization of CHS-1420 and Humira by a multi-dimensional analytical study, demonstrating a high degree of similarity between Humira and CHS-1420. Through extensive biochemical, biophysical and biological analysis we have shown that CHS-1420 has a structure and *in vitro* activity similar to that of Humira with respect to primary sequence (the linear sequence of the amino acids in the protein), protein folding (the structure of the protein in three dimensions which is critical to its biological function) and charge profiles (the overall electrical charge characteristic of the protein resulting from the electrical charges of its constituent amino acids), as well as the protein's glycosylation profile and potency.

We have also shown CHS-1420 to be highly similar to Humira through *in vitro* receptor binding studies, specifically in its ability to inhibit TNF-α mediated cell death. In all of these studies we demonstrated CHS-1420 to have similar pharmacological activity to Humira by evaluating the binding of both CHS-1420 and Humira to Fc receptors, complement (C1q) and Fc-mediated functional activities: ADCC and CDC.

Step 3: In Vivo Animal Comparability

We conducted two nonclinical studies in monkeys in order to compare the PK and nonclinical safety profile of CHS-1420 to Humira. Following one month of repeat dosing, we determined the pharmacokinetics of CHS-1420 to be similar to that of Humira.

Step 4: Pivotal Phase 1 Human Pharmacokinetic and Pharmacodynamic Study

In April 2014, we initiated a Phase 1 pivotal PK study in human subjects. This is a single dose, double-blind parallel group study designed to demonstrate bioequivalence between CHS-1420 and Humira. A secondary objective was to assess the safety and tolerability of CHS-1420 in this population. The study has been successfully completed and met the primary endpoint and demonstrated bioequivalence with respect to the three prospectively defined PK endpoints. CHS-1420 and Humira were both well tolerated in this single-dose study in healthy adult volunteers.

We initiated a Phase 1 PK bridging studies comparing our Phase 3 material to U.S. manufactured Humira in the first quarter of 2016 and plan to initiate a Phase 1 bridging study to E.U. manufactured Humira in mid-2016.

Step 5: Phase 3 Confirmatory Safety and Efficacy Clinical Trials

In August 2015, we initiated a multi-center, global, randomized, double-blind, active-controlled, Phase 3 clinical trial in psoriasis that plans to enroll approximately 500 subjects. This study would be considered the primary confirmatory safety and efficacy study to support a registration filing.

Ophthalmology Pipeline Opportunity

CHS-3351 (Our Ranibizumab (Lucentis) Biosimilar Candidate)

Ranibizumab is a monoclonal antibody fragment (Fab) created from the same parent mouse antibody as bevacizumab and produced through a microbial culture. It is an anti-angiogenic that has been first approved to treat age-related wet macular degeneration, or AMD. Like bevacizumab, ranibizumab blocks angiogenesis by inhibiting VEGF-A.

Ranibizumab achieved approximately $4.3 billion in worldwide sales in 2014, and is expected to decrease to approximately $3 billion in 2020, when the composition of matter patent on ranibizumab expires in the United States. We selected ranibizumab (Lucentis) as the biosimilar development target for our biosimilar, CHS-3351, to leverage the analytics deployed on bevacizumab and because we could address a concentrated market where we can focus resources and establish a therapeutic franchise.

Current Development Status and Data

Step 1: Cell Line Development and Manufacturing

We have identified the amino acid sequence of CHS-3351 and confirmed that it is identical to the reference product, Lucentis. We are currently establishing Master Cell Banks, or MCBs, as well as Working Cell Banks, or WCBs. We are currently transferring the manufacturing process to a US CMO for production of material to supply toxicology studies and clinical trials.

Early-Stage Biosimilar Pipeline

Beyond the products we are currently advancing, there is significant value in the biosimilar product development platform we have built. With the same rigorous discipline we have put in place to develop our current clinical portfolio, we have created a repeatable process that we believe will accelerate new products through our pipeline and create long term value.

We are continuously performing a product opportunity review of additional biosimilar pipeline candidates in conjunction with our scientific advisory board and we plan to submit one or two new investigational new drug (IND) applications per year.

Sales and Marketing

Our strategy entails licensing product rights outside of the United States to commercially proficient entities, while retaining U.S. rights to commercialization. Because the sales call points for our clinical stage assets in the United States are highly concentrated and addressable by a relatively small commercial organization, the preservation of U.S. rights allows us the flexibility to cost effectively build our own commercial capability should we determine that to be the most effective path. For example, the majority of Humira prescriptions flow through rheumatology physicians, the smallest prescribing set in the category. In the circumstance of a collaboration model outside of the United States involving a joint governance structure, a strategic marketing capability will be employed to provide decision support to the collaboration.

Manufacturing

We have entered into agreements with several CMOs for the manufacture and clinical drug supply for our lead products candidates. We continue to screen other contract manufacturers to meet our clinical, commercial and regulatory supply requirements on a product-by-product basis. In December 2015, we entered into a strategic commercial supply agreement with KBI Biopharma for the supply of CHS-1701. For a discussion of risks related to our sources and availability of supplies, please see “Risk Factors — Risks Related to our Ability to Hire Highly Qualified Personnel and our Reliance on Third Parties.”

Competition

The development and commercialization of protein-based therapeutics is highly competitive. While we believe that our biologics platform, knowledge, experience and scientific resources provide us with competitive advantages, we face potential competition from many different sources. Such competition includes larger and better-funded pharmaceutical, generic pharmaceutical, specialty pharmaceutical and biotechnology companies, as well as originator companies and any other firms developing the biosimilars that would compete with the product candidates in our pipeline and other novel products with similar indications. For example, CHS-0214 may compete with products developed by Pfizer, Inc., or Pfizer, (which holds ex-North America rights to Enbrel, the reference product of CHS-0214), Sandoz (as a biosimilar company) and Samsung Bioepis Co Ltd., or Samsung Bioepis. Similarly, CHS-1420 may face competition from AbbVie (the holder of rights to Humira, the reference product of CHS-1420), Sandoz (as a biosimilar company), Amgen, Actavis, Plc, or Actavis, Pfizer, Momenta Pharmaceuticals, Inc., or Momenta, and Boehringer Ingelheim (as biosimilar companies and as developers of novel products). CHS-1701 may face competition from Amgen (which holds rights to Neulasta, the reference product of CHS-1701), Sandoz (as a biosimilar company), Apotex Inc., or Apotex, and Hospira and Teva (as developers of novel products).

Many of our competitors, either alone or with their strategic partners, have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of treatments and commercializing those treatments. Accordingly, our competitors may be more successful than we are in obtaining approval for treatments and achieving widespread market acceptance. Our competitors' treatments may be more effective or more effectively marketed and sold than any treatment we may commercialize and may render our treatments obsolete or non-competitive before we can recover the expenses of developing and commercializing any of our product candidates.

Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical study sites and subject registration for clinical studies, as well as in acquiring technologies complementary to or necessary for our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

We expect any products that we develop and commercialize to compete on the basis of, among other things, efficacy, safety, price and the availability of reimbursement from government and other third-party payors. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

Collaboration and License Agreements

License Agreement with Daiichi Sankyo Company, Limited

In January 2012, we entered into a license agreement with Daiichi Sankyo for the development and commercialization of certain biosimilar products in certain territories. Under this agreement, we granted to Daiichi Sankyo an exclusive, royalty-bearing license to develop, commercialize and use biosimilar versions of etanercept (Enbrel) and rituximab (Rituxan) for the treatment of human diseases and conditions in Japan, Taiwan and South Korea. Under this agreement, Daiichi Sankyo has an option, exercisable only within a certain time period, to obtain an exclusive license to develop and commercialize certain biosimilar products in China. Daiichi Sankyo also has an option, exercisable at any time during the term of the agreement, to obtain a license to manufacture licensed products to support development and commercialization of licensed products in the licensed territory, on a product-by-product basis. Prior to Daiichi Sankyo's exercise of its manufacturing option, we are responsible for manufacturing and supplying to Daiichi Sankyo licensed products pursuant to a manufacturing and supply agreement to be entered under the terms of this agreement.

In May 2012, Daiichi Sankyo terminated its licensed rights, solely as to CHS-0214, in Taiwan and South Korea. In August 2012, Daiichi Sankyo declined its right to expand the territory to include China. In July 2014, Daiichi Sankyo terminated all of its licensed rights to a biosimilar rituximab product.

Upon execution of the agreement, we received an upfront payment in cash of $10.0 million and $20.0 million in the form of an equity investment. We are eligible to receive from Daiichi Sankyo tiered royalties based on a percentage of net sales of licensed products in the licensed territory ranging from the low double digits to high teens, on a product-by-product basis. If we are manufacturing product, we are eligible to receive an incremental royalty reflecting our manufacturing costs for each licensed product which, when combined with the base royalty, will result in royalties equal to a percentage of net sales of licensed products ranging from the low- to high-twenties, on a product-by-product basis.

Our agreement with Daiichi Sankyo will expire on a product-by-product and country-by-country basis ten years after receipt of regulatory approval for such product in such country, subject to possible three-year extensions at Daiichi Sankyo's sole discretion, if Daiichi Sankyo is then manufacturing the relevant product, or otherwise by mutual agreement of the parties, based on the approval of a commercial plan in the year before such extension would take effect. Either party may terminate the agreement for any material breach by the other party that is not cured within a specified time period. Prior to commercialization, Daiichi Sankyo may terminate the agreement on a product-by-product and country-by-country basis within specific time periods after achieving certain development milestones only if Daiichi Sankyo concludes, in good faith, that the product is not commercially viable, that there are material safety, efficacy or tolerability issues that cannot be overcome or that there would be difficulties caused by internal or portfolio reasons. After commencement of commercialization, Daiichi Sankyo may terminate the agreement on a product-by-product and country-by-country basis with one year's prior written notice to us only if Daiichi Sankyo concludes, in good faith, that the product is not commercially viable, that there are material safety, efficacy or tolerability issues that cannot be overcome or that there are difficulties caused by internal or portfolio reasons. Either party may terminate the agreement upon bankruptcy or insolvency of the other party, and we may terminate the agreement if Daiichi Sankyo challenges the licensed patents.

License Agreement with Baxalta Incorporated, Baxalta US Inc., and Baxalta GmbH

In August 2013, we entered into a license agreement with Baxter (now Baxalta) for the development, use and commercialization of a biosimilar version of etanercept (Enbrel). Under this agreement, we granted to Baxalta an exclusive, royalty-bearing license to develop, commercialize and use a biosimilar version of etanercept (Enbrel) for the treatment of human diseases and conditions worldwide, excluding the United States, Japan and certain Caribbean and Latin American countries. Under this agreement, Baxalta has the exclusive, time-limited right to negotiate and enter into a definitive agreement with a third party relating to the commercialization of the licensed product in an additional, specified country. If Baxalta fails to do so within the specified time period, we will obtain a right to pursue such an agreement for such product in such country as well. Baxalta may also elect to enter into an agreement with us for the development and commercialization of an additional biosimilar product. Additionally, if Baxalta decides not to proceed with development of the licensed product solely based on certain clinical results failing to demonstrate pharmacokinetic bioequivalence, material safety issues with the licensed product based on such clinical results that cannot be remedied or overcome or the identification of violations by third party vendors of applicable laws relating to quality of licensed products that in the aggregate would preclude the ability of such vendors to qualify under Baxalta's standard vendor qualification policies and procedures, then Baxalta has the right to identify up to two additional biosimilar products for which Baxalta would have a right of first refusal or the right to negotiate a term sheet for development and commercialization of such additional products at Baxalta's election. We are responsible for the manufacture and supply of licensed product pursuant to a manufacturing agreement to be entered into under the terms of this Agreement.

Upon execution of the license agreement, we received an upfront payment in cash of $30.0 million. We are eligible to receive from Baxalta tiered royalties, based on the manufacturing cost as a percentage of net sales of licensed products, ranging from the mid-single digits to the high teens on a country-by-country basis. These royalties are subject to certain offsets and reductions. We are also eligible to receive milestone payments for achievement of specified development and regulatory milestones totaling up to $216.0 million. In February 2014, we amended the license agreement to increase the eligible milestone payments by $5.3 million to an aggregate amount of $221.3 million. Contingent payments intended to cover development-related expenses are potentially reimbursable, in part, to Baxalta in certain limited circumstances. The amounts that are potentially reimbursable to Baxalta contain a claw-back feature that, in the event that we commercialize a biosimilar version of etanercept (Enbrel) in the United States, as opposed to Baxalta opting-in to commercialize the molecule in the United States, fifty percent (50%) of those contingent payments are refundable to Baxalta.

In April 2015, we entered into a second amendment (the "Second Amendment") to the license agreement with Baxalta . Under the terms of the Second Amendment, a revised milestone payment structure totaling $130.0 million replaced certain existing milestone and funding obligations under the license agreement as originally executed. Therefore, we are eligible to receive up to $335.3 million in milestones payments for achievement of specific development and regulatory milestones. The Second Amendment does not provide for any change in the contracted deliverables set forth in the license agreement. Likewise, if we commercialize CHS-0214, our etanercept biosimilar product, in the United States, we will be required to refund a portion of the milestone payments received from Baxalta as specified in the Second Amendment. A portion of each of the $130.0 million milestones would be subject to refund.

Our agreement with Baxalta will expire in its entirety ten years from August 2013, subject to possible three-year extensions on a country-by-country basis at Baxalta's discretion provided the parties have agreed upon a commercialization plan for such country at least six months prior to the date upon which the term would otherwise expire in such country. Either party may terminate the agreement for any material breach by the other party that is not cured within a specified time period. Baxalta may terminate the agreement in its entirety or on a country-by-country basis on written notice to us within specified time periods if Baxalta concludes in good faith that the product is not commercially viable or that there are material safety, efficacy or tolerability issues that cannot be overcome. Baxalta may also terminate the agreement in its entirety in Baxalta's sole discretion after first commercial sale upon 18 months prior written notice or if certain types of costs for which it is responsible exceed specified levels. Either party may terminate the agreement upon bankruptcy or insolvency of the other party, and we may terminate the agreement if Baxalta challenges the licensed patents.

Distribution Agreement with Orox Pharmaceuticals B.V.

In December 2012, we entered into a distribution agreement with Orox Pharmaceuticals B.V., or Orox, for the commercialization of biosimilar versions of etanercept (Enbrel), rituximab (Rituxan), adalimumab (Humira) and pegfilgrastim (Neulasta). Under this agreement, we granted to Orox an exclusive license to commercialize the products for the treatment of human diseases and conditions in certain Caribbean and Latin American countries. Under this agreement, Orox has an option, exercisable within a defined time period, to obtain an exclusive license to commercialize certain additional biosimilar products in the same field and territory. We are obligated to manufacture and supply licensed products to Orox.

We are obligated to develop licensed products and achieve regulatory approval for such products outside of the Caribbean and Latin American countries covered by the agreement by specified dates in order to support Orox's activities under the agreement in its licensed territory. We are eligible to receive from Orox a share of gross profits in the low 20 percent range from the sale of licensed products, on a product-by-product basis.

Our agreement with Orox will expire on a product-by-product and country-by-country basis ten years after regulatory approval of such product in such country, subject to automatic three-year extensions unless Orox notifies us in writing at least 18 months in advance of the date upon which the term would otherwise expire that it does not wish to extend the term for such product in such country. Either party may terminate the agreement for material breach by the other party that is not cured within a specified time period. Orox may terminate the Agreement for convenience on a product-by-product basis at any time upon 12-months prior written notice. Either party may terminate the agreement upon bankruptcy or insolvency of the other party, and we may terminate the agreement immediately upon written notice to Orox if Orox challenges the licensed patents or commits a breach of specified provisions of the agreement.

License Agreement with Genentech, Inc.

In July 2013, we entered into a license agreement with Genentech, under which we obtained a royalty-bearing, non-exclusive, sublicensable license under a family of patents, commonly referred to as the Cabilly patents, to manufacture, use and commercialize products containing antibodies that bind to TNF- α. In consideration for the rights granted to us under the agreement, we made a cash up-front payment to Genentech and are required to make a payment of $5.0 million based upon achievement of a regulatory milestone. We will also be required to pay tiered royalties on net sales of products covered by the in-licensed patents ranging from the low- to mid-single digits.

We may terminate the agreement at any time upon sixty days prior written notice to Genentech. Genentech may terminate the agreement for any material breach by us that is not cured within a specified time period or in the event of our insolvency. Genentech may also terminate the agreement if we challenge the licensed patents. Absent earlier termination, the agreement with Genentech will expire on a country-by-country basis on the expiration of the last valid patent claim.

License Agreements with Selexis SA

In April 2011 and June 2012, we entered into license agreements with Selexis SA, or Selexis, under which Selexis granted to us royalty-bearing, non-exclusive, sublicensable licenses under Selexis's intellectual property rights to manufacture, use and commercialize two of our biosimilar products using Selexis cell lines. In consideration for the rights granted to us under the agreements, we made cash upfront payments to Selexis and are required to make payments based upon the achievement of certain development, regulatory and commercial milestones for such biosimilar products, totaling up to €210,000 for each of the two products, or a total aggregate amount of €420,000. In addition, we are also required to pay a royalty as a percentage of revenue on a product-by-product and country-by-country basis in the low-single digits.

We may terminate each agreement at any time upon sixty days written notice to Selexis. Either we or Selexis may terminate an agreement for any material breach by the other party that is not cured within a specified time period or in the event of the other party's insolvency. Absent earlier termination, the agreements with Selexis terminate on a country-by-country and product-by-product basis on the expiration of the last-to-expire or lapse of the valid patent claims covering such product in such country.

Intellectual Property

Our commercial success depends in part on our ability to avoid infringing the proprietary rights of third parties, our ability to obtain and maintain proprietary protection for our technologies where applicable and to prevent others from infringing our proprietary rights. We seek to protect our proprietary technologies by, among other methods, filing U.S. and international patent applications on these technologies, inventions and improvements that are important to our business. We also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary position.

The term of individual patents depends upon the legal term of the patents in countries in which they are obtained. In most countries, including the United States, the patent term is generally 20 years from the earliest date of filing a non-provisional patent application in the applicable country. In the United States, a patent's term may, in certain cases, be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the United States Patent and Trademark Office in examining and granting a patent or may be shortened if a patent is terminally disclaimed over a commonly owned patent or a patent naming a common inventor and having an earlier expiration date.

In the normal course of business, we pursue patent protection for inventions related to our biosimilar product candidates, including protein manufacture and formulation inventions. We are owners of a portfolio of issued and pending patent applications, all of which pertain to our product candidates. We have 157 pending patent applications, and one issued patent, the United States and in other countries covering formulations and manufacture of CHS-0214, which if granted are expected to expire in 2032, 2033 and 2035. We have 35 pending patent applications in the United States and in other countries covering CHS-1420, which if granted are expected to expire in 2033, 2035, and 2036.

We have non-exclusive licenses from Selexis under patents and patent applications granted or filed in the United States and other countries that cover Selexis's recombinant cell line technology in two families. One family of patents is directed to methods for transfecting eukaryotic cells with nucleic acid vectors using Matrix Attachment Regions, or MARs, elements to increase stable and transient transfection efficiency. The second family of patents is related to purified and isolated DNA sequences having protein production increasing activity and to the use of MARs for increasing protein production activity in a eukaryotic cell. The licensed patents are expected to expire between 2023 and 2026.

We have a non-exclusive license from Genentech under two U.S. patents which are commonly known as the "Cabilly" patents. The Cabilly patents cover key steps of therapeutic antibody manufacturing methods. One of the Cabilly patent covers a process for producing an immunoglobulin molecule (Ig) in a single host cell; the second Cabilly patent covers a method for making an antibody heavy chain and antibody light chain in a recombinant host cell. Both licensed patents are expected to expire in December 2018.

To date we have not licensed any patents from Daiichi Sankyo or Baxalta.

We do not know whether any of the pending patent applications described above will result in the issuance of any patents or whether the rights granted under any patents issuing from these applications will prevent any of our competitors from marketing similar products that may be competitive with our own. Moreover, even if we do obtain issued patents, they will not guarantee us the right to use our patented technology for commercialization of our product candidates. Third parties may have blocking patents that could prevent us from commercializing our own products, even if our products use or embody our own, patented inventions.

The validity and enforceability of patents are generally uncertain and involve complex legal and factual questions. Any patents that may issue on our pending applications may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing products similar to ours. Furthermore, our competitors may develop similar or alternative technologies not covered by any patents that may issue to us.

In a merger completed February 12, 2014, we acquired InteKrin Therapeutics Inc., or InteKrin. InteKrin is developing a small molecule peroxisome proliferator-activated receptor, or PPAR, gamma inhibitor, CHS-131 (formerly INT-131), for the treatment of multiple sclerosis which we believe may be complementary with one or more biologic therapeutics for multiple sclerosis we are currently evaluating as a potential candidate for inclusion in our pipeline of biosimilar products. InteKrin is the exclusive licensee of certain U.S. and foreign patents and patent applications owned by Amgen, covering the specific PPAR gamma inhibitor molecule that InteKrin is developing. InteKrin also owns pending patent filings related to this PPAR gamma inhibitor.

InteKrin has an exclusive license from Amgen under 120 patents and patent applications granted or filed in the United States and other countries that cover PPAR gamma inhibitor molecules and therapeutic product compositions that are expected to expire in 2020 and 2021, as well as certain salt forms and polymorphic forms of PPAR gamma inhibitor molecules that are expected to expire in 2024 (with possible Hatch-Waxman patent term extension). Additionally, InteKrin owns 25 patents and patent applications granted or filed in the United States and other countries that cover solid forms of PPAR gamma pharmaceutical compositions, treatment of diabetes, treatment of multiple sclerosis and treatment of non-alcoholic fatty liver disease or lipodystrophy that, if granted, are expected to expire in 2031, 2034 and 2036.

In March 2015, we initiated a proof-of-concept Phase 2 trial in relapsing, remitting multiple sclerosis patients in the Russian Republic. This trial enrolled subjects in three treatment arms of 1 mg, 3mg and placebo with approximately 75 subjects per arm. We anticipate completion of this trial in mid-2016. The trial will continue with an open-label study of 24 weeks.

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

Regulatory

Government Regulation and Product Approval

Government authorities at the federal, state and local level in the United States and in other countries extensively regulate, among other things, the research, development, testing, manufacture, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, import and export of pharmaceutical products such as those we are developing. The processes for obtaining regulatory approvals in the United States and in foreign countries, along with subsequent compliance with applicable statutes and regulations, require the expenditure of substantial time and financial resources.

FDA Approval Process

All of our current product candidates are subject to regulation in the United States by the FDA as biological products, or biologics. The FDA subjects biologics to extensive pre- and post-market regulation. The Public Health Service Act, or PHSA, the Federal Food, Drug and Cosmetic Act, or FFDCA, and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling and import and export of biologics. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending BLAs, withdrawal of approvals, clinical holds, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties or criminal penalties.

The PHSA emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The PHSA also provides authority to the FDA to immediately suspend licenses in situations where there exists a danger to public health, to prepare or procure products in the event of shortages and critical public health needs and to authorize the creation and enforcement of regulations to prevent the introduction or spread of communicable diseases in the United States and between states.

The process required by the FDA before a new biologic may be marketed in the United States is long, expensive and inherently uncertain. Biologics development in the United States typically involves preclinical laboratory and animal tests, the submission to the FDA of an investigational new drug, or IND, which must become effective before clinical testing may commence and adequate and well-controlled clinical trials to establish the safety and effectiveness of the biologic for each indication for which FDA approval is sought. Developing the data to satisfy FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including good laboratory practices. An IND is a request for authorization from the FDA to administer an investigational new product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for human studies, although the IND must also include the results of preclinical testing and animal testing assessing the toxicology, pharmacokinetics, pharmacology and pharmacodynamic characteristics of the product along with other information, including information about product chemistry, manufacturing and controls and a proposed clinical trial protocol. Long-term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

An IND must become effective before United States clinical trials may begin. A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If during the 30-day waiting period the FDA raises concerns or questions related to the proposed clinical studies, the sponsor and the FDA must resolve any outstanding concerns or questions before clinical studies can begin. If the FDA has neither commented on nor questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin.

Clinical trials involve the administration of the investigational new drug or biologic to healthy volunteers or patients with the condition under investigation, all under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with good clinical practice, or GCP, an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors; as well as (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary or permanent discontinuation of a clinical trial at any time or impose other sanctions if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The study protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board, or IRB, for approval. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements or may impose other conditions. The study sponsor may also suspend a clinical trial at any time on various grounds, including a determination that the subjects or patients are being exposed to an unacceptable health risk.

Abbreviated Licensure Pathway of Biological Products as Biosimilar under 351(k)

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, amended the PHSA and created an abbreviated approval pathway for biological products shown to be highly similar to an FDA-licensed reference biological product. The BPCIA attempts to minimize duplicative testing and thereby lower development costs and increase patient access to affordable treatments. For example, in contrast to the 351(a) (novel biologic) approval pathway discussed above, our experience to date with the FDA indicates that an application for licensure of a biosimilar product under the 351(k) (biosimilar) approval pathway may proceed on the basis of only two clinical study phases (typically termed Phase 1 and Phase 3) with supporting analytical and animal studies, as compared with the requirement for three study phases under the 351(a) (novel biologics) approval pathway. Thus, under the 351(k) (biosimilar) approval pathway, an application for licensure of a biosimilar product must include information demonstrating biosimilarity based upon the following, unless the FDA determines otherwise:

- analytical studies demonstrating that the proposed biosimilar product is highly similar to the approved product notwithstanding minor differences in clinically inactive components;
- animal studies (including the assessment of toxicity); and
- two clinical study phases: first, a clinical study or studies (generally termed "Phase 1") that demonstrate the pharmacokinetic similarity (e.g. bioequivalence study) of the proposed biosimilar to the originator molecule, and second, a clinical study or studies (generally termed "Phase 3") that demonstrate the safety (including immunogenicity), purity and that potency is statistically not inferior to that of the originator in one or more conditions for which the reference product is licensed and intended to be used.

In addition, an application submitted under the 351(k) pathway must include information demonstrating that:

- the proposed biosimilar product and reference product utilize the same mechanism of action for the condition(s) of use prescribed, recommended or suggested in the proposed labeling, but only to the extent the mechanism(s) of action are known for the reference product;
- the condition or conditions of use prescribed, recommended or suggested in the labeling for the proposed biosimilar product have been previously approved for the reference product;

- the route of administration, the dosage form and the strength of the proposed biosimilar product are the same as those for the reference product; and
- the facility in which the biological product is manufactured, processed, packed or held meets standards designed to assure that the biological product continues to be safe, pure and potent.

Biosimilarity, as defined in PHSA §351(i), means that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components and that there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity and potency of the product. In addition, section 351(k)(4) of the PHSA provides for a designation of "interchangeability" between the reference and biosimilar products, whereby the biosimilar may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product. The higher standard of interchangeability must be demonstrated by information sufficient to show that:

- the proposed product is biosimilar to the reference product;
- the proposed product is expected to produce the same clinical result as the reference product in any given patient; and
- for a product that is administered more than once to an individual, the risk to the patient in terms of safety or diminished efficacy of alternating or switching between the biosimilar and the reference product is no greater than the risk of using the reference product without such alternation or switch.

FDA approval is required before a biosimilar may be marketed in the United States. However, complexities associated with the large and intricate structures of biological products and the process by which such products are manufactured pose significant hurdles to the FDA's implementation of the 351(k) approval pathway that are still being worked out by the FDA. For example, the FDA has discretion over the kind and amount of scientific evidence — laboratory, preclinical and/or clinical — required to demonstrate biosimilarity to a licensed biological product. The FDA intends to consider the totality of the evidence, provided by a sponsor to support a demonstration of biosimilarity, and recommends that sponsors use a stepwise approach in the development of their biosimilar products. Biosimilar product applications thus may not be required to duplicate the entirety of preclinical and clinical testing used to establish the underlying safety and effectiveness of the reference product. However, the FDA may refuse to approve a biosimilar application if there is insufficient information to show that the active ingredients are the same or to demonstrate that any impurities or differences in active ingredients do not affect the safety, purity or potency of the biosimilar product. In addition, as with BLAs, biosimilar product applications will not be approved unless the product is manufactured in facilities designed to assure and preserve the biological product's safety, purity and potency.

The submission of an application via the 351(k) pathway does not guarantee that the FDA will accept the application for filing and review, as the FDA may refuse to accept applications that it finds are incomplete. The FDA will treat a biosimilar application or supplement as incomplete if, among other reasons, any applicable user fees assessed under the Biosimilar User Fee Act of 2012 have not been paid. In addition, the FDA may accept an application for filing but deny approval on the basis that the sponsor has not demonstrated biosimilarity, in which case the sponsor may choose to conduct further analytical, preclinical or clinical studies to demonstrate such biosimilarity under section 351(k) or submit a BLA for licensure as a new biological product under section 351(a) of the PHSA. For example, the potential for different regulatory outcomes depending on the selected approval pathway has been illustrated in connection with our development program for CHS-1701. At the outset of our development effort for this product candidate, we elected to proceed under the 351(a) (novel biologic) approval pathway. However, although our Phase 1 PK / PD trial for CHS-1701 met its primary endpoint and was satisfactory for purposes of pursuing the 351(a) (novel biologic) approval pathway (which does not require bioequivalence to the originator drug), the trial did not establish bioequivalence to Neulasta sufficient to support the 351(k) (biosimilar) approval pathway. To preserve the option of pursuing a 351(k) (biosimilar) approval pathway for CHS- 1701, we are making necessary preparations that would enable us to conduct a new pivotal Phase 1 PK / PD study in healthy volunteers, but have not yet made a decision to proceed with this additional study.

The timing of final FDA approval of a biosimilar for commercial distribution depends on a variety of factors, including whether the manufacturer of the branded product is entitled to one or more statutory exclusivity periods, during which time the FDA is prohibited from approving any products that are biosimilar to the branded product. The FDA cannot approve a biosimilar application for 12 years from the date of first licensure of the reference product. Additionally, a biosimilar product sponsor may not submit an application under the 351(k) pathway for four years from the date of first licensure of the reference product. A reference product may also be entitled to exclusivity under other statutory provisions. For example, a reference product designated for a rare disease or condition, or an orphan drug, may be entitled to seven years of exclusivity under section 360cc of the FFDCA, in which case no product that is biosimilar to the reference product may be approved until either the end of the 12-year period provided under §351(k) or the end of the seven year orphan drug exclusivity period, whichever occurs later. In certain circumstances, a regulatory exclusivity period can extend beyond the life of a patent and thus block §351(k) applications from being approved on or after the patent expiration date. In addition, the FDA may under certain circumstances extend the exclusivity period for the reference product by an additional six months if the FDA requests, and the manufacturer undertakes, studies on the effect of its product in children, a so-called pediatric extension.

The first biological product determined to be interchangeable with a branded product for any condition of use is also entitled to a period of exclusivity, during which time the FDA may not determine that another product is interchangeable with the reference product for any condition of use. This exclusivity period extends until the earlier of: (1) one year after the first commercial marketing of the first interchangeable product; (2) 18 months after resolution of a patent infringement suit instituted under 42 U.S.C. § 262(l)(6) against the applicant that submitted the application for the first interchangeable product, based on a final court decision regarding all of the patents in the litigation or dismissal of the litigation with or without prejudice; (3) 42 months after approval of the first interchangeable product, if a patent infringement suit instituted under 42 U.S.C. § 262(l)(6) against the applicant that submitted the application for the first interchangeable product is still ongoing; or (4) 18 months after approval of the first interchangeable product if the applicant that submitted the application for the first interchangeable product has not been sued under 42 U.S.C. § 262(l)(6).

Advertising and Promotion

Once a BLA is approved, a product will be subject to continuing post-approval regulatory requirements, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. For instance, the FDA closely regulates the post-approval marketing and promotion of biologics, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet. Failure to comply with these regulations can result in significant penalties, including the issuance of warning letters directing a company to correct deviations from FDA standards, a requirement that future advertising and promotional materials be pre-cleared by the FDA and federal and state civil and criminal investigations and prosecutions.

Biologics may be marketed only for the approved indications and in accordance with the provisions of the approved labeling. After approval, most changes to the approved product, including changes in indications, labeling or manufacturing processes or facilities, require submission and FDA approval of a new BLA or BLA supplement before the change can be implemented. A BLA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing BLA supplements as it does in reviewing BLAs. There are also continuing annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

Adverse Event Reporting and GMP Compliance

Adverse event reporting and submission of periodic reports are required following FDA approval of a BLA. The FDA also may require post-marketing testing, including Phase 4 testing, REMS and surveillance to monitor the effects of an approved product, or the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, manufacture, packaging, labeling, storage and distribution procedures must continue to conform to current cGMPs after approval. Biologics manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals, request product recalls or impose marketing restrictions through labeling changes or product removals if a company fails to comply with regulatory standards, if it encounters problems following initial marketing or if previously unrecognized problems are subsequently discovered.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency or with manufacturing processes or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications or suspension or revocation of product license approvals;
- product seizure or detention or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

Other Healthcare Laws and Compliance Requirements

Although we currently do not have any products on the market, if our product candidates are approved and we begin commercialization, we will be subject to healthcare regulation and enforcement by the federal government and the states and foreign governments in which we conduct our business. These laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, privacy and security and physician sunshine laws and regulations.

The federal Anti-Kickback Statute prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs. The Anti-Kickback Statute is subject to evolving interpretations. In the past, the government has enforced the Anti-Kickback Statute to reach large settlements with healthcare companies based on sham consulting and other financial arrangements with physicians. Further, the recently enacted Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the PPACA, among other things, amends the intent requirement of the federal Anti-Kickback Statute and the criminal statute governing healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them. In addition, the PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act or federal civil money penalties statute. The majority of states also have anti-kickback laws which establish similar prohibitions and in some cases may apply to items or services reimbursed by any third-party payor, including commercial insurers.

Additionally, the civil False Claims Act prohibits knowingly presenting or causing the presentation of a false, fictitious or fraudulent claim for payment to the U.S. government. Actions under the False Claims Act may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. Violations of the False Claims Act can result in very significant monetary penalties and treble damages. The federal government is using the False Claims Act, and the accompanying threat of significant liability, in its investigation and prosecution of pharmaceutical and biotechnology companies throughout the country, for example, in connection with the promotion of products for unapproved uses and other sales and marketing practices. The government has obtained multi-million and multi-billion dollar settlements under the False Claims Act in addition to individual criminal convictions under applicable criminal statutes. Given the significant size of actual and potential settlements, it is expected that the government will continue to devote substantial resources to investigating healthcare providers' and manufacturers' compliance with applicable fraud and abuse laws.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians and other healthcare providers. The PPACA, among other things, imposes new reporting requirements on drug manufacturers for payments made by them to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to submit required information may result in civil monetary penalties of up to an aggregate of $150,000 per year (or up to an aggregate of $1 million per year for "knowing failures"), for all payments, transfers of value or ownership or investment interests that are not timely, accurately and completely reported in an annual submission. Drug manufacturers were required to begin collecting data on August 1, 2013 and submit reports on aggregate payment data to the government for the first reporting period (August 1, 2013 — December 31, 2013) by March 31, 2014 and to report detailed payment data for the first reporting period and submit legal attestation to the accuracy of such data by June 30, 2014. Thereafter, drug manufacturers must submit reports by the 90th day of each subsequent calendar year. Certain states also mandate implementation of commercial compliance programs, impose restrictions on pharmaceutical manufacturer marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to physicians.

The shifting commercial compliance environment and the need to build and maintain robust systems to comply with different compliance and/or reporting requirements in multiple jurisdictions increase the possibility that a healthcare company may violate one or more of the requirements. If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to operate our business and our financial results.

International Regulation

In addition to regulations in the United States, a variety of foreign regulations govern clinical trials, commercial sales and distribution of product candidates. The approval process varies from country to country and the time to approval may be longer or shorter than that required for FDA approval. In Europe, the approval of a biosimilar for marketing is based on an opinion issued by the European Medicines Agency and a decision issued by the European Commission. However, substitution of a biosimilar for the originator is a decision that is made at the local (national) level on a country-by-country basis. Additionally, a number of European countries do not permit the automatic substitution of biosimilars for the originator product. Other regions, including Canada, Japan and Korea, also have their own legislation outlining a regulatory pathway for the approval of biosimilars. In some cases, other countries have either adopted European guidance (Singapore and Malaysia) or are following guidance issued by the World Health Organization (Cuba and Brazil). While there is overlap in the regulatory requirements across regions, there are also still some areas of non-overlap.

Pharmaceutical Coverage, Pricing and Reimbursement

In the United States and other countries, sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of coverage and reimbursement from third-party payors, including government health administrative authorities, managed care providers, private health insurers and other organizations. Third-party payors are increasingly examining the medical necessity and cost effectiveness of medical products and services in addition to safety and efficacy and, accordingly, significant uncertainty exists as to the reimbursement status of newly approved therapeutics. In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures and adoption of more restrictive policies in jurisdictions with existing controls and measures could further limit our net revenue and results. Decreases in third-party reimbursement for our product candidates or a decision by a third-party payor to not cover our product candidates could reduce physician utilization of our products and have a material adverse effect on our sales, results of operations and financial condition.

Employees

As of December 31, 2015, we had 109 full-time employees, including a total of 24 employees with M.D. or Ph.D. degrees. Within our workforce, 76 employees are engaged in research and development and 33 in business development, finance, legal, human resources, facilities, information technology and general management and administration.

Corporate and Available Information

We were incorporated in Delaware in 2010. We completed the initial public offering of our common stock in November 2014. Our common stock is currently listed on The NASDAQ Global Market under the symbol “CHRS.”

Our principal executive offices are located at 333 Twin Dolphin Drive, Suite 600, Redwood City, CA 94065, and our telephone number is (650) 649-3530.

You may find on our website at http://www.coherus.com electronic copies of our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934. Such filings are placed on our website as soon as reasonably possible after they are filed with the SEC. Our most recent charter for our audit, compensation, and nominating and corporate governance committees and our Code of Ethics are available on our website as well. Any waiver of our Code of Ethics may be made only by our Board of Directors. Any waiver of our Code of Ethics for any of our directors or executive officers must be disclosed on a Current Report on Form 8-K within four business days, or such shorter period as may be required under applicable regulation.

You can read our SEC filings over the Internet at the SEC's web site at www.sec.gov. You may also read and copy any document we file with the SEC at its public reference facilities at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You may also obtain copies of the documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. Please call the SEC at (202) 551-8090 or (800) 732-0330 for further information on the operation of the public reference facilities.

Item 1A. *Risk Factors*

You should consider carefully the risks and uncertainties described below, together with all of the other information in this Annual Report on Form 10-K. If any of the following risks are realized, our business, financial condition, results of operations and prospects could be materially and adversely affected. The risks described below are not the only risks facing the Company. Risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition, results of operations and/or prospects.

Risks Related to Our Financial Condition and Capital Requirements

We have a limited operating history in an emerging regulatory environment on which to assess our business, have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future.

We are a biopharmaceutical company with a limited operating history in an emerging regulatory environment. We have incurred net losses in each year since our inception in September 2010, including net losses of $223.9 million, $87.2 million and $53.6 million for the years ended December 31, 2015, 2014 and 2013, respectively. As of December 31, 2015, we had an accumulated deficit of $410.0 million.

We have devoted substantially all of our financial resources to identify and develop our product candidates, including conducting, among other things, analytical characterization, process development and manufacturing, formulation and clinical studies, and providing general and administrative support for these operations. To date, we have financed our operations primarily through the sale of equity securities and convertible notes, as well as through our license agreements with Baxalta Incorporated, Baxalta US Inc., and Baxalta GmbH (collectively "Baxalta"), and Daiichi Sankyo Company, Limited, or Daiichi Sankyo. In the second quarter of 2015, Baxalta assigned its rights and obligations under our license agreement to Baxalta. The amount of our future net losses will depend, in part, on the rate of our future expenditures and our ability to obtain funding through equity or debt financings or strategic collaborations. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We are in Phase 3 or other BLA-enabling clinical development with all three of our lead products, CHS-0214 (our etanercept (Enbrel) biosimilar candidate), CHS-1420 (our adalimumab (Humira) biosimilar candidate) and CHS-1701 (our pegfilgrastim (Neulasta) biosimilar candidate). It may be several years, if ever, before we complete Phase 3 or other BLA-enabling clinical trials and have a product candidate ready to file for market approval with the relevant regulatory agencies. If we obtain regulatory approval to market a biosimilar product candidate, our future revenue will depend upon the size of any markets in which our product candidates may receive approval and our ability to achieve sufficient market acceptance, pricing, reimbursement from third-party payors and adequate market share for our product candidates in those markets. However, even if one or more of our product candidates gain regulatory approval and are commercialized, we may never become profitable.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We anticipate that our expenses will increase substantially if and as we:

- continue our nonclinical and clinical development of our product candidates;
- expand the scope of our current clinical studies for our product candidates;
- advance our programs into more expensive clinical studies;
- initiate additional nonclinical, clinical or other studies for our product candidates;
- change or add contract manufacturers, clinical research service providers, testing laboratories, device suppliers, legal service providers or other vendors or suppliers;
- seek regulatory and marketing approvals for our product candidates that successfully complete clinical studies;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- seek to identify, assess, acquire and/or develop other biosimilar product candidates or products that may be complementary to our products;

- make upfront, milestone, royalty or other payments under any license agreements;
- seek to create, maintain, protect and expand our intellectual property portfolio;
- engage legal counsel and technical experts to help us evaluate and avoid infringing any valid and enforceable intellectual property rights of third parties;
- engage in litigation including patent litigation and Inter Partes Reviews ("IPR's") with originator companies or others that may hold patents;
- seek to attract and retain skilled personnel;
- create additional infrastructure to support our operations as a public company and our product development and planned future commercialization efforts; and
- experience any delays or encounter issues with any of the above, including but not limited to failed studies, conflicting results, safety issues, manufacturing delays, litigation or regulatory challenges that may require longer follow-up of existing studies, additional major studies or additional supportive studies in order to pursue marketing approval.

Further, the net losses we incur may fluctuate significantly from quarter-to-quarter and year-to-year such that a period-to-period comparison of our results of operations may not be a good indication of our future performance quarter-to-quarter and year-to-year due to factors including the timing of clinical trials, any litigation that we may initiate or that may be initiated against us, the execution of collaboration, licensing or other agreements and the timing of any payments we make or receive thereunder.

We have never generated any revenue from product sales and may never be profitable.

Although we have received upfront payments, milestone and other contingent payments and/or funding for development from some of our collaboration and license agreements (e.g., Baxalta and Daiichi Sankyo), we have no products approved for commercialization and have never generated any revenue from product sales. Our ability to generate revenue and achieve profitability depends on our ability, alone or with strategic collaboration partners, to successfully complete the development of, and obtain the regulatory and marketing approvals necessary to commercialize, one or more of our product candidates. We cannot predict when we will begin generating revenue from product sales, as this depends heavily on our success in many areas, including but not limited to:

- attracting, hiring and retaining qualified personnel;
- completing nonclinical and clinical development of our product candidates;
- developing and testing of our product formulations;
- obtaining regulatory and marketing approvals for product candidates for which we complete clinical studies;
- developing a sustainable and scalable manufacturing process for any approved product candidates and establishing and maintaining supply and manufacturing relationships with third parties that can conduct the process and provide adequate (in amount and quality) products to support clinical development and the market demand for our product candidates, if approved;
- launching and commercializing product candidates for which we obtain regulatory and marketing approval, either directly or with collaboration partners or distributors;
- obtaining adequate third-party coverage and reimbursements for our products;
- obtaining market acceptance of our product candidates as viable treatment options;
- addressing any competing technological and market developments;
- identifying, assessing and developing (or acquiring/in-licensing) new product candidates;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how; and
- defending against any litigation including patent infringement lawsuits, that may be filed against us; or achieving successful outcomes in IPR's that we have filed, or may in the future file, against third parties.

Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs to commercialize any such product. Our expenses could increase beyond our expectations if we are required by the U.S. Food and Drug Administration, or the FDA, the European Medicines Agency, or the EMA, other regulatory agencies, domestic or foreign, or by any unfavorable outcomes in intellectual property litigation filed against us, to change our manufacturing processes or assays or to perform clinical, nonclinical or other types of studies in addition to those that we currently anticipate. In cases where we are successful in obtaining regulatory approvals to market one or more of our product candidates, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the number of biosimilar competitors in such markets, the accepted price for the product, the ability to get reimbursement at any price, the nature and degree of competition from originators and other biosimilar companies (including competition from large pharmaceutical companies entering the biosimilar market that may be able to gain advantages in the sale of biosimilar products based on brand recognition and/or existing relationships with customers and payors) and whether we own (or have partnered) the commercial rights for that territory. If the market for our product candidates (or our share of that market) is not as significant as we expect, the indication approved by regulatory authorities is narrower than we expect or the reasonably accepted population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. If we are unable to successfully complete development and obtain regulatory approval for our products, our business may suffer. Additionally, if we are not able to generate revenue from the sale of any approved products, we may never become profitable.

We expect that we will need to raise substantial additional funding. This additional funding may not be available on acceptable terms or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development efforts or other operations.

We are currently advancing three product candidates through late-stage clinical development, which is expensive.

As of December 31, 2015, our cash and cash equivalents were $158.2 million. We expect that our existing cash and cash equivalents, together with gross proceeds of $100.0 million received in February 2016 from the issuance of convertible debt and funding we expect to receive under our license agreements with Daiichi Sankyo and Baxalta, will be sufficient to fund our current operations for at least the next 12 months; however, we will require additional capital to obtain regulatory approval for, and to commercialize, our product candidates. In addition, our operating plans may change as a result of many factors that may currently be unknown to us, and we may need to seek additional funds sooner than planned. Our future funding requirements will depend on many factors, including but not limited to:

- the scope, rate of progress, results and cost of our clinical studies, nonclinical testing and other related activities;
- the cost of manufacturing clinical supplies and establishing commercial supplies, of our product candidates and any products that we may develop;
- the number and characteristics of product candidates that we pursue;
- the cost, timing and outcomes of regulatory approvals;
- the cost and timing of establishing sales, marketing and distribution capabilities;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish, including any milestone and royalty payments thereunder; and
- the cost, timing and outcomes of any litigation that we may file or that may be filed against us by third parties.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders, and the issuance of additional securities, whether equity or debt, by us or the possibility of such issuance may cause the market price of our shares to decline. The sale of additional equity or convertible securities would dilute the share ownership of our existing stockholders. The incurrence of indebtedness could result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborative partners or otherwise at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or for specific strategic considerations.

If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or the commercialization of any product candidates or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our financial condition and results of operations.

Risks Related to the Discovery and Development of Our Product Candidates

We are heavily dependent on the clinical success, regulatory approval and commercial success of our product candidates. We cannot give any assurance that any of our product candidates will receive regulatory approval, which is necessary before they can be commercialized.

To date, we have invested substantially all of our efforts and financial resources to identify, acquire and develop our product candidates. Our future success is dependent on our ability to develop, obtain regulatory approval for, and then commercialize and obtain adequate third party coverage and reimbursement for one or more product candidates. We currently do not have any approved products and generate no revenue from sales of any products, and we may never be able to develop or commercialize a marketable product.

Our product candidates are in varying stages of development and will require additional clinical development, management of nonclinical, clinical and manufacturing activities, regulatory approval, adequate manufacturing supplies, commercial organization and significant marketing efforts before we generate any revenue from product sales. CHS-1701, CHS-0214 and CHS-1420 have entered Phase 3 or BLA-enabling clinical development.

Our clinical trials must use originator products as comparators, and such supplies may not be available on a timely basis to support such trials.

Although certain of our employees have prior experience with submitting marketing applications to the FDA or comparable foreign regulatory authorities, neither we nor our collaboration partners have submitted such applications for our product candidates. We cannot be certain that any of our product candidates will be successful in clinical trials or receive regulatory approval. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials. If we and our collaboration partners do not receive regulatory approvals for our product candidates, we may not be able to continue our operations.

We, together with our collaboration partners, generally plan to seek regulatory approval to commercialize our product candidates in the United States, the European Union, or E.U., and in additional foreign countries where we or our partners have commercial rights. To obtain regulatory approval, we and our collaboration partners must comply with numerous and varying regulatory requirements of such countries regarding safety, efficacy, chemistry, manufacturing and controls, clinical studies, commercial sales and pricing and distribution of our product candidates. Even if we and our collaboration partners are successful in obtaining approval in one jurisdiction, we cannot ensure that we will obtain approval in any other jurisdictions. If we and our collaboration partners are unable to obtain approval for our product candidates in multiple jurisdictions, our revenue and results of operations could be negatively affected.

The regulatory approval processes of the FDA, EMA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and the regulatory approval requirements for biosimilars are evolving. If we and our collaboration partners are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The research, development, testing, manufacturing, labeling, packaging, approval, promotion, advertising, storage, marketing, distribution, post-approval monitoring and reporting and export and import of biologic products are subject to extensive regulation by the FDA and other regulatory authorities in the United States, by the EMA and EEA Competent Authorities in the European Economic Area, or EEA, and by other regulatory authorities in other countries, which regulations differ from country to country. Neither we nor any collaboration partner is permitted to market our product candidates in the United States until we and our collaboration partners receive approval from the FDA, or in the EEA until we and our collaboration partners receive E.U. Commission or EEA Competent Authority approvals.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable, may take many years following the completion of clinical studies and depends upon numerous factors. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. Neither we nor any collaboration partner has obtained regulatory approval for any of our product candidates, and it is possible that none of our current or future product candidates will ever obtain regulatory approval.

Applications for our product candidates could fail to receive regulatory approval for many reasons, including but not limited to the following:

- the data collected from clinical studies of our product candidates may not be sufficient to support the submission of a BLA, a biosimilar product application under the 351(k) pathway of the Public Health Service Act, or PHSA, a biosimilar marketing authorization under Article 6 of Regulation (EC) No. 726/2004 and/or Article 10(4) of Directive 2001/83/EC in the EEA or other submission or to obtain regulatory approval in the United States, the EEA or elsewhere;
- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical studies;
- the population studied in the clinical program may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from analytical and bioanalytical studies, nonclinical studies or clinical studies;
- we may be unable to demonstrate to the FDA or comparable foreign regulatory authorities that a product candidate's risk-benefit ratio for its proposed indication is acceptable;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This approval process, as well as the unpredictability of the results of clinical studies, may result in our failure to obtain regulatory approval to market any of our product candidates, which would significantly harm our business. Any delays in the commencement or completion of clinical testing could significantly impact our product development costs and could result in the need for additional financing.

If we are not able to demonstrate biosimilarity of our biosimilar product candidates to the satisfaction of regulatory authorities, we will not obtain regulatory approval for commercial sale of our biosimilar product candidates and our future results of operations would be adversely affected.

Our future results of operations depend, to a significant degree, on our ability to obtain regulatory approval for and to commercialize our proposed biosimilar products. To obtain regulatory approval for the commercial sale of these product candidates, we will be required to demonstrate to the satisfaction of regulatory authorities, among other things, that our proposed biosimilar products are highly similar to biological reference products already licensed by the regulatory authority pursuant to marketing applications, notwithstanding minor differences in clinically inactive components, and that they have no clinically meaningful differences as compared to the marketed biological products in terms of the safety, purity and potency of the products. Each individual jurisdiction may apply different criteria to assess biosimilarity, based on a preponderance of the evidence that can be interpreted subjectively in some cases. In the EEA, the similar nature of a biosimilar and a reference product is demonstrated by comprehensive comparability studies covering quality, biological activity, safety and efficacy.

It is uncertain if regulatory authorities will grant the full originator label to biosimilar product candidates when they are approved. For example, an infliximab (Remicade) biosimilar molecule was approved in Europe for the full originator label but did not receive the full originator label when approved in Canada. A similar outcome could occur with respect to one or more of our product candidates.

In the event that regulatory authorities require us to conduct additional clinical trials or other lengthy processes, the commercialization of our proposed biosimilar products could be delayed or prevented. Delays in the commercialization of or the inability to obtain regulatory approval for these products could adversely affect our operating results by restricting or significantly delaying our introduction of new biosimilars.

The structure of complex proteins used in protein-based therapeutics is inherently variable and highly dependent on the processes and conditions used to manufacture them. If we are unable to develop manufacturing processes that achieve a requisite degree of biosimilarity to the originator drug, and within a range of variability considered acceptable by regulatory authorities, we may not be able to obtain regulatory approval for our products.

Protein-based therapeutics are inherently heterogeneous and their structures are highly dependent on the production process and conditions. Products from one production facility can differ within an acceptable range from those produced in another facility. Similarly, physicochemical differences can also exist among different lots produced within a single facility. The physicochemical complexity and size of biologic therapeutics create significant technical and scientific challenges in the context of their replication as biosimilar products.

The inherent variability in protein structure from one production lot to another is a fundamental consideration with respect to establishing biosimilarity to an originator product to support regulatory approval requirements. For example, the glycosylation of the protein, meaning the manner in which sugar molecules are attached to the protein backbone of a therapeutic protein when it is produced in a living cell, is critical to therapeutic efficacy, half-life (how long the drug stays in the body), efficacy and even safety of the therapeutic and is therefore a key consideration for biosimilarity. Defining and understanding the variability of an originator molecule in order to match its glycosylation profile requires significant skill in cell biology, protein purification and analytical protein chemistry. Furthermore, manufacturing proteins with reliable and consistent glycosylation profiles at scale is challenging and highly dependent on the skill of the cell biologist and process scientist.

There are extraordinary technical challenges in developing complex protein-based therapeutics that not only must achieve an acceptable degree of similarity to the originator molecule in terms of characteristics such as the unique glycosylation pattern, but also the ability to develop manufacturing processes that can replicate the necessary structural characteristics within an acceptable range of variability sufficient to satisfy regulatory authorities.

Given the challenges caused by the inherent variability in protein production, we may not be successful in developing our products if regulators conclude that we have not achieved a sufficient level of biosimilarity to the originator product, or that the processes we use are unable to generate our products within an acceptable range of variability.

Clinical drug development involves a lengthy and expensive process and we may encounter substantial delays in our clinical studies or may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we (and/or our collaboration partners) must conduct clinical studies to demonstrate the safety and efficacy of the product candidates in humans.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical study process. The results of preclinical studies and early clinical studies of our product candidates may not be predictive of the results of later-stage clinical studies. Product candidates that have shown promising results in early-stage clinical studies may still suffer significant setbacks in subsequent registration clinical studies. There is a high failure rate for product candidates proceeding through clinical studies, and product candidates in later stages of clinical studies may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical studies. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical studies due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier studies. Nonclinical and clinical data are also often susceptible to varying interpretations and analyses. We do not know whether any clinical studies we may conduct will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval.

We cannot guarantee that any clinical studies will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical studies can occur at any stage of testing, and our future clinical studies may not be successful. Events that may prevent successful or timely completion of clinical development include but are not limited to:

- inability to generate sufficient preclinical, toxicology or other *in vivo* or *in vitro* data to support the initiation of human clinical studies;
- delays in reaching a consensus with regulatory agencies on study design;
- delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical study sites;
- delays in obtaining required Institutional Review Board, or IRB, approval at each clinical study site;

- imposition of a clinical hold by regulatory agencies, after review of an investigational new drug, or IND, application or amendment or equivalent application or amendment, or an inspection of our clinical study operations or study sites or as a result of adverse events reported during a clinical trial;
- delays in recruiting suitable patients to participate in our clinical studies sponsored by us or our partners;
- difficulty collaborating with patient groups and investigators;
- failure by our CROs, other third parties or us to adhere to clinical study requirements;
- failure to perform in accordance with the FDA's good clinical practices requirements or applicable regulatory guidelines in other countries;
- delays in having patients complete participation in a study or return for post-treatment follow-up, or patients dropping out of a study;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- the cost of clinical studies of our product candidates being greater than we anticipate;
- clinical studies of our product candidates producing negative or inconclusive results, which may result in us deciding or regulators requiring us to conduct additional clinical studies or abandon product development programs; and
- delays in manufacturing, testing, releasing, validating or importing/exporting and/or distributing sufficient stable quantities of our product candidates and originator products for use in clinical studies or the inability to do any of the foregoing.

Any inability to successfully complete nonclinical and clinical development could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes to our product candidates, we may need to conduct additional studies to bridge our modified product candidates to earlier versions.

For example, we intend to alter the manufacturing processes for CHS-0214 and CHS-1420 and will need to provide data to the FDA and foreign regulatory authorities demonstrating that the change in manufacturing process has not changed the product candidate. If we are unable to make that demonstration to the FDA or comparable foreign regulatory authorities, we could face significant delays or fail to obtain regulatory approval to market the product, which could significantly harm our business.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following marketing approval, if granted.

As with most pharmaceutical products, use of our product candidates could be associated with side effects or adverse events which can vary in severity (from minor reactions to death) and frequency (infrequent or prevalent). Side effects or adverse events associated with the use of our product candidates may be observed at any time, including in clinical trials or when a product is commercialized. Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical studies and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. Results of our studies could reveal a high and unacceptable severity and prevalence of side effects such as toxicity or other safety issues and could require us or our collaboration partners to perform additional studies or halt development or sale of these product candidates or expose us to product liability lawsuits which will harm our business. In such an event, we may be required by regulatory agencies to conduct additional animal or human studies regarding the safety and efficacy of our product candidates which we have not planned or anticipated or our studies could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny or withdraw approval of our product candidates for any or all targeted indications. There can be no assurance that we will resolve any issues related to any product-related adverse events to the satisfaction of the FDA or any other regulatory agency in a timely manner, if ever, which could harm our business, prospects and financial condition.

Additionally, product quality characteristics have been shown to be sensitive to changes in process conditions, manufacturing techniques, equipment or sites and other such related considerations, hence any manufacturing process changes we implement prior to or after regulatory approval could impact product safety and efficacy.

Drug-related side effects could affect patient recruitment for clinical trials, the ability of enrolled patients to complete our studies or result in potential product liability claims. We currently carry product liability insurance and we are required to maintain product liability insurance pursuant to certain of our license agreements. We believe our product liability insurance coverage is sufficient in light of our current clinical programs; however, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. A successful product liability claim or series of claims brought against us could adversely affect our results of operations and business. In addition, regardless of merit or eventual outcome, product liability claims may result in impairment of our business reputation, withdrawal of clinical study participants, costs due to related litigation, distraction of management's attention from our primary business, initiation of investigations by regulators, substantial monetary awards to patients or other claimants, the inability to commercialize our product candidates and decreased demand for our product candidates, if approved for commercial sale.

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including but not limited to:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label;
- we may be required to create a Risk Evaluation and Mitigation Strategy, or REMS, plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers and/or other elements to assure safe use;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects.

If we receive approval, regulatory agencies including the FDA and foreign regulatory agencies, regulations require that we report certain information about adverse medical events if those products may have caused or contributed to those adverse events. The timing of our obligation to report would be triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events we become aware of within the prescribed timeframe. We may also fail to appreciate that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of our products. If we fail to comply with our reporting obligations, the FDA or foreign regulatory agencies could take action including criminal prosecution, the imposition of civil monetary penalties, seizure of our products or delay in approval or clearance of future products.

The development, manufacture and commercialization of biosimilar products under various global regulatory pathways pose unique risks.

United States Regulatory Framework for Biosimilars

We and our collaboration partners intend to pursue market authorization globally. In the United States, an abbreviated pathway for approval of biosimilar products was established by the Biologics Price Competition and Innovation Act of 2009, or BPCIA, enacted on March 23, 2010, as part of the Patient Protection and Affordable Care Act. The BPCIA established this abbreviated pathway under section 351(k) of the Public Health Service Act, or PHSA. Subsequent to the enactment of the BPCIA, the FDA issued draft guidance regarding the demonstration of biosimilarity as well as the submission and review of biosimilar applications. Moreover, market acceptance of biosimilar products in the United States is unclear. Numerous states are considering or have already enacted laws that regulate or restrict the substitution by state pharmacies of biosimilars for originator products already licensed by the FDA. Market success of biosimilar products will depend on demonstrating to patients, physicians, payors and relevant authorities that such products are similar in quality, safety and efficacy as compared to the reference product.

We will continue to analyze and incorporate into our biosimilar development plans any final regulations issued by the FDA, pharmacy substitution policies enacted by state governments and other applicable requirements established by relevant authorities. The costs of development and approval, along with the probability of success for our biosimilar product candidates, will be dependent upon the application of any laws and regulations issued by the relevant regulatory authorities.

Biosimilar products may also be subject to extensive patent clearances and patent infringement litigation, which may delay and could prevent the commercial launch of a product. Moreover, the BPCIA prohibits the FDA from accepting an application for a biosimilar candidate to a reference product within four years of the reference product's licensure by the FDA. In addition, the BPCIA provides innovative biologics with 12 years of exclusivity from the date of their licensure, during which time the FDA cannot approve any application for a biosimilar candidate to the reference product.

The BPCIA is complex and only beginning to be interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning are evolving and subject to significant uncertainty. Future implementation decisions by the FDA could result in delays in the development or commercialization of our product candidates or increased costs to assure regulatory compliance and could adversely affect our operating results by restricting or significantly delaying our ability to market new biosimilar products.

Regulatory Framework for Biosimilars Outside the United States

In 2004, the European Parliament issued legislation allowing the approval of biosimilar therapeutics. Since then, the European Commission has granted marketing authorizations for more than 20 biosimilars pursuant to a set of general and product class-specific guidelines for biosimilar approvals issued over the past few years. Because of their extensive experience in the review and approval of biosimilars, Europe has more guidelines for these products than the FDA, including data requirements needed to support approval.

Under current EU regulations, an application for regulatory approval of a biosimilar drug cannot be submitted in the EU until expiration of an eight year data exclusivity period for the reference (originator) product, measured from the date of the reference product's initial marketing authorization. Furthermore, once approved, the biosimilar cannot be marketed until expiration of a 10-year period following the initial marketing authorization of the reference product, such ten year period being extendible to 11 years if the reference product received approval of an additional therapeutic indication, within the first eight years following its initial marketing authorization, representing a significant clinical benefit in comparison with existing therapies. However, we understand that reference products approved prior to November 20, 2005 (which would include, for example, Enbrel, Humira and Neulasta, approved in the EU on March 2, 2000, August 9, 2003 and August 22, 2002, respectively) are subject to a 10 year period of data exclusivity. While the data exclusivity periods for Enbrel, Humira and Neulasta have now expired in Europe, these reference products are presently still subject to unexpired patents and such patents may or may not be susceptible to challenges to their validity and enforceability.

In Europe, the approval of a biosimilar for marketing is based on an opinion issued by the EMA and a decision issued by the European Commission. Therefore, the marketing approval will cover the entire EEA. However, substitution of a biosimilar for the originator is a decision that is made at the national level. Additionally, a number of countries do not permit the automatic substitution of biosimilars for the originator product. Therefore, even if we obtain marketing approval for the entire EEA, we may not receive substitution in one or more European nations, thereby restricting our ability to market our products in those jurisdictions.

Other regions, including Canada, Japan and Korea, also have their own legislation outlining a regulatory pathway for the approval of biosimilars. In some cases other countries have either adopted European guidance (Singapore and Malaysia) or are following guidance issued by the World Health Organization (Cuba and Brazil). While there is overlap in the regulatory requirements across regions, there are also some areas of non-overlap. Additionally, we cannot predict whether countries that we may wish to market in, which do not yet have an established or tested regulatory framework could decide to issue regulations or guidance and/or adopt a more conservative viewpoint than other regions. Therefore, it is possible that even if we obtain agreement from one health authority to an accelerated or optimized development plan, we will need to defer to the most conservative view to ensure global harmonization of the development plan. Also, for regions where regulatory authorities do not yet have sufficient experience in the review and approval of a biosimilar product, these authorities may rely on the approval from another region (e.g., the United States or the E.U.), which could delay our approval in that region. Finally, it is possible that some countries will not approve a biosimilar without clinical data from their population and/or may require that the biosimilar product be manufactured within their region.

If other biosimilars of pegfilgrastim (Neulasta), etanercept (Enbrel) or adalimumab (Humira)) are approved and successfully commercialized before our product candidates for these originator products (CHS-1701, CHS-0214 or CHS-1420, respectively), our business would suffer.

We expect other companies to seek approval to manufacture and market biosimilar versions of Neulasta, Enbrel, or Humira. If other biosimilars of Neulasta, Enbrel or Humira are approved and successfully commercialized before CHS-0214, CHS-1420 or CHS-1701, respectively, we may never achieve significant market share for these products, our revenue would be reduced and, as a result, our business, prospects and financial condition could suffer.

If other biosimilars of pegfilgrastim (Neulasta), etanercept (Enbrel) or adalimumab (Humira) are determined to be interchangeable and our biosimilars candidates for these originator products are not, our business would suffer.

The FDA or other relevant regulatory authorities may determine that a proposed biosimilar product is "interchangeable" with a reference product, meaning that the biosimilar product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product, if the application includes sufficient information to show that the product is biosimilar to the reference product and that it can be expected to produce the same clinical result as the reference product in any given patient. If the biosimilar product may be administered more than once to a patient, the applicant must demonstrate that the risk in terms of safety or diminished efficacy of alternating or switching between the biosimilar product candidate and the reference product is not greater than the risk of using the reference product without such alternation or switch. To make a final determination of interchangeability, regulatory authorities may require additional confirmatory information beyond what we plan to initially submit in our applications for approval, such as more in-depth analytical characterization, animal testing or further clinical studies. Provision of sufficient information for approval may prove difficult and expensive.

We cannot predict whether any of our biosimilar product candidates will meet regulatory authority requirements for approval not only as a biosimilar product but also as an interchangeable product in any jurisdiction. Furthermore, legislation governing interchangeability could differ by jurisdiction on a state or national level worldwide.

The concept of "interchangeability" is important because, in the United States for example, the first biosimilar determined to be interchangeable with a particular reference, or originator, product for any condition of use is eligible for a period of market exclusivity that delays an FDA determination that a second or subsequent biosimilar product is interchangeable with that originator product for any condition of use until the earlier of: (1) one year after the first commercial marketing of the first interchangeable product; (2) 18 months after resolution of a patent infringement suit instituted under 42 U.S.C. § 262(l)(6) against the applicant that submitted the application for the first interchangeable product, based on a final court decision regarding all of the patents in the litigation or dismissal of the litigation with or without prejudice; (3) 42 months after approval of the first interchangeable product, if a patent infringement suit instituted under 42 U.S.C. § 262(l)(6) against the applicant that submitted the application for the first interchangeable product is still ongoing; or (4) 18 months after approval of the first interchangeable product if the applicant that submitted the application for the first interchangeable product has not been sued under 42 U.S.C. § 262(l)(6). Thus, a determination that another company's product is interchangeable with the originator biologic before we obtain approval of our corresponding biosimilar product candidates may delay the potential determination that our products are interchangeable with the originator product, which could materially adversely affect our results of operations and delay, prevent or limit our ability to generate revenue.

Failure to obtain regulatory approval in any targeted regulatory jurisdiction would prevent us from marketing our products to a larger patient population and reduce our commercial opportunities.

We and our collaboration partners have not initiated marketing efforts in any regulatory jurisdiction. Subject to product approvals and relevant patent expirations, we or our collaboration partners intend to market our etanercept (Enbrel) biosimilar product, CHS-0214 in Japan (through our licensee Daiichi Sankyo), Europe (through our licensee Baxalta) and certain Latin American countries (through our licensee, Orox). We intend to market our pegfilgrastim (Neulasta) biosimilar product, CHS-1701, and future oncology biosimilar candidates in the United States and may seek to partner commercially all oncology biosimilars outside the United States. We intend to find favorable strategic commercialization partners or retain rights for some or all of our immunology (anti-TNF) biosimilar candidates.

In order to market our products in the E.U., the United States and other jurisdictions, we and our collaboration partners must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The EMA is responsible for the centralized procedure for the regulation and approval of human medicines. This procedure results in a single marketing authorization that is valid in all E.U. countries, as well as in Iceland, Liechtenstein and Norway. The time required to obtain approval abroad may differ from that required to obtain FDA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval and we may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. We or our collaboration partners may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products within the United States or in any market outside the United States. Failure to obtain these approvals would materially and adversely affect our business, financial condition and results of operations.

Even if we obtain regulatory approval for a product candidate, our products will remain subject to regulatory scrutiny.

If our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies and submission of safety, efficacy and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA, and comparable foreign regulatory authority, requirements, including ensuring that quality control and manufacturing procedures conform to current Good Manufacturing Practices, or cGMP, regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any NDA, BLA or marketing authorization application, or MAA. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Any regulatory approvals that we or our collaboration partners receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval or may contain requirements for potentially costly additional clinical trials and surveillance to monitor the safety and efficacy of the product candidate. We will be required to report certain adverse events and production problems, if any, to the FDA and comparable foreign regulatory authorities. Any new legislation addressing drug safety issues could result in delays in product development or commercialization or increased costs to assure compliance. We will have to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. As such, we may not promote our products for indications or uses for which they do not have approval. If our product candidates are approved, we must submit new or supplemental applications and obtain approval for certain changes to the approved products, product labeling or manufacturing process. We or our collaboration partners could also be asked to conduct post-marketing clinical studies to verify the safety and efficacy of our products in general or in specific patient subsets. If original marketing approval is obtained via an accelerated biosimilar approval pathway, we could be required to conduct a successful post-marketing clinical study to confirm clinical benefit for our products. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency or problems with the facility where the product is manufactured or disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other possibilities:

- issue warning letters;
- impose civil or criminal penalties;
- suspend or withdraw regulatory approval;
- suspend any of our ongoing clinical studies;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our contract manufacturers' facilities; or
- seize or detain products or require a product recall.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected.

Adverse events involving an originator product, or other biosimilars of such originator product, may negatively affect our business.

In the event that use of an originator product, or other biosimilar for such originator product, results in unanticipated side effects or other adverse events, it is likely that our biosimilar product candidate will be viewed comparably and may become subject to the same scrutiny and regulatory sanctions as the originator product or other biosimilar, as applicable. Accordingly, we may become subject to regulatory supervisions, clinical holds, product recalls or other regulatory actions for matters outside of our control that affect the originator product, or other biosimilar, as applicable, if and until we are able to demonstrate to the satisfaction of our regulators that our biosimilar product candidate is not subject to the same issues leading to the regulatory action as the originator product or other biosimilar, as applicable.

Risks Related to our Ability to Hire Highly Qualified Personnel and our Reliance on Third Parties

We are highly dependent on the services of our key executives and personnel, including our President and Chief Executive Officer, Dennis M. Lanfear, and if we are not able to retain these members of our management or recruit additional management, clinical and scientific personnel, our business will suffer.

We are highly dependent on the principal members of our management and scientific and technical staff. The loss of service of any of our management or key scientific and technical staff could harm our business. In addition, we are dependent on our continued ability to attract, retain and motivate highly qualified additional management, clinical and scientific personnel. If we are not able to retain our management, particularly our President and Chief Executive Officer, Mr. Lanfear, and to attract, on acceptable terms, additional qualified personnel necessary for the continued development of our business, we may not be able to sustain our operations or grow.

Our future performance will also depend, in part, on our ability to successfully integrate newly hired executive officers into our management team and our ability to develop an effective working relationship among senior management. Our failure to integrate these individuals and create effective working relationships among them and other members of management could result in inefficiencies in the development and commercialization of our product candidates, harming future regulatory approvals, sales of our product candidates and our results of operations. Additionally, we do not currently maintain "key person" life insurance on the lives of our executives or any of our employees.

We will need to expand and effectively manage our managerial, scientific, operational, financial and other resources in order to successfully pursue our clinical development and commercialization efforts. Our success also depends on our continued ability to attract, retain and motivate highly qualified management and scientific personnel. We may not be able to attract or retain qualified management and scientific and clinical personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses, particularly in the San Francisco Bay Area. If we are not able to attract, retain and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

We will need to expand our organization and we may experience difficulties in managing this growth, which could disrupt our operations.

As of December 31, 2015, we had 109 full-time employees. As our development and commercialization plans and strategies develop, we expect to need additional managerial, operational, sales, marketing, financial, legal and other resources. Our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of our current and potential future product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

We rely on third parties to conduct our nonclinical and clinical studies and perform other tasks for us. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third-party CROs to monitor and manage data for our ongoing nonclinical and clinical programs. We rely on these parties for execution of our nonclinical and clinical studies and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs and other vendors are required to comply with cGMP, current good clinical practices, or cGCP, and Good Laboratory Practices, or GLP, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the EEA and comparable foreign regulatory authorities for all of our product candidates in clinical development. Regulatory authorities enforce these regulations through periodic inspections of study sponsors, principal investigators, study sites and other contractors. If we, any of our CROs, service providers or investigators fail to comply with applicable regulations or cGCPs, the data generated in our nonclinical and clinical studies may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional nonclinical and clinical studies before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical studies comply with cGCP regulations. In addition, our clinical studies must be conducted with product generated under cGMP regulations. Failure to comply by any of the participating parties or ourselves with these regulations may require us to repeat clinical studies, which would delay the regulatory approval process. Moreover, our business may be implicated if our contract research organization, or CRO, or any other participating parties violate federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our on-going nonclinical and clinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our protocols, regulatory requirements or for other reasons, our clinical studies may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. CROs may also generate higher costs than anticipated. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, a transition period is necessary when a new CRO commences work, which can materially impact our ability to meet our desired clinical development timelines. Though we strive to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, prospects and financial condition

We rely on third parties, and in some cases a single third party, to manufacture nonclinical and clinical supplies of our product candidates and to store critical components of our product candidates for us. Our business could be harmed if those third parties fail to provide us with sufficient quantities of product candidates or fail to do so at acceptable quality levels or prices.

We do not currently have the infrastructure or capability internally to manufacture supplies of our product candidates for use in our nonclinical and clinical studies, and we lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale. We rely on third party manufacturers to manufacture and supply us with our product candidates for our preclinical and clinical studies. Successfully transferring complicated manufacturing techniques to contract manufacturing organizations and scaling up these techniques for commercial quantities is time consuming and we may not be able to achieve such transfer or do so in a timely manner. Moreover, the availability of contract manufacturing services for protein-based therapeutics is highly variable and there are periods of relatively abundant capacity alternating with periods in which there is little available capacity. If our need for contract manufacturing services increases during a period of industry-wide production capacity shortage, we may not be able to produce our product candidates on a timely basis or on commercially viable terms. Although we will plan accordingly and generally do not begin a clinical study unless we believe we have a sufficient supply of a product candidate to complete such study, any significant delay or discontinuation in the supply of a product candidate for an ongoing clinical study due to the need to replace a third-party manufacturer could considerably delay completion of our clinical studies, product testing and potential regulatory approval of our product candidates, which could harm our business and results of operations.

Reliance on third-party manufacturers entails additional risks, including reliance on the third party for regulatory compliance and quality assurance, the possible breach of the manufacturing agreement by the third party and the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us. In addition, third party manufacturers may not be able to comply with cGMP or similar regulatory requirements outside the United States. Our failure or the failure of our third party manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates or any other product candidates or products that we may develop. Any failure or refusal to supply the components for our product candidates that we may develop could delay, prevent or impair our clinical development or commercialization efforts. If our contract manufacturers were to breach or terminate their manufacturing arrangements with us, the development or commercialization of the affected products or product candidates could be delayed, which could have an adverse effect on our business. Any change in our manufacturers could be costly because the commercial terms of any new arrangement could be less favorable and because the expenses relating to the transfer of necessary technology and processes could be significant.

If any of our product candidates are approved, in order to produce the quantities necessary to meet anticipated market demand, any contract manufacturer that we engage may need to increase manufacturing capacity. If we are unable to build and stock our product candidates in sufficient quantities to meet the requirements for the launch of these candidates or to meet future demand, our revenue and gross margins could be adversely affected. Although we believe that we will not have any material supply issues, we cannot be certain that we will be able to obtain long-term supply arrangements for our product candidates or materials used to produce them on acceptable terms, if at all. If we are unable to arrange for third-party manufacturing, or to do so on commercially reasonable terms, we may not be able to complete development of our product candidates or market them.

We have entered into collaborations with third parties in connection with the development of certain of our product candidates. Even if we believe that the development of our technology and product candidates is promising, our partners may choose not to proceed with such development.

We have collaborations with several partners for the development and commercialization of certain of our product candidates. Our existing agreements with our collaboration partners are generally subject to termination by the counterparty on short notice under certain circumstances. Accordingly, even if we believe that the development of certain product candidates is worth pursuing, our partners may choose not to continue with such development. If any of our collaborations are terminated, we may be required to devote additional resources to the development of our product candidates or seek a new collaboration partner on short notice, and the terms of any additional collaborations or other arrangements that we establish may not be favorable to us or available at all.

We are also at risk that our collaborations or other arrangements may not be successful. Factors that may affect the success of our collaborations include the following:

- our collaboration partners may incur financial, legal or other difficulties that force them to limit or reduce their participation in our joint projects;
- our collaboration partners may be pursuing alternative technologies or developing alternative products that are competitive to our technology and products, either on their own or in partnership with others. For example, in December 2014 Momenta Pharmaceuticals, or Momenta, announced acceptance by the UK of a clinical trial application for an adalimumab (Humira) biosimilar being developed by Momenta in collaboration with Baxalta;
- our collaboration partners may terminate their collaborations with us, which could make it difficult for us to attract new partners or adversely affect perception of us in the business and financial communities. For example, in July 2014 our partner Daiichi terminated its license with us pertaining to a rituximab (Rituxan) biosimilar; and
- our collaboration partners may pursue higher priority programs or change the focus of their development programs, which could affect their commitment to us.

If we cannot maintain successful collaborations, our business, financial condition and operating results may be adversely affected.

We are dependent on Daiichi Sankyo, Baxalta and Orox for the commercialization of our biosimilar product candidates in certain major markets, and their failure to commercialize in those markets could have a material adverse effect on our business and operating results.

Our exclusive licensee, Baxalta, is responsible for commercialization of CHS-0214 in Europe, Brazil and other jurisdictions outside the U.S. (excluding Japan and certain Caribbean and Latin American countries). Our exclusive licensee, Daiichi Sankyo, is responsible for commercialization of CHS-0214 in Japan. Our exclusive licensee, Orox Pharmaceuticals B.V., or Orox, is responsible for commercialization of certain of our products, including CHS-1701, CHS-0214 and CHS-1420, in certain Caribbean and Latin American countries (excluding Brazil). If these entities fail to exercise commercially reasonable efforts to market and sell our products in their respective licensed jurisdictions or are otherwise ineffective in doing so, our business will be harmed and we may not be able to adequately remedy the harm through negotiation, litigation, arbitration or termination of the license agreements. Moreover, any disputes with our collaboration partners concerning the adequacy of their commercialization efforts will substantially divert the attention of our senior management from other business activities and will require us to incur substantial costs associated with litigation or arbitration proceedings.

We are subject to a multitude of manufacturing risks. Any adverse developments affecting the manufacturing operations of our biosimilar product candidates could substantially increase our costs and limit supply for our product candidates.

The process of manufacturing our product candidates is complex, highly regulated and subject to several risks, including but not limited to:

- product loss due to contamination, equipment failure or improper installation or operation of equipment or vendor or operator error; and
- equipment failures, labor shortages, natural disasters, power failures and numerous other factors associated with the manufacturing facilities in which our product candidates are produced.

Even minor deviations from normal manufacturing processes for any of our product candidates could result in reduced production yields, product defects and other supply disruptions. For example, we have experienced failures with respect to the manufacturing of certain lots of each of our product candidates resulting in delays prior to our taking corrective action. Additionally, if microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.

For example in October 2014, as part of our quality process and upon routine visual inspection during storage, four syringes containing CHS-0214 (our etanercept (Enbrel) biosimilar candidate) from a production lot in use in our ongoing Phase 3 clinical trials were observed to contain small dark particles. We immediately initiated a visual inspection of remaining unlabeled inventory of this lot as well as a subsequent lot. While none of the approximately 8,000 unlabeled syringes inspected exhibited any such particulate, we decided in the interests of patient safety, to temporarily stop dosing in the ongoing Phase 3 clinical trials of CHS-0214 in order to determine a potential cause and incidence of the observed phenomenon. Based on our investigation, including a chemical analysis of the particles by a qualified independent laboratory, we concluded that the particulates did not result from any instability in the CHS-0214 protein product or its formulation, but were most likely a result of a non-recurring anomaly related to first use of new process equipment. We therefore concluded that the approximately 7,000 unlabeled syringes that were 100% inspected and found free of any particulates were safe for patient use in our clinical trials. In consultation with the FDA, our Phase 3 trials were resumed in December 2014 and are ongoing.

Any adverse developments affecting manufacturing operations for our product candidates may result in shipment delays, inventory shortages, lot failures, withdrawals or recalls or other interruptions in the supply of our product candidates. We may also have to take inventory write-offs and incur other charges and expenses for product candidates that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives.

We currently engage single suppliers for manufacture, clinical trial services, formulation development and product testing of our product candidates. The loss of any of these suppliers or vendors could materially and adversely affect our business.

For each of our lead products, CHS-1701, CHS-0214 and CHS-1420, we currently engage a distinct vendor or service provider for each of the principal activities supporting our manufacture and development of these lead products, such as manufacture of the biological substance present in each of the products, manufacture of the final filled and finished presentation of these products, as well as laboratory testing, formulation development and clinical testing of these products. Because we currently have not engaged back up suppliers or vendors for these single-sourced services, and although we believe that there are alternate sources that could fulfill these activities, we cannot assure you that identifying and establishing relationships with alternate suppliers and vendors would not result in significant delay in the development of our product candidates. Additionally, we may not be able to enter into arrangements with alternative service providers on commercially reasonable terms or at all. A delay in the development of our product candidates, or having to enter into a new agreement with a different third party on less favorable terms than we have with our current suppliers, could have a material adverse impact on our business.

We and our collaboration partners and contract manufacturers are subject to significant regulation with respect to manufacturing our product candidates. The manufacturing facilities on which we rely may not continue to meet regulatory requirements or may not be able to meet supply demands.

All entities involved in the preparation of therapeutics for clinical studies or commercial sale, including our existing contract manufacturers for our product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical studies must be manufactured in accordance with cGMP. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of contaminants or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We, our collaboration partners or our contract manufacturers must supply all necessary documentation in support of a BLA or MAA on a timely basis and must adhere to GLP and cGMP regulations enforced by the FDA and other regulatory agencies through their facilities inspection program. Some of our contract manufacturers may have never produced a commercially approved pharmaceutical product and therefore have not obtained the requisite regulatory authority approvals to do so. The facilities and quality systems of some or all of our collaboration partners and third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates or any of our other potential products. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. Although we oversee the contract manufacturers, we cannot control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements. If these facilities do not pass a pre-approval plant inspection, regulatory approval of the products may not be granted or may be substantially delayed until any violations are corrected to the satisfaction of the regulatory authority, if ever.

The regulatory authorities also may, at any time following approval of a product for sale, audit the manufacturing facilities of our collaboration partners and third-party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical study or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business.

If we, our collaboration partners or any of our third-party manufacturers fail to maintain regulatory compliance, the FDA or other applicable regulatory authority can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new product candidate, withdrawal of an approval or suspension of production. As a result, our business, financial condition and results of operations may be materially harmed.

Additionally, if supply from one approved manufacturer is interrupted, an alternative manufacturer would need to be qualified through a BLA supplement or MAA variation or equivalent foreign regulatory filing, which could result in further delay. The regulatory agencies may also require additional studies if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

These factors could cause us to incur additional costs and could cause the delay or termination of clinical studies, regulatory submissions, required approvals or commercialization of our product candidates. Furthermore, if our suppliers fail to meet contractual requirements and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical studies may be delayed or we could lose potential revenue.

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

Because we rely on third parties to develop and manufacture our product candidates, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaboration partners, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, such as trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business.

Risks Related to Commercialization of Our Product Candidates

Our biosimilar product candidates, if approved, will face significant competition from the reference products and from other pharmaceuticals approved for the same indication as the originator products. Our failure to effectively compete may prevent us from achieving significant market penetration and expansion.

We expect to enter highly competitive pharmaceutical markets. Successful competitors in the pharmaceutical market have demonstrated the ability to effectively discover, obtain patents, develop, test and obtain regulatory approvals for products, as well as an ability to effectively commercialize, market and promote approved products. Numerous companies, universities and other research institutions are engaged in developing, patenting, manufacturing and marketing of products competitive with those that we are developing. Many of these potential competitors are large, experienced pharmaceutical companies that enjoy significant competitive advantages, such as substantially greater financial, research and development, manufacturing, personnel and marketing resources. These companies also have greater brand recognition and more experience in conducting preclinical testing and clinical trials of product candidates and obtaining FDA and other regulatory approvals of products.

If an improved version of an originator product, such as Enbrel, Humira or Neulasta, is developed or if the market for the originator product significantly declines, sales or potential sales of our biosimilar product candidates may suffer.

Originator companies may develop improved versions of a reference product as part of a life cycle extension strategy and may obtain regulatory approval of the improved version under a new or supplemental BLA filed with the applicable regulatory authority. Should the originator company succeed in obtaining an approval of an improved biologic product, it may capture a significant share of the collective reference product market in the applicable jurisdiction and significantly reduce the market for the reference product and thereby the potential size of the market for our biosimilar product candidates. In addition, the improved product may be protected by additional patent rights that may subject our follow-on biosimilar to claims of infringement.

Biologic reference products may also face competition as technological advances are made that may offer patients a more convenient form of administration or increased efficacy or as new products are introduced. As new products are approved that compete with the reference product to our biosimilar product candidates, or sales of the reference originator products may be adversely impacted or rendered obsolete. If the market for the reference product is impacted, we may lose significant market share or experience limited market potential for our approved biosimilar products or product candidates, and the value of our product pipeline could be negatively impacted. As a result of the above factors, our business, prospects and financial condition could suffer.

If efforts by manufacturers of originator products to delay or limit the use of biosimilars are successful, our sales of biosimilar products may suffer.

Many manufacturers of originator products have increasingly used legislative, regulatory and other means, such as litigation, to delay regulatory approval and to seek to restrict competition from manufacturers of biosimilars. These efforts may include or have included:

- settling patent lawsuits with biosimilar companies, resulting in such patents remaining an obstacle for biosimilar approval by others;
- submitting Citizen Petitions to request the FDA Commissioner to take administrative action with respect to prospective and submitted biosimilar applications;
- appealing denials of Citizen Petitions in United States federal district courts and seeking injunctive relief to reverse approval of biosimilar applications;
- restricting access to reference brand products for equivalence and biosimilarity testing that interferes with timely biosimilar development plans;
- attempting to influence potential market share by conducting medical education with physicians, payors, regulators and patients claiming that biosimilar products are too complex for biosimilar approval or are too dissimilar from originator products to be trusted as safe and effective alternatives;
- implementing payor market access tactics that benefit their brands at the expense of biosimilars;
- seeking state law restrictions on the substitution of biosimilar products at the pharmacy without the intervention of a physician or through other restrictive means such as excessive recordkeeping requirements or patient and physician notification;
- seeking federal or state regulatory restrictions on the use of the same non-proprietary name as the reference brand product for a biosimilar or interchangeable biologic;
- seeking changes to the United States Pharmacopeia, an industry recognized compilation of drug and biologic standards;
- obtaining new patents covering existing products or processes which could extend patent exclusivity for a number of years or otherwise delay the launch of biosimilars; and
- influencing legislatures so that they attach special patent extension amendments to unrelated federal legislation.

In 2012, Abbott Laboratories filed a Citizen Petition with the FDA asking the agency to refrain from accepting biosimilar applications under the BPCIA arguing that to approve such applications, without compensation to the originator, would constitute an unconstitutional taking of an originator company's valuable trade secrets under the fifth amendment of the United States constitution. The FDA has not yet acted on this petition and its outcome is uncertain. If the FDA grants Abbott Laboratories' petition, we may be precluded from applying for approval of CHS-1701, CHS-0214 and CHS-1420 under the 351(k) pathway. Even if the FDA rejects Abbott Laboratories' petition, we think it is likely that Abbott will file appeals to the federal courts and ultimately pursue its appeals to the United States Supreme Court. Other originator companies may file Citizen Petitions in an effort to restrict or prevent the introduction of biosimilars.

We face intense competition and rapid technological change and the possibility that our competitors may develop therapies that are similar, more advanced or more effective than ours, which may adversely affect our financial condition and our ability to successfully commercialize our product candidates.

We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies. Some of the pharmaceutical and biotechnology companies we expect to compete with include, for example, Apotex Inc., or Apotex, Sandoz International GmbH, or Sandoz, Amgen, Pfizer Inc., or Pfizer, Boehringer Ingelheim GmbH, or Boehringer, Teva Pharmaceutical Industries, Ltd., or Teva, Samsung Bioepis, Ltd., or Bioepis, (a Merck/Biogen/Samsung biosimilar venture) and Hanwha Chemical Corporation, or Hanwha Momenta, as well as other smaller companies. We are currently aware that such competitors are engaged in the development of biosimilar product candidates to pegfilgrastim (Neulasta), etanercept (Enbrel) and adalimumab (Humira). For example, we understand that Sandoz and Apotex have each submitted a Neulasta (pegfilgrastim) biosimilar product candidate for market approval in the United States. We understand that Mylan Inc. appears to have an ongoing Phase 3 clinical trial for a Neulasta biosimilar. Similarly, we understand that Sandoz and Samsung Bioepis are each currently engaged in the development of competing biosimilar product candidates for etanercept (Enbrel). Both Sandoz and Samsung Bioepis have each submitted an etanercept biosimilar product candidate for market approval in the E.U. and Sandoz has filed a BLA for its candidate in the United States. On January 16, 2016 the European Commission (EC) approved

Samsung Bioepis' entanercept biosimilar (Benepali), also known as SB4, for the treatment of rheumatoid arthritis, psoriatic arthritis, axial spondyloarthritis (ankylosing spondylitis and non-radiographic axial spondyloarthritis) and plaque psoriasis. Boehringer, Amgen, Sandoz, Samsung Bioepis and Pfizer are examples of companies engaged in development of biosimilar product candidates for adalimumab (Humira). We understand Boehringer Ingelheim's program and Pfizer's program are in Phase 3, and that Amgen's program has successfully completed Phase 3. On November 25, 2015, Amgen announced the submission with the FDA of a BLA for its adalimumab (Humira) biosimilar, ABP 501.

Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations. Additional mergers and acquisitions in the pharmaceutical industry may result in even more resources being concentrated in our competitors. As a result, these companies may obtain regulatory approval more rapidly than we are able to and may be more effective in selling and marketing their products. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis, products that are more effective or less costly than any product candidate that we may develop; they may also obtain patent protection that could block our products; and they may obtain regulatory approval, product commercialization and market penetration earlier than we do. Biosimilar product candidates developed by our competitors may render our potential product candidates uneconomical, less desirable or obsolete, and we may not be successful in marketing our product candidates against competitors. Competitors may also assert in their marketing or medical education programs that their biosimilar products demonstrate a higher degree of biosimilarity to the originator products than do ours or other competitor's biosimilar products, thereby seeking to influence health care practitioners to select their biosimilar products, versus ours or other competitors.

We currently have no marketing and sales organization. If we are unable to establish sales and marketing capabilities in jurisdictions for which we choose to retain commercialization rights or if we are unable to enter into agreements with third parties to market and sell our product candidates, we may be unable to generate any revenue.

We currently have no marketing or sales organization. Although our employees may have sold other biologic products in the past while employed at other companies, our products have not yet been approved for sale, and thus we as a company have no experience selling and marketing our product candidates. To successfully commercialize any products that may result from our development programs, we will need to develop these capabilities, either on our own or with others. If our product candidates receive regulatory approval, we intend to establish a sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize our product candidates in major markets where we may choose to retain commercialization rights. Doing so will be expensive, difficult and time consuming. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of our products.

Further, given our lack of prior experience in marketing and selling biopharmaceutical products, our initial estimate of the size of the required sales force may be materially more or less than the size of the sales force actually required to effectively commercialize our product candidates. As such, we may be required to hire substantially more sales representatives to adequately support the commercialization of our product candidates or we may incur excess costs as a result of hiring more sales representatives than necessary. With respect to certain geographical markets, we may enter into collaborations with other entities to utilize their local marketing and distribution capabilities, but we may be unable to enter into such agreements on favorable terms, if at all. If our future collaboration partners do not commit sufficient resources to commercialize our future products, if any, and we are unable to develop the necessary marketing capabilities on our own, we will be unable to generate sufficient product revenue to sustain our business. We expect competition from companies such as Sandoz, Samsung Bioepis, Teva, Boehringer, Pfizer and Amgen that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

We may need to enter into alliances with other companies that can provide capabilities and funds for the development and commercialization of our product candidates. If we are unsuccessful in forming or maintaining these alliances on favorable terms, our business could be adversely affected.

Because we have limited or no internal capabilities for late-stage product development, manufacturing, sales, marketing and distribution, we have found it necessary to enter into alliances with other companies. For example, we entered into a collaboration agreement with Baxalta for the development and commercialization of CHS-0214 in Europe, Brazil and other jurisdictions outside the United States. Similarly, we entered into a collaboration agreement with Daiichi Sankyo for the development and commercialization of CHS-0214 in Japan. For commercialization of our biosimilar product candidates in certain Caribbean and Latin American countries, we entered into an exclusive distribution arrangement with Orox. In the future, we may also find it necessary to form alliances or joint ventures with major pharmaceutical companies to jointly develop and/or commercialize specific biosimilar product candidates. In such alliances, we would expect our collaboration partners to provide substantial capabilities in clinical development, manufacturing, regulatory affairs, sales and marketing. We may not be successful in entering into any such alliances. Even if we do

succeed in securing such alliances, we may not be able to maintain them if, for example, development or approval of a product candidate is delayed or sales of an approved product are disappointing. If we are unable to secure or maintain such alliances, we may not have the capabilities necessary to continue or complete development of our product candidates and bring them to market, which may have an adverse effect on our business.

In addition to product development and commercialization capabilities, we may depend on our alliances with other companies to provide substantial additional funding for development and potential commercialization of our product candidates. We may not be able to obtain funding on favorable terms from these alliances, and if we are not successful in doing so, we may not have sufficient funds to develop a particular product candidate internally or to bring product candidates to market. Failure to bring our product candidates to market will prevent us from generating sales revenue, and this may substantially harm our business. Furthermore, any delay in entering into these alliances could delay the development and commercialization of our product candidates, reduce their competitiveness even if they reach the market, and harm our business and operating results.

The commercial success of any current or future product candidate will depend upon the degree of market acceptance by physicians, patients, third-party payors and others in the medical community.

Even with the requisite approvals from the FDA and comparable foreign regulatory authorities, the commercial success of our product candidates will depend in part on the medical community, patients and third-party payors accepting our product candidates as medically useful, cost-effective and safe. Any product that we bring to the market may not gain market acceptance by physicians, patients, third-party payors and others in the medical community. The degree of market acceptance of any of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the safety and efficacy of the product as demonstrated in clinical studies and potential advantages over competing treatments;
- the prevalence and severity of any side effects, including any limitations or warnings contained in a product's approved labeling;
- the clinical indications for which approval is granted;
- the possibility that a competitor may achieve interchangeability and we may not;
- relative convenience and ease of administration;
- the extent to which our product may be similar to the originator product than competing biosimilar product candidates;
- policies and practices governing the naming of biosimilar product candidates;
- prevalence of the disease or condition for which the product is approved;
- the cost of treatment, particularly in relation to competing treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support and timing of market introduction of competitive products;
- the extent to which the product is approved for inclusion on formularies of hospitals and managed care organizations;
- publicity concerning our products or competing products and treatments;
- the extent to which third-party payors provide adequate third-party coverage and reimbursement for our product candidates, if approved; and
- our ability to maintain compliance with regulatory requirements.

Even if a potential product displays a favorable efficacy and safety profile in nonclinical and clinical studies, market acceptance of the product will not be fully known until after it is launched and may be negatively affected by a potential poor safety experience and the track record of other biosimilar product candidates. Our efforts to educate the medical community and third-party payors on the benefits of the product candidates may require significant resources, may be under-resourced compared to large well-funded pharmaceutical entities and may never be successful. If our product candidates are approved but fail to achieve an adequate level of acceptance by physicians, patients, third-party payors and others in the medical community, we will not be able to generate sufficient revenue to become or remain profitable.

Policies and practices governing the naming of biosimilar product candidates are neither fully established nor fully harmonized and are subject to debate and change. Failure to achieve a non-proprietary name sufficiently close to the reference product or be competitively disadvantaged in this regard, could adversely affect the commercial performance of our biosimilar product candidate.

United States Adopted Name, and International Nonproprietary Names, or INN, two important bodies involved in nonproprietary nomenclature, have no policy for the naming of biosimilar product candidates, and products are named on a case-by-case basis. Non-glycosylated proteins can follow the approach established for small molecule generics, which is to retain the same non-proprietary name if it is synthesized by a different route provided the substance is the same. Glycosylated proteins from different sources are given distinct names, as these proteins are expected to differ in their glycosylation profile. The same approach is valid for all other modifications to the protein that can occur in a cell after the cell has finished making the protein. A system currently under discussion at the World Health Organization that would enable the clear definition of all Similar Biotherapeutic Proteins would include the INN of the reference product in the first part of the name, and some form of biological qualifier that could uniquely identify the substance. Currently the FDA and EMA have final authority regarding names in the United States and the E.U. respectively, and it is unclear how they will handle nonproprietary nomenclature in the future. However, if they adopt policies requiring non-proprietary names that are distinct from the reference product or chose to assign a competing biosimilar product candidate to a Coherus product with a lower degree of nomenclature distinction from the reference product, payors, providers and patients may be more hesitant to use our biosimilar product candidate, believing the difference in nomenclature to be indicative of an important difference in quality of function from the reference product or the competing biosimilar product candidate. If this were to occur, our business could be negatively affected.

The third-party coverage and reimbursement status of newly-approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for new or current products could limit our ability to market those products and decrease our ability to generate revenue.

Pricing, coverage and reimbursement of our biosimilar product candidates, if approved, may not be adequate to support our commercial infrastructure. Our per-patient prices may not be sufficient to recover our development and manufacturing costs and potentially achieve profitability. Accordingly, the availability and adequacy of coverage and reimbursement by governmental and private payors are essential for most patients to be able to afford expensive treatments such as ours, if approved. Sales of our product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid for by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations or reimbursed by government authorities, private health insurers and other third-party payors. If coverage and reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be adequate to allow us to establish or maintain pricing sufficient to realize a return on our investment.

There is significant uncertainty related to third-party coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologics will be covered and reimbursed. The Medicare program covers certain individuals aged 65 or older or those who are disabled or suffering from end-stage renal disease. The Medicaid program, which varies from state to state, covers certain individuals and families who have limited financial means. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our biosimilar product candidates, if approved. In addition, in the United States, no uniform policy of coverage and reimbursement for biologics exists among third-party payors. Therefore, coverage and reimbursement for biologics can differ significantly from payor to payor. As a result, the process for obtaining favorable coverage determinations often is time-consuming and costly and may require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained. For example, Centers for Medicare & Medicaid Services (“CMS”) issued a proposed Part B rule in the third quarter of 2015 on biosimilar payment and coding which requires that multiple biosimilars to the same reference product be grouped and issued the same J-code for Medicare reimbursement purposes and that the payment amount for a billing code that describes a biosimilar is based on the average sales price (ASP) of all biosimilar products that reference a common biological product’s license application. This reimbursement rule could potentially create greater pricing pressure for biosimilars reimbursed in the medical benefit (Part B) segment. The final CMS rule is expected by the middle of the fourth quarter of 2015.

Outside the United States, pharmaceutical businesses are generally subject to extensive governmental price controls and other market regulations. We believe the increasing emphasis on cost-containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of our product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own

prices for medical products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

Increasing efforts by governmental and third-party payors in the United States and abroad to control healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our product candidates. While cost containment practices generally benefit biosimilars, severe cost containment practices may adversely affect our product sales. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes.

Our biosimilar product candidates, if approved, could face price competition from other biosimilars of the same reference products for the same indication. This price competition could exceed our capacity to respond, detrimentally affecting our market share and revenue as well as adversely affecting the overall financial health and attractiveness of the market for the biosimilar.

We expect to enter highly competitive biosimilar markets. Successful competitors in the biosimilar market have the ability to effectively compete on price through payors and their third-party administrators who exert downward pricing pressure. It is possible our biosimilar competitors' compliance with price discounting demands in exchange for market share could exceed our capacity to respond in kind and reduce market prices beyond our expectations. Such practices may limit our and our collaboration partners' ability to increase market share and will also impact profitability.

Risks Related to Intellectual Property

If we infringe or are alleged to infringe intellectual property rights of third parties, our business could be harmed. Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.

Our commercial success depends in large part on avoiding infringement of the patents and proprietary rights of third parties. There have been many lawsuits and other proceedings involving patent and other intellectual property rights in the pharmaceutical industry, including patent infringement lawsuits, interferences, oppositions and reexamination proceedings before the U.S. Patent and Trademark Office, or USPTO, and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. As the pharmaceutical industry expands and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

Our research, development and commercialization activities may infringe or otherwise violate or be claimed to infringe or otherwise violate patents owned or controlled by other parties. The companies that originated the products for which we intend to introduce biosimilar versions, such as Amgen, AbbVie Inc., or AbbVie, and Genentech, as well as other competitors (including other companies developing biosimilars) have developed, and are continuing to develop, worldwide patent portfolios of varying sizes and breadth, many of which are in fields relating to our business, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use.

Third parties may assert that we are employing their proprietary technology without authorization. We are aware of third-party patents or patent applications with claims, for example, to compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. While we have conducted freedom to operate analyses with respect to our lead product candidates CHS-0214, CHS-1420 and CHS-1701, we cannot guarantee that any of our analyses are complete and thorough, nor can we be sure that we have identified each and every patent and pending application in the United States and abroad that is relevant or necessary to the commercialization of our product candidates. Moreover, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents covering our product candidates. With respect to products we are evaluating for inclusion in our future biosimilar product pipeline, our freedom to operate analyses, including our research on the timing of potentially relevant patent expirations, are ongoing.

There may also be patent applications that have been filed but not published and if such applications issue as patents, they could be asserted against us. For example, in most cases, a patent filed today would not become known to industry participants for at least 18 months given patent rules applicable in most jurisdictions which do not require publication of patent applications until 18 months after filing. We may also face claims from non-practicing entities that have no relevant product revenue and against whom our own patent portfolio may have no deterrent effect. In addition, coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our product candidates, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid and/or unenforceable, and

we may not be able to do this. Proving that a patent is invalid or unenforceable is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Also in proceedings before courts in Europe, the burden of proving invalidity of the patent usually rests on the party alleging invalidity. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on us. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

Third parties could bring claims against us that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial monetary damages. Further, if a patent infringement suit were brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit. Ultimately, we could be prevented from commercializing a product or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on commercially acceptable terms or at all. If, as a result of patent infringement claims or to avoid potential claims, we choose or are required to seek licenses from third parties, these licenses may not be available on acceptable terms or at all. Even if we are able to obtain a license, the license may obligate us to pay substantial license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would likely involve substantial litigation expense and would likely be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may, in addition to being blocked from the market, have to pay substantial monetary damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference, *inter partes* review, or IPR, derivation or post-grant proceedings declared or granted by the USPTO and similar proceedings in foreign countries, regarding intellectual property rights with respect to our current or future products. An unfavorable outcome in any such proceedings could require us to cease using the related technology or to attempt to license rights to it from the prevailing party or could cause us to lose valuable intellectual property rights. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, if any license is offered at all. Litigation or other proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may also become involved in disputes with others regarding the ownership of intellectual property rights. For example, we jointly develop intellectual property with certain parties, and disagreements may therefore arise as to the ownership of the intellectual property developed pursuant to these relationships. If we are unable to resolve these disputes, we could lose valuable intellectual property rights.

On November 7, 2015 and December 9, 2015, we filed petitions for *Inter Partes* Review ("IPR") in the United States Patent Office against three AbbVie patents: U.S. patents 8,889,135; 9,017,680; and 9,073,987, all of which concern a 40 mg. biweekly subcutaneous dosing regimen for treating rheumatoid arthritis ("RA") with Humira® (Adalimumab). This treatment regimen is referenced in the approved FDA label for Humira. IPR filings, including ours, are a matter of public record and can be viewed at the USPTO website. We expect the USPTO to reach a decision in May, 2016 on whether to institute our IPR's. If the USPTO decides to institute the IPR's, it will then conduct an administrative trial to determine the patentability of patent claims challenged in the IPR's. If the USPTO refuses to institute the IPR's, we and others will be able to challenge these patents in further IPR's or in district court litigation. However, if the PTO institutes the IPR's but the arguments we raise therein fail to persuade the USPTO, after trial, that the challenged patent claims are unpatentable, we will not be able to raise those same arguments in district court litigation. However, other biosimilar entities may be in a position to challenge the patents in IPR's or district court litigation, and we could still assert certain bases of invalidity or unenforceability that are not subject to review in IPR proceedings. We note that on December 29, 2015, Boehringer Ingelheim filed two IPR's against AbbVie's U.S. patent 8,889,135. If we do not prevail in the IPR's or in any subsequent litigation that may occur between us and AbbVie concerning AbbVie's RA dosing patents, and if other parties are not successful in challenging the validity of these patents, we could be precluded from marketing a 40 mg biweekly subcutaneous dosage for RA until the expiration of AbbVie's dosing patents directed to this treatment regimen. AbbVie's public statements have indicated that the earliest expiration of these patents will occur in 2022.

Third parties may submit applications for patent term extensions in the United States or other jurisdictions where similar extensions are available and/or Supplementary Protection Certificates in the E.U. states (including Switzerland) seeking to extend certain patent protection which, if approved, may interfere with or delay the launch of one or more of our biosimilar products.

The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Patent litigation and other proceedings may fail, and even if successful, may result in substantial costs and distract our management and other employees. The companies that originated the products for which we intend to introduce biosimilar versions, as well as other competitors (including other biosimilar companies) may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could impair our ability to compete in the marketplace.

So called "submarine" patents may be granted to our competitors that may significantly alter our launch timing expectations, reduce our projected market size, cause us to modify our product or process or block us from the market altogether.

The term "submarine" patent has been used in the pharmaceutical industry and in other industries to denote a patent issuing from an application that was not published, publically known or available prior to its grant. Submarine patents add substantial risk and uncertainty to our business. Submarine patents may issue to our competitors covering our biosimilar product candidates or our pipeline candidates and thereby cause significant market entry delay, defeat our ability to market our products or cause us to abandon development and/or commercialization of a molecule.

Examples of submarine patents include Brockhaus, *et al*., U.S. patents 8,063,182 and 8,163,522 (controlled by Amgen), which are directed to the fusion protein in Enbrel. If challenges to the scope, validity or enforceability of the Brockhaus patents are not initiated, or, if initiated, are not successful, these patents, unless licensed to us by Amgen, will preclude our ability to introduce an etanercept (Enbrel) biosimilar product candidate in the U.S. market until at least 2029.

The issuance of one or more submarine patents may harm our business by causing substantial delays in our ability to introduce a biosimilar candidate into the U.S. market.

We may not identify relevant patents or may incorrectly interpret the relevance, scope or expiration of a patent which might adversely affect our ability to develop and market our products.

We cannot guarantee that any of our patent searches or analyses, including but not limited to the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete and thorough, nor can we be certain that we have identified each and every patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products or pipeline molecules. We may incorrectly determine that our products are not covered by a third party patent.

Many patents may cover a marketed product, including but not limited to the composition of the product, methods of use, formulations, cell line constructs, vectors, growth media, production processes and purification processes. The identification of all patents and their expiration dates relevant to the production and sale of an originator product is extraordinarily complex and requires sophisticated legal knowledge in the relevant jurisdiction. It may be impossible to identify all patents in all jurisdictions relevant to a marketed product. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect which may negatively impact our ability to develop and market our products.

Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products.

Although we are not currently involved in any litigation, we may be involved in lawsuits to protect or enforce our patents, which could be expensive, time consuming and unsuccessful.

Although we have no issued patents, when and if we do obtain issued patents, we may discover that competitors are infringing those patents. Expensive and time-consuming litigation may be required to abate such infringement. Although we are not currently involved in any litigation to enforce patents, if we or one of our collaboration partners, such as Baxalta, Daiichi Sankyo or Orox, were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including but not limited to lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could include an allegation that someone involved in the prosecution of the patent withheld relevant or material information related to the patentability of the invention from the USPTO or made a misleading statement during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable.

Interference proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if we cannot obtain a license from the prevailing party on commercially reasonable terms. Third parties may request an IPR of our patents in the USPTO. An unfavorable decision may result in the revocation of our patent or a limitation to the scope of the claims of our patents. Our defense of litigation, interference or IPR proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties or enter into development partnerships that would help us bring our product candidates to market.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during any litigation we initiate to enforce our patents. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

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

We employ individuals, retain independent contractors and consultants and members on our board of directors or Scientific Advisory Board who were previously employed at universities or other pharmaceutical companies, including our competitors or potential competitors. For example, our Chief Executive Officer, Dennis M. Lanfear, and our Chief Technical Officer, Peter K. Watler, Ph.D., are former employees of Amgen. Our Chief Scientific Officer, Alan C. Herman, Ph.D., is a former employee of Amgen and Genentech. Mr. Lanfear and Drs. Watler and Herman were employed at Amgen during periods when Amgen's operations included the development and commercialization of Neupogen, Neulasta and Enbrel. Our Chief Medical Officer, Barbara K. Finck, M.D., is a former employee of Immunex Corporation, or Immunex (the company that initially discovered the drug Enbrel and was later acquired by Amgen). Dr. Finck was involved in the clinical development of etanercept (Enbrel) while at Immunex and is a named inventor on at least four U.S. patents assigned to Amgen directed to the use of etanercept (Enbrel) for the treatment of psoriasis and psoriatic arthritis. Our board of directors and Scientific Advisory Board include members that were former employees of Genentech, Amgen and Abbott Laboratories. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us and we are not currently subject to any claims that they have done so, we may in the future be subject to such claims. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

If we are unable to obtain and maintain effective patent rights for our product candidates or any future product candidates, we may not be able to prevent competitors from using technologies we consider important in our successful development and commercialization of our product candidates, resulting in loss of any potential competitive advantage our patents may have otherwise afforded us.

While our principal focus in matters relating to intellectual property is to avoid infringing the valid and enforceable rights of third parties, we also rely upon a combination of patents, trade secret protection and confidentiality agreements to protect our own intellectual property related to our product candidates and development programs. Our ability to enjoy any competitive advantages afforded by our own intellectual property depends in large part on our ability to obtain and maintain patents and other intellectual property protection in the United States and in other countries with respect to various proprietary elements of our product candidates, such as, for example, our product formulations and processes for manufacturing our products and our ability to maintain and control the confidentiality of our trade secrets and confidential information critical to our business.

We have sought to protect our proprietary position by filing patent applications in the United States and abroad related to our products that are important to our business. This process is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. There is no guarantee that any patent application we file will result in an issued patent having claims that protect our products. Additionally, while the basic requirements for patentability are similar across jurisdictions, each jurisdiction has its own specific requirements for patentability. We cannot guarantee that we will obtain identical or similar patent protection covering our products in all jurisdictions where we file patent applications.

The patent positions of biopharmaceutical companies generally are highly uncertain and involve complex legal and factual questions for which legal principles remain unresolved. As a result, the patent applications that we own or license may fail to result in issued patents with claims that cover our product candidates in the United States or in other foreign countries for many reasons. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found, considered or cited during patent prosecution, which can be used to invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue, and even if such patents cover our product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patent claims being narrowed, found unenforceable or invalidated. Our patents and patent applications, even if they are unchallenged, may not adequately protect our intellectual property, provide exclusivity for our product candidates or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competitors from using the technologies claimed in any patents issued to us, which may have an adverse impact on our business.

In addition, recent changes to the patent laws of the United States provide additional procedures for third parties to challenge the validity of issued patents based on patent applications filed after March 15, 2013. If the breadth or strength of protection provided by the patents and patent applications we hold or pursue with respect to our current or future product candidates is challenged, then it could threaten our ability to prevent competitive products using our proprietary technology. Further, because patent applications in the United States and most other countries are confidential for a period of time, typically for 18 months after filing, we cannot be certain that we were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our patents or patent applications. Furthermore, for applications filed before March 16, 2013 or patents issuing from such applications, an interference proceeding can be provoked by a third party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications and patents. As of March 16, 2013, the United States transitioned to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications claiming the same invention are filed by different parties. A third party that files a patent application in the USPTO before we do, could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. The change to "first-to-file" from "first-to-invent" is one of the changes to the patent laws of the United States resulting from the Leahy-Smith America Invents Act, or the Leahy-Smith Act, signed into law on September 16, 2011. Among some of the other significant changes to the patent laws are changes that limit where a patentee may file a patent infringement suit and provide opportunities for third parties to challenge any issued patent in the USPTO. It is not yet clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

Patents granted by the European Patent Office may be opposed by any person within nine months from the publication of their grant and, in addition, may be challenged before national courts at any time. If the breadth or strength of protection provided by the patents and patent applications we hold, license or pursue with respect to our product candidates is threatened, it could threaten our ability to prevent third parties from using the same technologies that we use in our product candidates.

We do not have any issued patents, but we have filed patent applications, which are currently pending, covering various aspects of our product candidates. We cannot offer any assurances about which, if any, patents will issue, the breadth of any such patent or whether any issued patents will be found invalid and unenforceable or will be threatened or infringed by third parties. Any successful actions by third parties to challenge the validity or enforceability of any patents which may issue to us could deprive us of the ability to prevent others from using the technologies claimed in such issued patents. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced.

While our business is based primarily on the timing of our biosimilar product launches to occur after the expiration of relevant patents, we have filed a number of patents covering our own proprietary formulations and processes for our product candidates when we have believed securing such patents may afford a competitive advantage. For example, the companies that originated Enbrel and Humira (Amgen and AbbVie, respectively) own patents directed to formulations for these products. We have developed our own proprietary formulations for these products which we believe are not covered by valid, enforceable third party patents, including Amgen or AbbVie's formulation patents, and we have filed patent applications covering our formulations which are currently pending in the U.S. and globally. We cannot guarantee that our proprietary formulations will avoid infringement of third party patents. Moreover, because competitors may be able to develop their own proprietary product formulations, it is uncertain whether issuance of any of our pending patent applications directed to formulations of etanercept (Enbrel) and adalimumab (Humira) would cover the formulations of any competitors. As in the case of formulations, originators have also filed patents directed to methods for manufacturing their products. We have filed patent applications, currently pending, both in the U.S. and globally, directed to aspects of our manufacturing processes for CHS-0214 and CHS-1420. We believe the proprietary technologies embodied in our process-related patent filings may provide us with competitive advantage and are not covered by valid, enforceable intellectual property rights of third party patents, including AbbVie and Amgen. However, as in the case of our formulation patent filings, it is highly uncertain and we cannot predict whether our patent filings on process enhancements will afford us a competitive advantage against third parties, and we cannot guarantee that the methods we use to manufacture our products will avoid infringement of third party patents.

We do not consider it necessary for us or our competitors to obtain or maintain a proprietary patent position in order to engage in the business of biosimilar development and commercialization. Hence, while our ability to secure patent coverage on our own proprietary developments may improve our competitive position with respect to the product candidates we intend to commercialize, we do not view our own patent filings as a necessary or essential requirement for conducting our business nor do we rely on our own patent filings or the potential for any commercial advantage they may provide us as a basis for our success.

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

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case.

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

Filing, prosecuting, defending and enforcing patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Further, licensing partners such as Baxalta or Daiichi Sankyo may chose not to file patent applications in certain jurisdictions in which we may obtain commercial rights, thereby precluding the possibility of later obtaining patent protection in these countries. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States or importing products made using our inventions into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export infringing products to territories where we have patent protection, but the ability to enforce our patents is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our

business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Governments of foreign countries may force us to license our patents to third parties on terms that are not commercially reasonable or acceptable to us. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time consuming and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations.

In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on future actions by the United States Congress, the Federal Courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

If we are unable to maintain effective (non-patent) proprietary rights for our product candidates or any future product candidates, we may not be able to compete effectively in our markets.

While we have filed patent applications to protect certain aspects of our own proprietary formulation and process developments, we also rely on trade secret protection and confidentiality agreements to protect proprietary scientific, business and technical information and know-how that is not or may not be patentable or that we elect not to patent. However, confidential information and trade secrets can be difficult to protect. Moreover, the information embodied in our trade secrets and confidential information may be independently and legitimately developed or discovered by third parties without any improper use of or reference to information or trade secrets. We seek to protect the scientific, technical and business information supporting our operations, as well as the confidential information relating specifically to our product candidates by entering into confidentiality agreements with parties to whom we need to disclose our confidential information, for example, our employees, consultants, scientific advisors, board members, contractors, potential collaborators and investors. However, we cannot be certain that such agreements have been entered into with all relevant parties. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems, but it is possible that these security measures could be breached. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. Our confidential information and trade secrets thus may become known by our competitors in ways we cannot prove or remedy.

Although we expect all of our employees and consultants to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed. We cannot guarantee that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. For example, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may have a material adverse effect on our business. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. We cannot guarantee that our employees, former employees or consultants will not file patent applications claiming our inventions. Because of the “first-to-file” laws in the United States, such unauthorized patent application filings may defeat our attempts to obtain patents on our own inventions.

We may be subject to claims challenging the inventorship of our patent filings and other intellectual property.

Although we are not currently aware of any claims challenging the inventorship of our patent applications or ownership of our intellectual property, we may in the future be subject to claims that former employees, collaborators or other third parties have an interest in our patent applications or patents we may be granted or other intellectual property as an inventor or co-inventor. For example, we may have inventorship or ownership disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship

or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of or right to use valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

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

We are a party to certain non-exclusive intellectual property license agreements with Genentech (pertaining to the production of monoclonal antibodies) and Selexis SA and other vendors (pertaining to cell lines for CHS-0214 and CHS-1420) that are important to our business, and we expect to enter into additional license agreements in the future. Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty and other obligations on us. If we fail to comply with our obligations under these agreements or we are subject to a bankruptcy, we may be required to make certain payments to the licensor, we may lose the exclusivity of our license or the licensor may have the right to terminate the license, in which event we would not be able to develop or market products covered by the license. Additionally, the milestone and other payments associated with these licenses will make it less profitable for us to develop our product candidates.

In the event we breach any of our obligations related to such agreements, we may incur significant liability to our licensing partners. Disputes may arise regarding intellectual property subject to a licensing agreement, including but not limited to:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patents and other rights;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our collaborators; and
- the priority of invention of patented technology.

If disputes over intellectual property and other rights that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates and that could have a material adverse effect on our business.

We may not be successful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses.

We currently have rights to certain intellectual property, through licenses from third parties and under patent applications that we own, to develop CHS-0214 and CHS-1420. Because we may find that our programs require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights. We may be unable to acquire or in-license compositions, methods of use, processes or other third party intellectual property rights from third parties that we identify as necessary for our product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, financial resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment.

If we are unable to successfully obtain required third party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of that program and our business and financial condition could suffer.

Our ability to market our products in the United States may be significantly delayed or prevented by the BPCIA patent dispute resolution mechanism.

The Biologics Price Competition and Innovation Act of 2009, Title VII, Subtitle A of the Patent Protection and Affordable Care Act, Pub.L.No.111-148, 124 Stat.119, Sections 7001-02 signed into law March 23, 2010, and codified in 42 U.S.C. §262, or the BPCIA, created an elaborate and complex patent dispute resolution mechanism for biosimilars that, if we choose to implement it, could prevent us from launching our product candidates in the United States or could substantially delay such launches.

The BPCIA establishes a patent disclosure and briefing process between the biosimilar applicant and the originator that is demanding and time-sensitive. While certain aspects of this process are still being tested in the federal courts, the Federal Circuit, as discussed further below, recently ruled that this process is not mandatory, such that a biosimilar applicant may elect to engage in this process, but is not required to do so. The following is an overview of the patent exchange and patent briefing procedures established by the BPCIA for biosimilar applicants that elect to employ them:

1. Disclosure of the Biosimilar Application. Within 20 days after the FDA publishes a notice that its application has been accepted for review, a 351(k) biosimilar applicant may elect to provide a copy of its application to the originator if it chooses to engage in the BPCIA patent exchange mechanism.

2. Identification of Pertinent Patents. Within 60 days of the date of receipt of the application the originator must identify patents owned or controlled by the originator which it believes could be asserted against the biosimilar applicant.

3. Statement by the Biosimilar Applicant. Following the receipt of the originator's patent list, the biosimilar applicant must state either that it will not market its product until the relevant patents have expired or alternatively provide its arguments that the patents are invalid, unenforceable or would not be infringed by the proposed biosimilar product candidate. The biosimilar applicant may also provide the originator with a list of patents it believes the brand-name firm could assert against the reference product.

4. Statement by the Originator. In the event the biosimilar applicant has asserted that the patents are invalid, unenforceable or would not be infringed by the proposed follow-on product, the originator must provide the biosimilar applicant with a response within 60 days. The response must provide the legal and factual basis of the opinion that such patent will be infringed by the commercial marketing of the proposed biosimilar.

5. Patent Resolution Negotiations. If the originator provides its detailed views that the proposed biosimilar would infringe valid and enforceable patents, then the parties are required to engage in good faith negotiations to identify which of the discussed patents will be the subject of a patent infringement action. If the parties agree on the patents to be litigated, the brand-name firm must bring an action for patent infringement within 30 days.

6. Simultaneous Exchange of Patents. If those negotiations do not result in an agreement within 15 days, then the biosimilar applicant must notify the originator of how many patents (but not the identity of those patents) that it wishes to litigate. Within five days, the parties are then required to exchange lists identifying the patents to be litigated. The number of patents identified by the originator may not exceed the number provided by the biosimilar applicant. However, if the biosimilar applicant previously indicated that no patents should be litigated, then the originator may identify one patent.

7. Commencement of Patent Litigation. The originator must then commence patent infringement litigation within 30 days. That litigation will involve all of the patents on the originator's list and all of the patents on the follow-on applicant's list. The follow-on applicant must then notify the FDA of the litigation. The FDA must then publish a notice of the litigation in the Federal Register.

8. Notice of Commercial Marketing. The BPCIA requires the biosimilar applicant to provide notice to the originator 180 days in advance of its first commercial marketing of its proposed follow-on biologic. The originator is allowed to seek a preliminary injunction blocking such marketing based upon any patents that either party had preliminarily identified, but were not subject to the initial phase of patent litigation. The litigants are required to "reasonably cooperate to expedite such further discovery as is needed" with respect to the preliminary injunction motion. The federal courts have not yet settled the issue as to when, or under what circumstances, the biosimilar applicant must provide the 180 notice of commercial marketing provided in the BPCIA.

On July 21, 2015 the Federal Circuit court in litigation between Amgen and Sandoz ruled that the BPCIA patent exchange process is optional and that applicants that choose not to engage in it must comply with the BPCIA's requirement to provide the originator180 days prior notice of commercial marketing. The court also ruled that such notice is not effective unless given after FDA licensure. Thus, biosimilar applicants that opt out of the BPCIA patent exchange process must wait at least 180 days after licensure to launch their biosimilar products. On February 16, 2016 Sandoz filed a petition for writ of *certiorari* to the United States Supreme Court, asking the Court to reverse the Federal Circuit court's decision that the BPCIA 180 day pre-marketing notification can only be given after FDA has approved the biosimilar product. The Supreme Court may or may not choose to review the Federal Circuit

decision. Regardless of how the 180 day notice provision is applied by the courts, patent infringement lawsuits filed by originators could result in preliminary or permanent injunctions extending beyond the 180 day notice period.

On December 9, 2015, in litigation between Amgen and Apotex (relating to Apotex's biosimilar for Neulasta (pegiflgrastim), the Florida District court ruled that although Apotex had engaged in the BPCIA patent exchange process voluntarily, it was nonetheless required to provide 180 days prior notice of commercial marketing to Amgen, and that it could only provide such notice upon regulatory approval. Apotex has appealed this decision to the Federal Circuit, where the matter is presently pending. Thus, despite the Florida District Court decision, the issue remains unsettled as to whether a party that engages voluntarily in the BPCIA patent exchange process must nevertheless provide 180 days' notice of commercial marketing to the originator. A further open issue is whether such notice may be given before, or only after, FDA licensure of the biosimilar. If a panel of the Federal Circuit affirms the Florida District Court decision and such decision is not overturned upon reconsideration by a full panel of the Federal Circuit or by the US. Supreme Court, all 351(k) biosimilar applicants will be required to refrain from launching an approved biosimilar product for 180 days following 351(k) regulatory approval, without regard to whether such applicants elected to participate in the BPCIA patent exchange process.

A significant legal risk for a biosimilar applicants that pursue regulatory approval under the 351(k) regulatory approval route, and also elect to engage in the above-described BPCIA patent exchange mechanism, is that the process could result in the initiation of patent infringement litigation prior to FDA approval of a 351(k) application, and such litigation could result in blocking the market entry of the biosimilar product. However, even if biosimilar applicants opt out of the BPCIA patent exchange process, originators will still have the right to assert patent infringement as a basis to enjoin a biosimilar product launch. Thus, whether or not we engage in the BPCIA patent exchange process, there is risk that patent infringement litigation initiated by originators could prevent us indefinitely from launching our biosimilar products.

The legal and strategic considerations weighing for or against a decision to voluntarily engage in the BPCIA patent exchange process are complex and will differ on a product-by-product basis. If we decide to engage in the BPCIA patent exchange process, preparing for and conducting the patent exchange, briefing and negotiation process outlined above will require extraordinarily sophisticated legal counseling and extensive planning, all under extremely tight deadlines. Moreover, it may be difficult for us to secure or retain such legal support if large, well-funded originators have already entered into engagements with highly qualified law firms or if the most highly qualified law firms choose not to represent biosimilar applicants due to their long standing relationships with originators.

Furthermore, we could be at a serious disadvantage in this process, as an originator company such as Amgen (in the case of CHS-1420 or CHS-0214) or AbbVie (in the case of CHS-1420) may be able to apply substantially greater legal and financial resources to this process than we could.

If we file a 351(k) regulatory approval application for one or more of our products, we may consider it necessary or advisable to adopt the strategy of selecting one or more patents of the originator to litigate in the above described BPCIA process (for example in steps 3 and 7, of the process, as outlined above), either to assert our non-infringement of such patents or to challenge their validity, or both; but we may ultimately not be successful in that strategy and could be prevented, indefinitely, from marketing the product in the United States.

Under the complex, and uncertain rules of the BPCIA patent provisions, coupled with the inherent uncertainty surrounding the legal interpretation of any originator patents that might be asserted against us in this new process, we see substantial risk that the BPCIA process may significantly delay or defeat our ability to market our products in the United States.

Risks Related to Our Business Operations

We may not be successful in our efforts to identify, develop or commercialize additional product candidates.

Although a substantial amount of our effort will focus on the continued clinical testing, potential approval and commercialization of our existing product candidates, the success of our business also depends upon our ability to identify, develop and commercialize additional product candidates. Research programs to identify new product candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful. Our development efforts may fail to yield additional product candidates suitable for clinical development and commercialization for a number of reasons, including but not limited to the following:

- we may not be successful in identifying potential product candidates that pass our strict screening criteria;
- we may not be able to overcome technological hurdles to development or a product candidate may not be capable of producing commercial quantities at an acceptable cost or at all;

- we may not be able to assemble sufficient resources to acquire or discover additional product candidates;
- our product candidates may not succeed in nonclinical or clinical testing;
- our potential product candidates may fail to show sufficient biosimilarity to originator molecules; and
- competitors may develop alternatives that render our product candidates obsolete or less attractive or the market for a product candidate may change such that a product candidate may not justify further development.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs or we may not be able to identify, develop or commercialize additional product candidates, which would have a material adverse effect on our business and could potentially cause us to cease operations.

We incur significant increased costs as a result of operating as a public company, and our management is required to devote substantial time to compliance initiatives. We may fail to comply with the rules that apply to public companies, including Section 404 of the Sarbanes-Oxley Act of 2002, which could result in sanctions or other penalties that would harm our business.

We incur significant legal, accounting and other expenses as a public company, including costs resulting from public company reporting obligations under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and regulations regarding corporate governance practices. The listing requirements of The NASDAQ Global Market require that we satisfy certain corporate governance requirements relating to director independence, distributing annual and interim reports, stockholder meetings, approvals and voting, soliciting proxies, conflicts of interest and a code of conduct. Our management and other personnel must devote a substantial amount of time to ensure that we maintain compliance with all of these requirements. Moreover, the reporting requirements, rules and regulations will increase our legal and financial compliance costs and make some activities more time consuming and costly. Any changes we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, may also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or board committees or to serve as executive officers, or to obtain certain types of insurance, including directors' and officers' insurance, on acceptable terms.

We are subject to Section 404 of The Sarbanes-Oxley Act of 2002, or Section 404, and the related rules of the Securities and Exchange Commission, or SEC, which generally require our management and independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting. Under the Jumpstart Our Business Startups Act of 2012, or JOBS Act, we previously took advantage of certain exemptions from various reporting requirements that are applicable to public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404. Once we are no longer an emerging growth company or, if prior to such date, we opt to no longer take advantage of the applicable exemption. Based on our non-affiliated market capitalization as of June 30, 2015, we ceased to be an emerging growth company under the JOBS Act on January 1, 2016 and therefore are now required to include an opinion from our independent registered public accounting firm on the effectiveness of our internal controls over financial reporting.

Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may also lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time consuming and costly. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain our current levels of such coverage.

We have experienced a material weakness in our internal controls over financial reporting.

In connection with the audit of our financial statements from inception through December 31, 2013, we identified a material weakness in our internal control over financial reporting. 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. The material weakness related to a deficiency in the design and operating effectiveness of our internal control related to the valuation of complex securities.

We implemented changes to our disclosure controls and procedures and internal control over financial reporting to remediate the material weakness identified above. We strengthened the operation of our internal controls over the accounting for non-routine, complex equity transactions, including increasing the depth and experience within our accounting and finance organization, as well as designing and implementing improved processes and internal controls to identify such matters. We have hired additional personnel to

build our financial management and reporting infrastructure, including the hiring of our Chief Financial Officer and Vice President of Finance, in the third and fourth quarter of 2014, respectively.

Although we have taken steps that we believe have addressed the underlying causes of the material weakness described above and there were no material weaknesses identified in connection with the reviews of our financial statements for the first, second and third quarters of 2015 and in connection with the audit of our financial statements for 2015, other material weaknesses or deficiencies in our control environment may be identified in the future and we may be unable to accurately report our financial results, or report them within the time frames required by law or exchange regulations.

Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or together, the PPACA, was passed, which substantially changes the way health care is financed by both governmental and private insurers and significantly impacts the U.S. pharmaceutical industry. The PPACA, among other things, addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations, adds a provision to increase the Medicaid rebate for line extensions or reformulated drugs, establishes annual fees and taxes on manufacturers of certain branded prescription drugs and promotes a new Medicare Part D coverage gap discount program.

In addition, other legislative changes have been proposed and adopted in the United States since the PPACA was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect on April 1, 2013 and will stay in effect through 2024 unless additional Congressional action is taken. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012 which, among other things, further reduced Medicare payments to certain providers, including physicians, hospitals and cancer treatment centers. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures, such as a single reimbursement code for biosimilar products.

We may be subject, directly or indirectly, to federal and state healthcare laws, including fraud and abuse, false claims, physician payment transparency and health information privacy and security laws. If we are unable to comply or have not fully complied with such laws, we could face substantial penalties.

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our operations may be directly or indirectly through our customers subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act and physician sunshine laws and regulations. These laws may impact, among other things, our proposed sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, to induce or in return for the purchase, recommendation, order or furnishing of an item or service reimbursable, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting or causing to be presented claims for payment from Medicare, Medicaid or other third-party payors that are false or fraudulent and which may apply to entities that provide coding and billing advice to customers;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;
- the federal physician "sunshine" requirements under the PPACA, which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services information related to payments and other transfers of value made by such manufacturers to physicians and teaching hospitals and ownership and investment interests held by physicians and their immediate family members and applicable group purchasing organizations; and
- state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers, state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened these laws. For example, the PPACA, among other things, amends the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. Moreover, the PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

The international aspects of our business expose us to business, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States.

We currently have limited international operations of our own and have a number of international collaborations. Doing business internationally involves a number of risks, including but not limited to:

- multiple, conflicting and changing laws and regulations such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us or our collaboration partners to obtain and maintain regulatory approvals for the use of our products in various countries;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining protection and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations by us or our collaboration partners;
- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems by our collaboration partners;
- limits in our or our collaboration partners' ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions;

- certain expenses including, among others, expenses for travel, translation and insurance; and
- regulatory and compliance risks that relate to maintaining accurate information and control over sales and activities that may fall within the purview of the U.S. Foreign Corrupt Practices Act its books and records provisions or its anti-bribery provisions.

Sanctions against Russia, and Russia's response to those sanctions, could materially adversely affect our business, financial condition and results of operations.

Due to Russia's recent military intervention in Ukraine, the United States and the E.U. have imposed sanctions on certain individuals and one financial institution in Russia and have proposed the use of broader economic sanctions. In response, Russia has imposed entry bans on certain U.S. lawmakers and officials. Our wholly owned subsidiary, InteKrin Therapeutics, Inc., or InteKrin, which we acquired in February 2014 is majority owner of a Russian pharmaceutical development entity, ZAO InteKrin, which holds $111,000 of cash in Russian banks as of December 31, 2015. This Russian subsidiary of InteKrin conducts research and development activities for a product we acquired as part of our acquisition of InteKrin. The product is a small molecule peroxisome proliferator-activated receptor, or PPAR, gamma inhibitor that may hold promise in treatment of multiple sclerosis, or MS. While not a biosimilar, this PPAR gamma inhibitor compound may be complementary to biosimilar products for treatment of MS that we are currently evaluating for inclusion in our pipeline. If the United States and the E.U. were to impose sanctions on Russian businesses, or if Russia were to take retaliatory action against U.S. companies operating in Russia, our research and development activities related to the InteKrin PPAR gamma inhibitor product could be materially adversely affected.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

Our research and development activities and our third-party manufacturers' and suppliers' activities involve the controlled storage, use and disposal of hazardous materials, including the components of our product candidates and other hazardous compounds. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly cleanup and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by us and our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. We do not currently carry biological or hazardous waste insurance coverage.

We or the third parties upon whom we depend may be adversely affected by earthquakes or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our corporate headquarters and laboratory are located in the San Francisco Bay Area and in Southern California (Camarillo), respectively, and one of our collaboration partners, Daiichi Sankyo, is located in Japan. These locations have in the past experienced severe earthquakes and other natural disasters. We do not carry earthquake insurance. Earthquakes or other natural disasters could severely disrupt our operations or those of our collaboration partners and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure (such as the manufacturing facilities of our third-party contract manufacturers) or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business.

Risks Related to Ownership of Our Common Stock

The market price of our common stock may be highly volatile, and purchasers of our common stock could incur substantial losses.

The market price of our common stock has been highly volatile since our IPO and the intraday sales price per share has ranged from $12.04 to $38.10 per share during the period from November 6, 2014 through February 26, 2016 and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include those discussed in this "Risk Factors" section of this Annual Report on Form 10-K and others such as:

- adverse results or delays in preclinical or clinical studies;
- any inability to obtain additional funding;
- any delay in filing an IND, NDA, BLA or other regulatory submission for any of our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory agency's review of that IND, NDA, BLA or other regulatory submission;
- the perception of limited market sizes or pricing for our product candidates;
- failure to successfully develop and commercialize our product candidates;
- post-marketing safety issues relating to our product candidates or biosimilars generally;
- failure to maintain our existing strategic collaborations or enter into new collaborations;
- failure by us or our licensors and strategic collaboration partners to prosecute, maintain or enforce our intellectual property rights;
- changes in laws or regulations applicable to our products;
- any inability to obtain adequate product supply for our product candidates or the inability to do so at acceptable prices;
- adverse regulatory decisions;
- introduction of new products, services or technologies by our competitors;
- failure to meet or exceed financial projections we may provide to the public;
- failure to meet or exceed the financial projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us, our strategic collaboration partners or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key scientific or management personnel;
- lawsuits, including stockholder litigation and litigation filed by us or filed against us pertaining to patent infringement or other violations of intellectual property rights;
- the outcomes of any citizens petitions filed by parties seeking to restrict or limit the approval of biosimilar products;
- if securities or industry analysts do not publish research or reports about our business or if they issue an adverse or misleading opinion regarding our stock;
- changes in the market valuations of similar companies;
- general market or macroeconomic conditions;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- issuance of patents to third parties that could prevent our ability to commercialize our product candidates;
- reductions in the prices of originator products that could reduce the overall market opportunity for our product candidates intended as biosimilars to such originator products;

- the loss of one or more employees constituting our leadership team; and
- changes in biosimilar regulatory requirements that could make it more difficult for us to develop our product candidates.

In addition, biopharmaceutical companies in particular have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

As of December 31, 2015, our executive officers, directors, five percent stockholders and their affiliates beneficially owned approximately 58.5% of our voting stock (assuming no exercise of outstanding options). These stockholders have the ability to influence us through their ownership positions, which may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may believe are in your best interest as one of our stockholders.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

If our existing stockholders sell or indicate an intention to sell substantial amounts of our common stock in the public market after the lock-up and other legal restrictions on resale lapse, the market price of our common stock could decline. As of December 31, 2015, there were 39,005,589 shares of common stock outstanding. Of these shares, the shares of our common stock sold in our IPO and our follow-on offering are currently freely tradable, without restriction (except as otherwise applicable), in the public market.

In addition, as of December 31, 2015, approximately 8.9 million shares of common stock that are either subject to outstanding options or reserved for future issuance under our equity incentive plans became eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold or if it is perceived that they will be sold in the public market, the market price of our common stock could decline.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We will need additional capital in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

Pursuant to our 2014 Equity Incentive Award Plan, or the 2014 Plan, our management is authorized to grant stock options and other equity-based awards to our employees, directors and consultants. Under the 2014 Plan, the number of shares of our common stock initially reserved for issuance is 2,300,000 plus the number of shares remaining available for future awards under the 2010 Plan. The number of shares available for future grant under the 2014 Plan will be increased by (i) the number of shares pursuant to outstanding awards under the 2010 Plan that are forfeited or lapse unexercised and which following the effective date are not issued under the 2010 Plan and (ii) an annual increase on the first day of each fiscal year beginning in 2015 and ending in 2024, equal to 4% of the shares of stock outstanding as of the last day of the preceding fiscal year, or such smaller number of shares as determined by our board of directors. Pursuant to our 2014 Employee Stock Purchase Plan, or 2014 ESPP, eligible employees are able to acquire shares of our common stock at a discount to the prevailing market price, and an aggregate of 320,000 shares are initially available for issuance under the 2014 ESPP. The number of shares available for issuance under the 2014 ESPP will automatically increase on the first day of each fiscal year beginning in 2015 and ending in 2024, equal to 1% of the shares of common stock outstanding on the last day of the immediately preceding fiscal year or such smaller number of shares as determined by our board of directors. If our board of directors elects to increase the number of shares available for future grant under the 2014 Plan or the 2014 ESPP, our stockholders may experience additional dilution, which could cause our stock price to fall.

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

We have incurred substantial losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an “ownership change,” generally defined as a greater than 50 percentage point change (by

value) in its equity ownership by certain stockholders over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards, or NOLs, and other pre-change tax attributes (such as research tax credits) to offset its post-change income or taxes may be limited. We have experienced ownership changes in the past and may experience ownership changes in the future as a result of shifts in our stock ownership (some of which shifts are outside our control). As a result, if we earn net taxable income, our ability to use our pre-change NOLs to offset such taxable income will be subject to limitations. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, even if we attain profitability, we may be unable to use a material portion of our NOLs and other tax attributes, which could adversely affect our future cash flows.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders or remove our current management.

Our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law contain provisions that may have the effect of delaying or preventing a change in control of us or changes in our management. Our amended and restated certificate of incorporation and bylaws include provisions that:

- authorize "blank check" preferred stock, which could be issued by our board of directors without stockholder approval and may contain voting, liquidation, dividend and other rights superior to our common stock;
- create a classified board of directors whose members serve staggered three-year terms;
- specify that special meetings of our stockholders can be called only by our corporate secretary pursuant to a resolution adopted by a majority of our board of directors;
- prohibit stockholder action by written consent;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors other than nominations made by or at the direction of the board of directors or a committee of the board of directors;
- provide that our directors may be removed only for cause or without cause by the holders of 66 2/3% of the voting power of all then outstanding shares of voting stock;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- specify that no stockholder is permitted to cumulate votes at any election of directors;
- expressly authorize our board of directors to modify, alter or repeal our amended and restated bylaws; and
- require holders of 66 2/3% of the voting power of all then outstanding shares of voting stock to amend specified provisions of our amended and restated certificate of incorporation except for the provision making it possible for our board of directors to issue "blank check" preferred stock, and amended and restated bylaws.

These provisions, alone or together, could delay, deter or prevent hostile takeovers and changes in control or changes in our management.

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.

Any provision of our amended and restated certificate of incorporation or amended and restated bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock and could also affect the price that some investors are willing to pay for our common stock.

Item 1B. ***Unresolved Staff Comments***

Not applicable.

Item 2. ***Properties***

Our headquarters are located in Redwood City, California, where we occupy office space under a lease that will expire in November 2022. Our analytical and process development laboratories are located in Camarillo, California under a lease that expires in June 2017 with a three year renewal option.

We believe that our existing facilities are adequate for our current needs. When our leases expire, or if we need to hire more employees, we may exercise our renewal option or look for additional or alternate space for our operations and we believe that suitable additional or alternative space will be available in the future on commercially reasonable terms.

Item 3. **Legal Proceedings**

We are not currently a party to any material litigation or legal proceedings.

On November 9, 2015 and December 7, 2015, we filed in the United States Patent and Trademark Office, pursuant to 35 U.S.C. §§ 311–319 AND 37 C.F.R. § 42, petitions for Inter Partes Review ("IPR") of AbbVie's United States Patent Nos. 8,889,135 (Case No. IPR2016-00172, filed December 7, 2015); 9,017,680 (Case No. IPR2016-00188, filed December 7, 2015); and 9,073,987 (Case No. IPR 2016-00189, filed December 7, 2015), each entitled "Methods of Administering Anti-TNFα antibodies" directed to treating rheumatoid arthritis in a human subject via subcutaneous administration, every 13-15 days, of 40 mg of a human anti-TNFα antibody.

Item 4. **Mine Safety Disclosures**

Not applicable.

PART II

Item 5. ***Market for Registrant's Common Equity, Related Stockholder Matters, and Issuer Purchases of Equity Securities***

Market Information

Our common stock has been listed on The NASDAQ Global Market under the symbol "CHRS" since November 6, 2014. Prior to that there was no public trading market for our common stock. The high and low closing sales price of our common stock for the period from November 6, 2014 to December 31, 2015 was $37.46 and $12.61, respectively.

On January 29, 2016, the closing sale price of our common stock was $13.26.

Common Stockholders

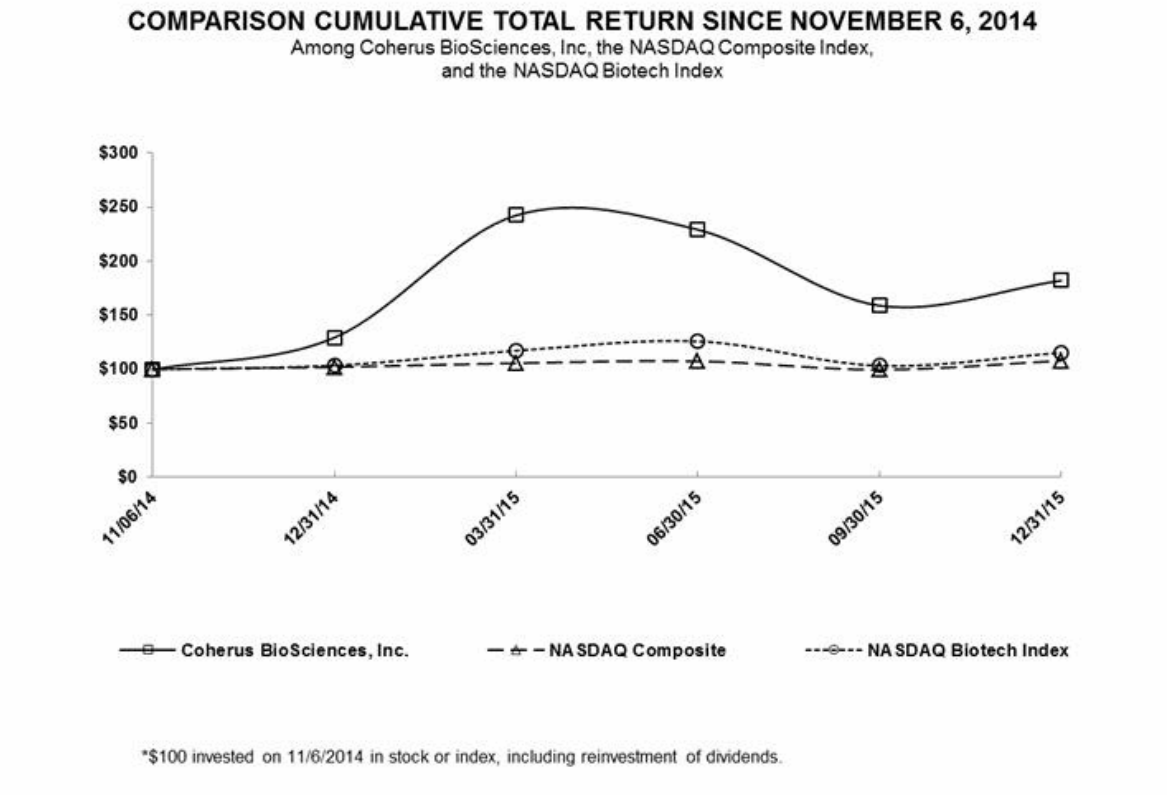
As of January 29, 2016, there were approximately 59 stockholders of record of our common stock. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock and do not anticipate paying any cash dividends in the foreseeable future. Payment of cash dividends, if any, in the future will be at the discretion of our board of directors and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant. In February 2016, we entered into senior convertible notes which preclude the Company, directly or indirectly, to declare dividends so long as any of the notes are outstanding.

Stock Performance Graph

The following graph shows the total stockholder's return on an investment of $100 in cash at market close on November 6, 2014 (the first day of trading of our common stock), through December 31, 2015 for (i) our common stock, (ii) the NASDAQ Composite Index and (iii) the NASDAQ Biotechnology Index. Pursuant to applicable Securities and Exchange Commission rules, all values assume reinvestment of the full amount of all dividends, however, no dividends have been declared on our common stock to date. The stockholder return shown on the graph below is not necessarily indicative of future performance, and we do not make or endorse any predictions as to future stockholder return. This graph shall not be deemed "soliciting material" or be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities under that Section, and shall not be deemed to be incorporated by reference into any of our filings under the Securities Act, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.



Securities Authorized for Issuance Under Equity Compensation Plans

The information required by this Item regarding equity compensation plans is incorporated by reference to the information set forth in PART III Item 12 of this Annual Report on Form 10-K.

Use of Proceeds from Registered Securities

On March 23, 2015, we filed our registration statement on Form S-1 (File No. 333-202936) relating to our follow-on offering of our common stock and it was declared effective by the SEC on March 31, 2015. The price of the shares sold in the follow-on offering was $29.00 per share. The follow-on offering closed on April 7, 2015, pursuant to which we sold 4,137,931 shares of common stock. We received total gross proceeds from the offering of $120.0 million. After deducting underwriting discounts and commissions of $7.2 million and offering expenses of $0.6 million, the net proceeds were $112.2 million.

The net proceeds from the follow-on offering described above have been used primarily to fund the development of one or more biosimilar candidates currently in the preclinical stage and to fund the proof-of-concept Phase 2 study of CHS-131.

Recent Sales of Unregistered Equity Securities

From January 1, 2015 through December 31, 2015, we sold and issued the following unregistered securities:

On September 10, 2015, we completed a private placement under a Stock Purchase Agreement with Baxalta and sold an aggregate of 390,167 shares of common stock for aggregate gross proceeds of approximately $10.0 million. The purchase price for each share was $25.63, which is equal to the closing trading price of our common stock on the NASDAQ Global Market on the day of pricing, September 9, 2015. The securities sold and issued in connection with the private placement were initially unregistered under the Securities Act or any state securities laws and could not be offered or sold in the United States absent registration with the SEC or an applicable exemption from the registration requirements. In connection with the Purchase Agreement, we entered into a Registration Rights Agreement (the "Registration Rights Agreement") with Baxalta GmbH. Pursuant to the Registration Rights Agreement, we filed a registration statement on Form S-3 (File No. 333-208625) to register the securities sold and issued in connection with the private placement with the SEC on December 18, 2015 and declared effective by the SEC on January 21, 2016.

The net proceeds from the private placement described above have been used and will be used to fund clinical and manufacturing development, working capital and other general corporate purposes.

Issuer Purchases of Equity Securities

We did not repurchase any of our equity securities during the fourth quarter of the fiscal year ended December 31, 2015.

Item 6. ***Selected Financial Data***

You should read the following selected consolidated financial data together with the information under "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes included in this Form 10-K. The consolidated statement of operations data for each of the years ended December 31, 2015, 2014 and 2013, and the consolidated balance sheet data as of December 31, 2015 and 2014 are derived from our audited consolidated financial statements included elsewhere in this Form 10-K. The selected consolidated statement of operations data for the year ended December 31, 2012 and the consolidated balance sheet data as of December 31, 2013 and 2012 are derived from our audited financial statements which are not included in this Annual Report on Form 10-K. The selected consolidated statement of operations data for the year ended December 31, 2011 and the consolidated balance sheet data as of December 31, 2011 are derived from our unaudited financial statements which are not included in this Annual Report on Form 10-K.

Consolidated Statement of Operations Data:

(in thousands, except share and per share data)	Year Ended December 31, 2015	2014	2013	2012	2011
Revenue:					*(unaudited)*
Collaboration and license revenue	$ 30,041	$ 28,481	$ 726	$ 1,899	$ —
Collaboration and license revenue - related party (1)	-	1,893	2,025	—	—
Other revenue	-	732	—	—	—
Total revenue	30,041	31,106	2,751	1,899	—
Operating expenses:					
Research and development (2)	213,062	78,224	31,279	34,886	2,451
General and administrative (2)	36,046	17,564	7,465	5,531	2,559
Total operating expenses	249,108	95,788	38,744	40,417	5,010
Loss from operations	(219,067)	(64,682)	(35,993)	(38,518)	(5,010)
Interest expense	(33)	(3,900)	(5,293)	(1,514)	(2,583)
Other income (expense), net	(4,838)	(18,595)	(12,349)	7,014	(40)
Net loss	(223,938)	(87,177)	(53,635)	(33,018)	(7,633)
Net loss attributable to non-controlling interest	678	44	—	—	—
Net loss attributable to Coherus	$ (223,260)	$ (87,133)	$ (53,635)	$ (33,018)	$ (7,633)
Net loss per share attributable to Coherus, basic and diluted (3)	$ (6.01)	$ (10.64)	$ (16.10)	$ (15.85)	$ (9.33)
Weighted-average number of shares used in computing net loss per share attributable to Coherus, basic and diluted (3)	37,122,008	8,186,529	3,332,020	2,082,622	818,234

(1) Represents revenue from Daiichi Sankyo through November 12, 2014 as a related party, a holder of more than 10% of our common stock for the periods presented until the closing of our IPO.

(2) Includes stock-based compensation expense as follows:

(in thousands)	Year Ended December 31, 2015	2014	2013	2012	2011
					(unaudited)
Research and development	$ 8,038	$ 5,625	$ 682	$ 268	$ 143
General and administrative	8,683	5,437	1,363	175	120
Total stock-based compensation	$ 16,721	$ 11,062	$ 2,045	$ 443	$ 263

(3) See Note 14 to our audited consolidated financial statements for an explanation of the method used to calculate basic and diluted net loss per share attributable to Coherus and the weighted-average shares outstanding used to calculate the per share amounts.

Consolidated Balance Sheet Data:

(in thousands)	December 31, 2015	2014	2013	2012	2011
					(unaudited)
Cash and cash equivalents	$ 158,226	$ 150,392	$ 39,554	$ 14,548	$ 7,694
Working capital (deficit)	91,368	127,353	(8,024)	13,546	(1,460)
Total assets	212,384	187,221	47,447	26,533	8,482
Convertible notes	—	—	1,111	—	2,591
Convertible notes - related party	—	—	3,092	—	2,264
Convertible preferred stock warrant liability	—	—	24,251	1,738	2,777
Convertible preferred stock	—	—	54,695	54,695	1,191
Accumulated deficit	(409,985)	(186,725)	(99,592)	(45,957)	(7,966)
Total stockholder's equity (deficit)	(6,929)	66,757	(97,077)	(45,503)	(1,117)

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion should be read in conjunction with the attached financial statements and notes thereto. This Annual Report on Form 10-K, including the following sections, contains forward-looking statements within the meaning of the federal securities laws. These statements are subject to risks and uncertainties that could cause actual results and events to differ materially from those expressed or implied by such forward-looking statements. For a detailed discussion of these risks and uncertainties, see the "Risk Factors" section in Item 1A of this Annual Report on Form 10-K. We caution the reader not to place undue reliance on these forward-looking statements, which reflect management's analysis only as of the date of this Form 10-K. We undertake no obligation to update forward-looking statements, which reflect events or circumstances occurring after the date of this Form 10-K.

Overview

We are a late-stage clinical biologics platform company focused on the global biosimilar market. Biosimilars are an emerging class of protein-based therapeutics with high similarity to approved originator products on the basis of various physicochemical and structural properties, as well as in terms of safety, purity and potency. Our goal is to become a global leader in the biosimilar market by leveraging our team's collective expertise in key areas such as process science, analytical characterization, protein production and clinical-regulatory development.

Our clinical-stage biosimilar pipeline includes the following three product candidates:

- CHS-1701 (our pegfilgrastim (Neulasta) biosimilar candidate). Our long-acting G-CSF product candidate, CHS-1701, is being developed as a pegfilgrastim (Neulasta) biosimilar. In October 2015, we completed a pivotal pharmacokinetic (PK) and pharmacodynamics (PD) study for CHS-1701 in the United States (U.S.). Although it did not meet the PK AUC bioequivalence endpoint due to low, anomalous PK profile in the Neulasta first period group, we believe this study will support the planned filing of a biologics license application (BLA) in the U.S. as it met all the other co-primary endpoints including the PD endpoints. An immunogenicity study in healthy volunteers pursuant to this BLA met its primary endpoints. In February 2016, we initiated a follow-on PK/PD study, which is expected to read-out late in the first half of 2016. We expect to file a BLA in the United States directly thereafter.
- CHS-0214 (our etanercept (Enbrel) biosimilar candidate). CHS-0214 is a product candidate for which we have partnered with Baxalta Incorporated, Baxalta US Inc., and Baxalta GmbH, (collectively "Baxalta") and Daiichi Sankyo Company, Limited ("Daiichi Sankyo"), to develop and commercialize in key markets outside of the United States. In October 2015, we completed part 1 of a Phase 3 clinical study in psoriasis comparing CHS-0214 to Enbrel. This study is on-going but has met all its primary efficacy endpoints at 12 weeks. There were no clinically important safety issues noted in either treatment group. We are currently conducting a Phase 3 clinical study in rheumatoid arthritis. This study met the primary endpoint at 24 weeks. We expect that results from these studies, combined with data from our Phase 1 studies will support the expected filing of a marketing application in Europe and Japan in 2016. We have retained the development and commercial rights to this product in the U.S. However, the therapeutic protein in etanercept is subject to certain originator-controlled U.S. patents expiring in 2028 and 2029. Assuming these patents are valid and enforceable, and that we would be unable to obtain a license to them, we do not expect to commercialize CHS-0214 in the U.S. prior to their expiration.
- CHS-1420 (our adalimumab (Humira) biosimilar candidate). Our second anti-TNF product candidate, CHS-1420, is being developed as an adalimumab (Humira) biosimilar. This product successfully completed a pivotal Phase 1 PK study in August 2014 by meeting the primary PK bioequivalence endpoint. We initiated a Phase 3 study in psoriasis in August 2015 to support the planned filing of a marketing application in the U.S. in 2016 and the E.U. in 2017. We initiated a bridging PK study comparing the Phase 3 CHS-1420 material to U.S. manufactured adalimumab (Humira) during the first quarter of 2016 and we plan to initiate a bridging PK study comparing the Phase 3 CHS-1420 material to E.U. manufactured adalimumab (Humira) in mid-2016.

Our revenue to date has been generated primarily from collaboration and license payments pursuant to our license agreements with Daiichi Sankyo and Baxalta. We have not generated any commercial product revenue. We have incurred significant losses in the past and expect to incur significant and increasing losses in the foreseeable future as we advance our product candidates into later stages of development and, if approved, commercialization. Our net losses were $223.9 million, $87.2 million and $53.6 million for the years ended December 31, 2015, 2014 and 2013, respectively. As of December 31, 2015, we had an accumulated deficit of $410.0 million.

In March 2015, our registration statement on Form S-1 (File No. 333-202936) relating to the follow-on offering of our common stock was declared effective by the SEC. The price of the shares sold in the follow-on offering was $29.00 per share. The follow-on offering closed on April 7, 2015, pursuant to which we sold 4,137,931 shares of common stock. We received total gross proceeds from

the offering of $120.0 million. After deducting underwriting discounts and commissions of $7.2 million and offering expenses of $0.6 million, the net proceeds were $112.2 million.

In April 2015, we entered into a second amendment to the license agreement with Baxalta. Under the terms of the second amendment, a revised milestone payment structure totaling $130.0 million replaced certain existing milestone and funding obligations under the license agreement as originally executed. Therefore, we are eligible to receive up to $335.3 million in contingent payments comprised of $215.3 million in clinical development payments, and $120.0 million in regulatory milestone payments. Pursuant to the second amendment, we received a total of $100.0 million in milestone payments in 2015 which are subject to the 50% claw-back feature.

We lease office spaces for our corporate headquarters in Redwood City, California and for laboratory facilities in Camarillo, California under operating lease agreements. In July 2015, we entered into a new office lease with Hudson 333 Twin Dolphin Plaza, LLC to lease approximately 27,532 square feet of office space located in Redwood City, California for our new corporate headquarters. The New Lease commenced and we moved into the new facility in December 2015.

In September 2015, we completed a private placement with Baxalta, in which we sold an aggregate of 390,167 shares of common stock for aggregate gross proceeds of approximately $10.0 million. In December 2015, we filed our registration statement on Form S-3 (File No. 333-208625) relating to the private placement of our common stock and was declared effective by the SEC on January 21, 2016.

In February 2016, we issued and sold $100.0 million aggregate principal amount of our 8.2% senior convertible notes due 2022 (“the Notes”). These Notes require quarterly interest distributions at a fixed coupon rate of 8.2% until maturity, redemption or conversion, which will be no later than March 31, 2022. The Notes are convertible into shares of common stock at an initial conversion rate of 44.7387 shares of common stock per $1,000 principal amount of the Notes (equivalent to a conversion price of approximately $22.35 per share of common stock, representing a 60% premium over the average last reported sale price of our common stock over the 15 trading days preceding the date the notes were issued), subject to adjustment in certain events. After March 31, 2020, the full amount of the Notes not previously converted are redeemable for cash at our option if the last reported sale price per share of our common stock exceeds 160% of the conversion price on 20 or more trading days during the 30 consecutive trading days preceding the date on which we send notice of such redemption to the holders of the Notes. Upon conversion of the Notes by a holder, the holder will receive shares of our common stock, together, if applicable, with cash in lieu of any fractional share. At maturity or redemption, if not earlier converted, we will pay 109% of the par value of the Notes, together with accrued and unpaid interest, in cash. The holders of the Notes are Healthcare Royalty Partners III, L.P., which holds $75.0 million in aggregate principal amount, and three related party investors, KKR Biosimilar L.P., which holds $20.0 million, MX II Associates LLC, which holds $4.0 million, and KMG Capital Partners, LLC, which holds $1.0 million.

Financial Operations Overview

Revenue

We have not generated any revenue from commercial product sales to date. Our revenue has been generated from license and collaboration agreements, which is composed of license payments and milestone and other contingent payments under our license agreements.

Research and Development Expenses

Research and development expenses represent costs incurred to conduct research, such as the discovery and development of our product candidates. We recognize all research and development costs as they are incurred. We currently track only the external research and development costs incurred for each of our product candidates. Our external research and development expenses consist primarily of:

- expenses incurred under agreements with consultants, third-party contract research organizations, or CROs, and investigative sites where a substantial portion of our preclinical studies and all of our clinical trials are conducted;
- costs of acquiring originator comparator materials and manufacturing preclinical study and clinical trial supplies and other materials from contract manufacturing organizations, or CMOs, and related costs associated with release and stability testing; and
- costs associated with manufacturing process development activities.

Internal costs are associated with activities performed by our research and development organization and generally benefit multiple programs. These costs are not separately allocated by product candidate. Unallocated, internal research and development costs consist primarily of:

- personnel-related expenses, which include salaries, benefits and stock-based compensation; and
- facilities and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities, depreciation and amortization of leasehold improvements and equipment and laboratory and other supplies.

The largest component of our total operating expenses has historically been our investment in research and development activities, including the clinical development of our product candidates. We expect these expenses to increase in absolute dollars in the future as we continue to invest in research and development activities related to our product candidates. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time consuming. Furthermore, in the past we have entered into collaborations with third parties to participate in the development and commercialization of our product candidates, and we may enter into additional collaborations in the future. In situations in which third parties have substantial influence over the development activities for product candidates, the estimated completion dates are not fully under our control. For example, pursuant to our collaboration agreements with respect to CHS-0214, our partners in licensed territories may exert considerable influence on the regulatory filing process globally. Therefore, we cannot forecast with any degree of certainty the duration and completion costs of these or other current or future clinical trials of our product candidates. We may never succeed in achieving regulatory approval for any of our product candidates. In addition, we may enter into other collaboration arrangements for our other product candidates, which could affect our development plans or capital requirements.

The following table summarizes our research and development expenses incurred during the respective periods:

	Phase of Development as of December 31, 2015	Year ended December 31, 2015	2014	2013
			(in thousands)	
External costs incurred by product candidate:				
CHS-0214 (6)	Phase 3 (1)	$ 83,377	$ 35,726	$ 10,011
CHS-1420	Phase 3 (2)	37,611	12,581	6,603
CHS-1701	BLA-enabling (3)	46,872	8,436	4,902
CHS-131	Phase 2 (4)	3,694	1,707	—
Other research and development expenses (5)		5,311	435	2,058
Internal costs		36,197	19,339	7,705
Total research and development expenses (6)		$ 213,062	$ 78,224	$ 31,279

(1) CHS-0214 entered into Phase 3 clinical trials in June and July 2014.

(2) CHS-1420 initiated a Phase 3 study in psoriasis in August 2015 to support the planned filing of a marketing application in the U.S. in 2016 and in the E.U. in 2017. We initiated a bridging PK study comparing the Phase 3 CHS-1420 material to U.S. manufactured adalimumab (Humira) during the first quarter of 2016 and we plan to initiate a bridging PK study comparing the Phase 3 CHS-1420 material to E.U. manufactured adalimumab (Humira) in mid-2016.

(3) We met with the FDA on October 9, 2014 and informed the agency of our decision to transition from a 351(a) (novel biologic) approval pathway to a 351(k) (biosimilar) approval pathway. In March 2015, we received written feedback from the FDA on our development plan for CHS-1701 and we initiated a pivotal pharmacokinetic and pharmacodynamic study for CHS-1701inhealthy volunteers, and an additional immunogenicity study in healthy volunteers in May 2015, both pursuant to this BLA. We continue to believe it may be possible to advance CHS-1701 to a 351(k) (biosimilar) approval application without a collaboration or licensing partner.

(4) CHS-131 (previously designated as INT-131, a small molecule PPARgamma partial agonist) currently in a Phase 2 trial in multiple sclerosis in Russia.

(5) Amount consists of costs for other pipeline candidates.

(6) Our research and development expenses have been reduced by reimbursements of certain research and development expenses pursuant to the cost-sharing provision of our licensing agreement with Daiichi Sankyo. Reimbursement of research and development expenses under the Baxalta licensing agreement was recognized as revenue pursuant to the revenue recognition accounting policy applicable to that agreement.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel costs, allocated facilities costs and other expenses for outside professional services, including legal, human resources, audit and accounting services. Personnel costs consist of salaries,

benefits and stock-based compensation. We incurred increased expenses in 2015 and expect future expenses to increase as a result of operating as a public company, including expenses related to compliance with the rules and regulations of the Securities and Exchange Commission, or SEC, or The NASDAQ Global Market, or NASDAQ, additional insurance expenses, investor relations activities and other administration and professional services.

Interest Expense

Interest expense consists primarily of interest incurred on our outstanding indebtedness and non-cash interest related to the amortization of debt discount associated with our various debt agreements outstanding during the years ended December 31, 2014 and 2013. The convertible notes issued in 2013 were converted into shares of our Series C convertible preferred stock in May 2014.

Other Expense, Net

Other income (expense), net for the year ended December 31, 2015 consists primarily of losses resulting from the remeasurement of our contingent consideration and foreign exchange gains and losses resulting from currency fluctuations. Additionally, for the year ended December 31, 2014, other income (expense), net includes gains and losses resulting from the remeasurement of the fair value of our convertible preferred stock warrant liability, derivative liability associated with our convertible notes, and the gain on the extinguishment of our convertible notes issued in 2013. In November 2014, in connection with the closing of our IPO all of our outstanding warrants for convertible preferred stock were exercised, for cash or on a net basis, and the convertible preferred stock warrant liability was reclassified to equity. As such, we no longer record adjustments to reflect the remeasurement of the fair values. In March 2015, the contingent consideration related to the Earn-Out Payment was settled for shares and cash, and the contingent liability related to the Earn-Out Payment was reclassified to equity. As such, we ceased recording adjustments to reflect the remeasurement of the Earn-Out Payment to fair value. We will still continue to record adjustments to the estimated fair value of our contingent consideration related to the Compound Transaction Payment until the contingency settles or expires.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with United States generally accepted accounting principles, or GAAP. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. On an on-going basis, we evaluate our critical accounting policies and estimates. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Revenue Recognition

We recognize revenue when persuasive evidence of an arrangement exists; transfer of technology has been completed, services have been performed or products have been delivered; the fee is fixed and determinable; and collection is reasonably assured.

Our collaboration and license agreements may provide for reimbursement by our collaborators of a portion of our research and development expenses, and we make judgments that affect how these reimbursements are recorded. In collaborations where we and our partner are actively and jointly engaged in the research activities and for which both parties are sharing costs, amounts reimbursed by our partner are recognized as a reduction of research and development expense. For example, Daiichi Sankyo reimburses certain of our research and development costs in quarterly advance payments pursuant to the cost-sharing provision of our collaboration and license agreement with them. Because Daiichi Sankyo is an active participant in the research and development activities, we account for these reimbursements as reductions in our research and development expense when the applicable research and development activity has been performed. Under our collaboration agreement with (Baxalta Incorporated, Baxalta US Inc., and Baxalta GmbH (collectively "Baxalta"), on the other hand, we recognize reimbursement of our research and development expenses thereunder as revenue because Baxalta is not actively participating in research and development activities.

For revenue agreements with multiple-elements, we identify the deliverables included within the agreement and evaluate which deliverables represent separate units of accounting based on the achievement of certain criteria including whether the deliverable has stand-alone value to the collaborator. Upfront payments received in connection with licenses of our technology rights are deferred if facts and circumstances dictate that the license does not have stand-alone value and are recognized as license revenue over the estimated period of performance that is generally consistent with the terms of the research and development obligations contained in

the specific collaboration and license agreement. We periodically review our estimated periods of performance based on the progress under each arrangement and account for the impact of any changes in estimated periods of performance on a prospective basis.

At the inception of each agreement that includes milestone payments, we evaluate whether each milestone is substantive and at risk to both parties on the basis of the contingent nature of the milestone. We evaluate factors such as the scientific, regulatory, commercial and other risks that must be overcome to achieve the respective milestone, the level of effort and investment required to achieve the respective milestone and whether the milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement in making this assessment. Non-refundable payments that are contingent upon achievement of a substantive milestone are recognized in their entirety in the period in which the milestone is achieved, assuming all other revenue recognition criteria are met. Other contingent payments in which a portion of the milestone consideration is refundable or adjusts based on future performance or non-performance (e.g., through a penalty or claw-back provision) are not considered to relate solely to past performance, and therefore, not considered substantive. Amounts that are not recognized as revenue due to the uncertainty as to whether they will be retained or because they are expected to be refunded are recorded as a liability. We recognize non-substantive milestone payments over the remaining estimated period of performance once the milestone is achieved. Contingent payments associated with the achievement of specific objectives in certain contracts that are not considered substantive because we do not contribute effort to the achievement of such milestones are recognized as revenue upon achievement of the objective, as long as there are no undelivered elements remaining and no continuing performance obligations by us, assuming all other revenue recognition criteria are met.

Contingent payments associated with the achievement of specific objectives in certain contracts that are not considered substantive because we do not contribute effort to the achievement of such milestones are recognized as revenue upon achievement of the objective, as long as there are no undelivered elements remaining and no continuing performance obligations by us, assuming all other revenue recognition criteria are met.

We also generate revenue from a Russian government contract. The government contract is an agreement that provides us with payments for certain types of expenditures in return for research and development activities over a contractually defined period. Revenue from the government contract is recognized as other revenue in the consolidated statement of operations in the period during which the related costs are incurred and the related services are rendered, provided that the funds received are not refundable and applicable conditions under the government contract have been met. Funds received in advance are recorded as deferred revenue.

Accrued Research and Development Expenses

As part of the process of preparing financial statements, we are required to estimate and accrue expenses, the largest of which are research and development expenses. This process involves the following:

- communicating with appropriate internal personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost;
- estimating and accruing expenses in our consolidated financial statements as of each balance sheet date based on facts and circumstances known to us at the time; and
- periodically confirming the accuracy of our estimates with service providers and making adjustments, if necessary.

Examples of estimated research and development expenses that we accrue include:

- fees paid to CROs in connection with preclinical and toxicology studies and clinical trials;
- fees paid to investigative sites in connection with clinical trials;
- fees paid to CMOs in connection with the production of clinical trial materials; and
- professional service fees for consulting and related services.

We base our expense accruals related to clinical trials on our estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that conduct and manage clinical trials on our behalf. The financial terms of these agreements vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors, such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If we do not identify costs that we have begun to incur or if we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates.

Due to the nature of these estimates, we cannot assure you that we will not make changes to our estimates in the future as we become aware of additional information about the status or conduct of our clinical trials and other research activities.

Derivative Liabilities

There were two contingent payments associated with the acquisition of InteKrin: (i) the completion of the first dosing of a human subject in the first Phase 2 clinical trial for InteKrin, or the Earn-Out Payment and (ii) upon the execution of any license, sublicense, development, collaboration, joint venture, partnering or similar agreement between us and the third-party, or the Compound Transaction Payment. The contingent consideration is accounted for as a liability and remeasured to estimated fair value as of each balance sheet date and the related remeasurement adjustment is recognized as other income (expense), net in the consolidated statement of operations. We determined the fair value of the two contingent consideration scenarios (the Earn-Out Payment and the Compound Transaction Payment) using a probability-weighted discounted cash flow approach. A probability-weighted value was determined by summing the probability of achieving a contingent payment threshold by the respective contingent payment. The expected cash flows were discounted at a rate selected to capture the risk of achieving the contingent payment thresholds and earning the contingent payment. This risk is comprised of InteKrin's continued development, a specific risk factor associated with meeting the contingent consideration threshold and related payout and counterparty risk associated with the payment of the contingent consideration.

Stock-Based Compensation

Common Stock Options

Stock-based compensation expense related to stock options granted to employees is measured at the date of grant, based on the estimated fair value of the award and recognized as an expense over the employee's requisite service period on a straight-line basis. We estimate the grant date fair value and the resulting stock-based compensation expense using the Black-Scholes option-pricing model.

We account for stock-based compensation arrangements with non-employees using a fair value approach. The fair value of these options is measured using the Black-Scholes option pricing model reflecting the same assumptions as applied to employee options in each of the reported periods, other than the expected life, which is assumed to be the remaining contractual life of the option. The fair value of the unvested options under these arrangements is subject to remeasurement over the vesting terms as earned.

We recorded non-cash stock-based compensation expense related to options granted to employees and non-employees of $16.7 million, $6.8 million and $764,000 for the years ended December 31, 2015, 2014 and 2013, respectively.

The Black-Scholes option-pricing model requires the use of highly subjective assumptions which determine the fair value of stock-based awards. These assumptions include:

- *Expected term.* The expected term represents the period that stock-based awards are expected to be outstanding and is based on the options' vesting term, contractual term and industry peers. We do not have sufficient historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior.
- *Expected volatility.* We use an average historical stock price volatility of industry peers to be representative of future stock price volatility as we do not have any trading history for our common stock.
- *Risk-free interest rate.* The risk free interest rate is based on the U.S. Treasury constant maturity rate in effect at the time of the grant for periods corresponding with the expected term.
- *Expected dividends.* We have not paid and do not anticipate paying any dividends in the near future, and therefore we used an expected dividend yield of zero in the valuation model.

In addition to the Black-Scholes assumptions, we estimate our forfeiture rate based on an analysis of our actual forfeitures and will continue to evaluate the adequacy of the forfeiture rate based on actual forfeiture experience, analysis of employee turnover behavior and other factors. The impact from any forfeiture rate adjustment would be recognized in full in the period of adjustment and if the actual number of future forfeitures differs from our estimates, we might be required to record adjustments to stock-based compensation in future periods.

Historically, for all periods prior to our IPO, the fair values of the shares of common stock underlying our share-based awards were estimated on each grant date by our board of directors. In order to determine the fair value of our common stock underlying option grants, our board of directors considered, among other things, valuations of our common stock prepared by an unrelated third-party valuation firm in accordance with the guidance provided by the American Institute of Certified Public Accountants Practice

Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. Given the absence of a public trading market for our common stock, our board of directors exercised reasonable judgment and considered a number of objective and subjective factors to determine the best estimate of the fair value of our common stock, including our stage of development; progress of our research and development efforts; the rights, preferences and privileges of our preferred stock relative to those of our common stock; equity market conditions affecting comparable public companies; and the lack of marketability of our common stock.

Founders' Shares

In October 2010 and January 2011, we issued 4,130,173 shares and 968,804 shares of common stock, respectively, at $0.0083 per share to our founders under the founder stock agreements. These founders' shares are subject to a repurchase option in our favor that lapses over time subject to continued service. As such, we recorded stock-based compensation based on the fair value of the common stock on the date of issuance. One of the holders of the founders' shares is a consultant, therefore the fair value of the consultant's founder shares is measured using the Black-Scholes option-pricing model reflecting the same assumptions as applied to employee options in each of the reported years, other than the expected life, which is assumed to be the remaining contractual life of the vesting period. We recorded non-cash stock-based compensation expense related to the founders' shares of $9,000, $1.6 million and $1.3 million for the years ended December 31, 2015, 2014 and 2013, respectively. As of December 31, 2015, there were no shares subject to repurchase.

Common Stock Warrants

In March 2014, we issued warrants to purchase 553,274 shares of common stock with an exercise price of $1.667 per share to two employees and a member of our board of directors in his capacity as a consultant to us for past services. We valued the warrants at $2.7 million using the Black-Scholes option-pricing model on the date of grant. Due to the immediate exercisability of the warrants upon issuance, we immediately recognized $1.3 million and $1.4 million in research and development expense and general and administrative expense, respectively, in the consolidated statement of operations. In connection with the closing of our IPO, all outstanding warrants for common stock were exercised on a net basis into 491,580 shares of common stock.

Income Taxes

We file U.S. federal and state income tax with varying statutes of limitations. The tax years from 2011 forward remain open to examination due to the carryover of unused net operating losses and tax credits. To date, we have not been audited by the Internal Revenue Service or any state income tax authority.

We use the liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and the tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. We assess the likelihood that the resulting deferred tax assets will be realized. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized.

As of December 31, 2015, our total net deferred tax assets, net of gross deferred tax liabilities, were $134.8 million. Due to our lack of earnings history, the net deferred tax assets have been fully offset by a valuation allowance. The deferred tax assets were primarily comprised of federal and state tax net operating losses and tax credit carryforwards. Utilization of the net operating loss and tax credit carryforwards may be subject to an annual limitation due to historical or future ownership percentage change rules provided by the Internal Review Code of 1986, and similar state provisions. The annual limitation may result in the expiration of certain net operating loss and tax credit carryforwards before their utilization.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2014-09, *Revenue from Contracts with Customers* ("ASU 2014-09"), which converges the FASB and the International Accounting Standards Board standards on revenue recognition. Areas of revenue recognition that will be affected include, but are not limited to, transfer of control, variable consideration, allocation of transfer pricing, licenses, time value of money, contract costs and disclosures. In August 2015, the FASB issued ASU 2015-14, Revenue from Contracts with Customers: Deferral of the Effective Date ("ASU 2015-14"). Under the amendments in ASU 2015-14, the FASB deferred the effective date of this standards update to fiscal years beginning after December 15, 2017, including interim reporting periods within that reporting period, with early adoption permitted on the original effective date of fiscal years beginning after December 15, 2016. We are currently evaluating the impact that the adoption of ASU 2014-09 will have on our consolidated financial statements and related disclosures.

In August 2014, the FASB issued ASU No. 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. ASU 2014-15 is effective for our annual reporting period ending December 31, 2016 and all annual and interim reporting periods thereafter, with early adoption permitted. We elected to not early adopt this standard. When adopted, ASU 2014-15 will require management to evaluate whether there is substantial doubt about our ability to continue as a going concern for at least 12 months from the issuance date of the financial statements and to provide related footnote disclosures.

In November 2015, the FASB issued ASU No. 2015-17, *Balance Sheet Classification of Deferred Taxes*. To simplify the presentation of deferred income taxes, the amendments in ASU 2015-17 requires that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. ASU 2015-17 is effective for our interim and annual reporting periods during the year ending December 31, 2017 and all annual and interim reporting periods thereafter, with early adoption permitted. We have elected to early adopt ASU 2015-17 prospectively. Such adoption did not have a material impact on our consolidated balance sheet and related disclosures as of December 31, 2015, and did not adjust prior periods presented.

In January 2016, the FASB issued ASU No. 2016-1, *Recognition and Measurement of Financial Assets and Financial Liabilities.* ASU 2016-1 makes amendments to the classification and measurement of financial instruments and revises the accounting related to: (1) the classification and measurement of investments in equity securities, and (2) the presentation of certain fair value changes for financial liabilities measured at fair value. In addition, the update also amends certain disclosure requirements associated with the fair value of financial instruments. ASU 2016-1 is effective for our interim and annual reporting periods during the year ending December 31, 2018, and all annual and interim reporting periods thereafter. Early adoptions of certain amendments within the update are permitted. We are currently evaluating the impact that the adoption of ASU 2016-1 will have on our consolidated financial statements and related disclosures.

In February 2016, the FASB issued ASU No. 2016-2, *Leases*. ASU 2016-2 is aimed at making leasing activities more transparent and comparable, and requires substantially all leases be recognized by lessees on their balance sheet as a right-of-use asset and corresponding lease liability, including leases currently accounted for as operating leases. ASU 2016-2 is effective for our interim and annual reporting periods during the year ending December 31, 2019, and all annual and interim reporting periods thereafter. Early adoption is permitted. We are currently evaluating the impact that the adoption of ASU 2016-2 will have on our consolidated financial statements and related disclosures.

We have reviewed other recent accounting pronouncements and concluded they are either not applicable to the business or no material effect is expected on the consolidated financial statements as a result of future adoptions.

Comparison of Years Ended December 31, 2015 and 2014

Revenue

	Year Ended December 31,		
	2015	2014	Change
	(in thousands)		
Revenue:			
Collaboration and license revenue	$ 30,041	$ 28,481	$ 1,560
Collaboration and license revenue - related party (1)	—	1,893	(1,893)
Other revenue	—	732	(732)
Total revenue	$ 30,041	$ 31,106	$ (1,065)

(1) Represents revenue from Daiichi Sankyo through November 12, 2014 as a related party, a holder of more than 10% of our common stock until the closing of our IPO.

Total revenue for the year ended December 31, 2015 was $30.0 million compared to $31.1 million for the same period in 2014, a decrease of $1.1 million. The decrease was primarily due to the $10.0 million receipt received for the achievement of a substantive milestone in the third quarter of 2014 under our license agreement with Baxalta. The decrease was partially offset by increased revenue recognized in connection with the amortization of deferred revenue under our license agreement with Baxalta.

Research and Development Expenses

	Year Ended December 31,		
	2015	2014	Change
	(in thousands)		
Research and development	$ 213,062	$ 78,224	$ 134,838

Research and development expenses for the year ended December 31, 2015 was $213.1 million compared to $78.2 million for the same period in 2014, an increase of $134.8 million. The increase in research and development expenses was primarily due to:

- an increase of $47.7 million in costs incurred for CHS-0214 due to the fully enrolling and completing Phase 3 clinical studies, which is net of an increase of $9.0 million in cost reimbursements from Daiichi Sankyo that were recognized as a reduction of research and development expense;
- an increase of $38.4 million related to initiating and completing two BLA-enabling studies for CHS-1701;
- an increase of $25.0 million to start and enroll subjects into a Phase 3 clinical study in psoriasis for CHS-1420;
- an increase of $9.8 million in personnel, consulting and other related expenses and $2.4 million in stock-based compensation due to a net increase of approximately 31 employees, annual salaries increases and additional stock options granted during 2015, partially offset by common stock warrant issued during 2014 and none in 2015, and higher stock-based compensation expense related to consultants during 2014 than during 2015;
- an increase of $4.8 million in facilities, supplies and materials and other infrastructure to support our research and development growth;
- an increase of $4.4 million to advance other product candidates in our pipeline; and
- an increase of $2.3 million to initiate and enroll a proof-of concept Phase 2 clinical study for CHS-131 (formerly INT-131).

General and Administrative Expenses

	Year Ended December 31,		
	2015	2014	Change
	(in thousands)		
General and administrative	$ 36,046	$ 17,564	$ 18,482

General and administrative expenses for year ended December 31, 2015 was $36.0 million compared to $17.6 million for the same period in 2014, an increase of $18.5 million. The increase was primarily due to an increase of $6.9 million in personnel, consulting and other related expenses and $3.2 million in stock-based compensation as a result of an increase in headcount, annual salaries increases, and costs associated with stock options granted in 2015. The increase in stock-based compensation was driven primarily from additional stock options granted during 2015, partially offset by common stock warrants issued during 2014. In addition, the increase in general and administrative expenses was due to an increase of $6.7 million in legal, accounting, recruiting and other professional services and $1.7 million in facilities, supplies and materials to support our growing infrastructure as we expanded our operations as a public company.

Interest Expense

	Year Ended December 31,		
	2015	2014	Change
	(in thousands)		
Interest expense	$ 33	$ 3,900	$ (3,867)

Interest expense for the year ended December 31, 2015 was $33,000, compared to $3.9 million for the same period in 2014, a decrease of $3.9 million. The decrease was due to the conversion of our 2013 convertible notes into shares of our Series C convertible preferred stock in May 2014 resulting in no interest expense during 2015 related to this debt compared to the recognition of non-cash interest expense and amortization of the debt discount during 2014.

Other Expense, Net

	Year Ended December 31,		
	2015	2014	Change
		(in thousands)	
Other expense, net	$ 4,838	$ 18,595	$ (13,757)

Other expense, net for the year ended December 31, 2015 was $4.8 million compared to $18.6 million for the same period in 2014, a decrease of $13.8 million. The decrease is primarily due to the change of $15.9 million in fair value of our convertible preferred stock warrant liability during 2014 which converted into equity contemporaneously with the closing of our IPO on November 12, 2014, therefore no remeasurement expense in 2015 and a decrease in the change in fair value of our contingent consideration related to the InteKrin acquisition of $0.6 million during 2015 when compared to 2014 as the fair value of the Earn-Out Payment portion of the contingent consideration was settled in May 2015. The decrease was partially offset by the gain on extinguishment of our convertible notes issued in 2013 of $2.0 million in May 2014 and the net expense increase of $1.1 million during 2015 when compared to 2014 due to foreign exchange fluctuations.

Comparison of Years Ended December 31, 2014 and 2013

Collaboration and License Revenue

	Year Ended December 31,		
	2014	2013	Change
		(in thousands)	
Revenue:			
Collaboration and license revenue	$ 28,481	$ 726	$ 27,755
Collaboration and license revenue - related party (1)	1,893	2,025	(132)
Other revenue	732	—	732
Total revenue	$ 31,106	$ 2,751	$ 28,355

(1) Represents revenue from Daiichi Sankyo, a holder of more than 10% of our common stock for the periods presented until the closing of our IPO on November 12, 2014.

Collaboration and license revenue for the year ended December 31, 2014 was $30.4 million, compared to $2.8 million for the same period in 2013, an increase of $27.6 million. The increase was primarily due to $20.3 million of revenue recognized in connection with the amortization of deferred revenue and a$10.0 million receipt for achievement of a substantive milestone in the third quarter of 2014 under our license agreement with Baxalta, which we entered into in August 2013.

Other revenue for the year ended December 31, 2014 was $0.7 million. The other revenue is related to the government contract received from the Russian government in connection with the clinical development of the CHS-131 drug candidate.

Research and Development Expenses

	Year Ended December 31,		
	2014	2013	Change
		(in thousands)	
Research and development	$ 78,224	$ 31,279	$ 46,945

Research and development expenses for the year ended December 31, 2014 was $78.2 million compared to $31.3 million for the same period in 2013, an increase of $46.9 million. The increase in research and development expenses was primarily due to the following:

- an increase of $25.6 million in costs incurred for CHS-0214 due to the ongoing Phase 3 clinical trial, which is net of an increase of $5.8 million in cost reimbursements from Daiichi Sankyo that was recognized as a reduction of research and development expense;
- an increase of $6.0 million to complete CHS-1420 to a Phase 1 study and to advance to Phase 3 clinical trial;
- an increase of $3.5 million to advance CHS-1701 to a 351 (k) approval pathway;
- an increase of $1.7 million to advance CHS-131 to a Phase 2 clinical trial;

- an increase of $9.9 million in personnel and consulting related expenses due to an increase in stock-based compensation expense related to common stock warrants and options granted in 2014, and an increase of 21 employees; and
- an increase of $1.6 million in facilities, supplies and materials and other infrastructure to support our research and development growth.

These increases were partly offset by a decrease of $1.4 million in costs for other pipeline biosimilars.

General and Administrative Expenses

	Year Ended December 31,		
	2014	2013	Change
		(in thousands)	
General and administrative	$ 17,564	$ 7,465	$ 10,099

General and administrative expenses for the year ended December 31, 2014 was $17.6 million compared to $7.5 million for the same period in 2013, an increase of $10.1 million. The increase was primarily due to a $7.2 million increase in personnel and consulting related expenses associated with an increase in stock-based compensation related to the common stock warrants and options granted in 2014, and an increase of nine employees. Additionally, the increase was due to increased costs of $2.3 million in legal, accounting and recruiting services, and increased costs of $0.7 million in insurance and facilities to support our growing infrastructure and our operations as a public company.

Interest Expense

	Year Ended December 31,		
	2014	2013	Change
		(in thousands)	
Interest expense	$ 3,900	$ 5,293	$ (1,393)

Interest expense for the year ended December 31, 2014 was $3.9 million compared to $5.3 million for the same period in 2013, a decrease of $1.4 million. The decrease of $0.9 million was due to the recognition of approximately four months in 2014 compared to approximately five months in 2013 of non-cash amortization of the debt discount and interest expense related to our convertible notes entered into during the third quarter of 2013 which converted into shares of our series C convertible preferred stock in May 2014. The additional $0.5 million decrease was due to the extended payment arrangement with one of our vendors in 2013.

Other Expense, Net

	Year Ended December 31,		
	2014	2013	Change
		(in thousands)	
Other expense, net	$ 18,595	$ 12,349	$ 6,246

Other expense, net for the year ended December 31, 2014 was $18.6 million compared to $12.3 million for the same period in 2013, an increase of $6.2 million. The increase is primarily due to a change in the fair value of our convertible preferred stock warrant liability of $3.3 million when compared to 2013 and the change in fair value of our contingent consideration of $5.2 million related to and as a result of the acquisition of InteKrin in February 2014. The increase was partly offset by the gain on extinguishment of our convertible notes issued in 2013 of $2.0 million in May 2014 and foreign currency gain of $0.7 million primarily due to the increase in the exchange rate of the U.S. Dollar against the Russian Ruble on U.S. Dollar denominated cash accounts held by InteKrin Russia whose functional currency is the Ruble.

Liquidity and Capital Resources

Due to our significant research and development expenditures, we have generated significant operating losses since our inception. We have funded our operations primarily through the issuance of debt, equity financing, sales of our convertible preferred stock and payments received under our collaboration and license agreements.

In May 2014, we completed our Series C convertible preferred stock financing, which resulted in aggregate net cash proceeds of $54.7 million. In addition, our outstanding convertible notes and accrued interest of $10.6 million were contemporaneously converted into shares of our Series C convertible preferred stock.

In November 2014, we completed our IPO and raised net proceeds of $80.2 million, after deducting underwriting discounts and commissions and offering expenses.

In April 2015, we completed a follow-on offering of common stock and raised net proceeds of $112.2 million, after deducting underwriting discounts and commissions and offering expenses. Additionally, in September 2015 we completed a private placement with Baxalta which raised net proceeds of approximately $10.0 million.

In February 2016, we issued and sold $100.0 million aggregate principal amount of 8.2% senior convertible notes due March 31, 2022.

As of December 31, 2015, we had an accumulated deficit of $410.0 million and cash and cash equivalents of $158.2 million. We believe that our current available cash and cash equivalents, together with the proceeds from the Notes issued in February 2016 and funding we expect to receive under our license agreement with Daiichi Sankyo and Baxalta, will be sufficient to fund our planned expenditures and meet our obligations through at least the next twelve months. We will need to raise additional funds in the future; however, there can be no assurance that such efforts will be successful or that, in the event that they are successful, the terms and conditions of such financing will be favorable**.**

Summary Statement of Cash Flows

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

	Year Ended December 31,		
	2015	2014	2013
	(in thousands)		
Net cash (used in) provided by operating activities	$ (107,990)	$ (23,927)	$ 15,423
Net cash used in investing activities	(6,949)	(525)	(373)
Net cash provided by financing activities	122,689	135,956	9,956
Effect of exchange rate changes in cash and cash equivalents	84	(666)	—
Net increase in cash and cash equivalents	$ 7,834	$ 110,838	$ 25,006

Net cash provided by (used in) operating activities

Cash used in operating activities was $108.0 million for the year ended December 31, 2015, reflecting a net loss of $223.9 million and an increase in prepaid and other assets of $15.9 million as a result of initiating clinical activities and timing of vendor payments. Cash used in operating activities was partially offset by non-cash charges of $4.6 million for the remeasurement of our contingent consideration obligations, $16.7 million for stock-based compensation, $2.3 million for depreciation and amortization and impairment of property and equipment, and $1.3 million related to a reserve for other receivables. Cash used in operating activities was also offset by an increase of $32.8 million in accounts payable, accounts payable-related parties, and accrued liabilities as a result of the increase in clinical activities and timing of vendor payments, an increase of $32.3 million in deferred revenue and $38.6 million in contingent liability to collaborator both related to $100.0 million milestone payments received from Baxalta under our license agreement, a decrease of $1.9 million in notes receivable as it was settled, and a decrease of $0.9 million in receivables from collaboration and license agreements.

Cash used in operating activities was $23.9 million for the year ended December 31, 2014 reflecting a net loss of $87.2 million, an increase in prepaid assets of $14.7 million as a result of the increase in clinical activities and expenses associated with becoming a public company, an increase in receivable from collaboration and license agreement of $2.1 million with Daiichi Sankyo, an increase in notes receivable of $1.8 million, and an increase in other assets of $2.1 million. The cash used in operating activities was partly offset by non-cash charges of $15.9 million for the remeasurement of our convertible preferred stock warrant liability and embedded derivative liabilities, $5.2 million for remeasurement of our contingent consideration obligations, $3.9 million of non-cash interest expense and amortization of debt discount, $11.1 million for stock-based compensation and $0.7 million for depreciation and amortization, partially offset by the gain on the extinguishment of our convertible notes issued in 2013 of $2.0 million. Cash used in operating activities was also offset by an increase in deferred revenue of $19.8 million and an increase in contingent liability to collaborator of $20.2 million both related to the additional payments received from Baxalta under our license agreement. In addition,

accounts payable and accounts payable-related parties increased by $5.3 million, and accrued liabilities increased by $3.9 million as a result of the increase in clinical activities and timing of vendor payments.

Cash provided by operating activities was $15.4 million for the year ended December 31, 2013 reflecting non-cash charges of $7.6 million in preferred stock issued in exchange for services received, $7.8 million for the fair value of warrants and embedded derivatives issued in excess of debt proceeds, $5.3 million of non-cash interest expense, $2.0 million for stock-based compensation, $0.4 million for depreciation and amortization and a non-cash gain of $4.6 million for the remeasurement of our convertible preferred stock warrant liability and embedded derivatives. Cash provided by operating activities also reflected an increase in deferred revenue of $34.7 million, an increase in contingent liability to collaborator of $7.5 million both related to the payments received from Baxalta and an increase in accrued liabilities of $2.8 million related to an increase in the accrual for clinical development activities. The cash provided by operating activities were partially offset by a net loss of $53.6 million, and an increase in prepaid and other current assets of $3.2 million related to an increase in prepaid clinical, material and manufacturing costs.

Net cash used in investing activities

Cash used in investing activities of $6.9 million for the year ended December 31, 2015 was due primarily to the purchase of capital equipment and leasehold improvements of $6.2 million, and an increase in restricted cash of $0.8 million as a result of the new headquarters lease requirement.

Cash used in investing activities of $525,000 for the year ended December 31, 2014 was due primarily to the purchases of capital equipment and leasehold improvements of $2.8 million, partially offset by the net cash acquired from the acquisition of InteKrin in February 2014 of $2.3 million.

Cash used in investing activities of $0.4 million for the year ended December 31, 2013 was related to capital equipment purchases.

Net cash provided by financing activities

Cash provided by financing activities of $122.7 million for the year ended December 31, 2015 was primarily related to the net proceeds of $112.8 million from the issuance of our common stock in connection with our follow-on offering, net proceeds of approximately $10.0 million from the private placement with Baxalta, and proceeds from the exercise of stock options of $1.4 million, partially offset by our payments of IPO and follow-on offering costs of $1.5 million.

Cash provided by financing activities of $136.0 million for the year ended December 31, 2014 was primarily related to the net proceeds from the issuance of our Series C convertible preferred stock of $54.7 million and the completion of our IPO in November 2014 resulting in net proceeds of $80.2 million.

Cash provided by financing activities of $10.0 million for the year ended December 31, 2013 was primarily related to proceeds from the issuance of convertible notes.

Funding Requirements

We believe that our current available cash and cash equivalents, together with the proceeds from the Notes issued in February 2016 and funding we expect to receive under our license agreements with Daiichi Sankyo and Baxalta, will be sufficient to fund our planned expenditures under our 2016 budget and meet our obligations through at least December 31, 2016. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Further, our operating plan may change, and we may need additional funds to meet operational needs and capital requirements for product development and commercialization sooner than planned. We currently have no credit facility or committed sources of capital although we may receive milestone and other contingent payments under our current license and collaboration agreements. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates and the extent to which we may enter into additional agreements with third parties to participate in their development and commercialization, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical trials. Our future funding requirements will depend on many factors, including the following:

- the scope, rate of progress, results and cost of our clinical trials, preclinical testing and other related activities;
- the cost of manufacturing clinical supplies and establishing commercial supplies of our product candidates and any products that we may develop;

- the costs of acquiring originator comparator materials and manufacturing preclinical study and clinical trial supplies and other materials from CMOs and related costs associated with release and stability testing;
- the receipt of any collaboration payments;
- the number and characteristics of product candidates that we pursue;
- the cost, timing and outcomes of regulatory approvals;
- the terms and timing of any other collaborative, licensing and other arrangements that we may establish;
- the timing, receipt and amount of sales, profit sharing or royalties, if any, from our potential products;
- the cost of preparing, filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and
- the extent to which we acquire or invest in businesses, products or technologies.

We will need to raise additional capital to fund our operations in the near future. Funding may not be available to us on acceptable terms, or at all. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of or suspend one or more of our clinical trials, research and development programs or commercialization efforts. We may seek to raise any necessary additional capital through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. We anticipate receiving up to $62 million in 2016 under our collaborations, and we will seek to enter into strategic partnerships to commercialize our biosimilar candidates in ex-US territories or globally for certain therapeutic areas. To the extent that we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we do raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

Off-Balance Sheet Arrangements

Since our inception, we have not engaged in any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Contractual Obligations

Our future contractual obligations as of December 31, 2015 were as follows:

	Payments Due by Period				
Contractual Obligations:	Total	Less than 1 year	1 to 3 years	4 to 5 years	More than 5 years
			(in thousands)		
Purchase commitments	$ 14,518	$ 14,518	$ —	$ —	$ —
Operating lease obligations	11,671	1,692	2,945	3,491	3,543
Contingent payments to InteKrin stockholders	1,245	1,245	—	—	—
Total contractual obligations	$ 27,434	$ 17,455	$ 2,945	$ 3,491	$ 3,543

We enter into contracts in the normal course of business with contract research organizations, or CROs, for preclinical studies and clinical trials and contract manufacturing organizations, or CMOs, for the manufacture of clinical trial materials. As of December 31, 2015, we had commitments of $14.5 million with CMOs for the manufacture of clinical trial material due within a year. We also have an agreement with a CRO vendor which provides for a minimum fee commitment of $35.0 million for clinical trial services. As of December 31, 2015, we have fulfilled the minimum fee commitment related to this agreement.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

As of December 31, 2015, we had cash and cash equivalents of $158.2 million. A portion of our cash equivalents, which are in money market funds, may be subject to interest rate risk and could fall in value if market interest rates increase. However, because our

cash equivalents are primarily short-term in duration, we believe that our exposure to interest rate risk is not significant and a 1% movement in market interest rates would not have a significant impact on the total value of our portfolio.

We are exposed to market risk related to changes in foreign exchange rates. We contract with CROs and contract manufacturers globally and thus we face foreign exchange risk as a result of entering into transactions denominated in currencies other than U.S. dollars. Due to the uncertain timing of expected payments in foreign currencies, we do not utilize any forward exchange contracts. All foreign transactions settle on the applicable spot exchange basis at the time such payments are made. An adverse movement in foreign exchange rates could have a material effect on payments made to foreign suppliers and for license agreements. A hypothetical 10% change in foreign exchange rates during any of the periods presented would not have had a material impact on our financial statements.

We acquired InteKrin in February 2014, which has a subsidiary based in Russia and thus subjects us to foreign currency rate fluctuations against the Russian Ruble. As of December 31, 2015, we had 8.1 million Rubles in cash, which was equal to $111,000 at that date. This cash is located in Russia.

Item 8. ***Consolidated Financial Statements and Supplementary Data***

COHERUS BIOSCIENCES, INC.

ANNUAL REPORT ON FORM 10-K

INDEX TO AUDITED CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders
Coherus BioSciences, Inc.

We have audited the accompanying consolidated balance sheets of Coherus BioSciences, Inc. (the "Company") as of December 31, 2015 and 2014, and the related consolidated statements of operations, comprehensive loss, convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2015. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of the Company at December 31, 2015 and 2014, and the consolidated results of its operations, comprehensive loss and its cash flows for each of the three years in the period ended December 31, 2015, in conformity with U.S. generally accepted accounting principles.

We have also audited, in accordance with the standards of the Public Accounting Oversight Board (United States), the Company's internal control over financial reporting as of December 31, 2015, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 Framework) and our report dated February 29, 2016 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Redwood City, California
February 29, 2016

Coherus BioSciences, Inc.

Consolidated Balance Sheets
(in thousands, except share and per share data)

	December 31,	
	2015	2014
Assets		
Current assets:		
Cash and cash equivalents	$ 158,226	$ 150,392
Restricted cash	60	60
Receivables from collaboration and license agreement	1,560	2,417
Notes receivable	—	1,815
Prepaid assets (includes related parties of $10,901 and $5,990 as of December 31, 2015 and 2014, respectively)	34,743	20,485
Other assets	2,797	2,276
Other assets - related party	—	1,691
Total current assets	197,386	179,136
Property and equipment, net	10,504	4,472
Intangible assets	2,620	2,620
Goodwill	943	943
Restricted cash, non-current	785	—
Other assets, non-current	146	50
Total assets	$ 212,384	$ 187,221
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 25,948	$ 8,778
Accounts payable - related parties	3,548	2,020
Accrued liabilities (includes related parties of $6,122 and $2,997 as of December 31, 2015 and 2014, respectively)	24,133	11,231
Advance payments under license agreement	1,330	1,192
Deferred revenue	49,621	22,800
Contingent consideration	1,245	5,710
Other liabilities	193	52
Total current liabilities	106,018	51,783
Deferred revenue, non-current	45,338	39,899
Contingent liability to collaborator	66,255	27,650
Contingent consideration, non-current	—	785
Other liabilities, non-current	1,702	347
Total liabilities	219,313	120,464
Commitments and contingencies (Note 8)		
Stockholders' equity (deficit):		
Preferred stock, $0.0001 par value; Shares authorized: 5,000,000; Shares issued and outstanding: no shares at December 31, 2015 and 2014.	—	—
Common stock, $0.0001 par value; Shares authorized: 300,000,000; Shares issued and outstanding: 39,005,589 and 33,257,978 at December 31, 2015 and 2014, respectively	4	3
Additional paid-in capital	404,175	254,048
Accumulated other comprehensive loss	(401)	(525)
Accumulated deficit	(409,985)	(186,725)
Total Coherus stockholders' equity (deficit)	(6,207)	66,801
Non-controlling interest	(722)	(44)
Total stockholders' equity (deficit)	(6,929)	66,757
Total liabilities and stockholders' equity (deficit)	$ 212,384	$ 187,221

See accompanying notes to consolidated financial statements.

Coherus BioSciences, Inc.

Consolidated Statements of Operations
(in thousands, except share and per share data)

	Year Ended December 31,		
	2015	2014	2013
Revenue:			
Collaboration and license revenue	$ 30,041	$ 28,481	$ 726
Collaboration and license revenue - related party (1)	—	1,893	2,025
Other revenue	—	732	—
Total revenue	30,041	31,106	2,751
Operating expenses:			
Research and development (includes related party of $42,768, $21,723 and $9,471 for the years ended December 31, 2015, 2014 and 2013, respectively)	213,062	78,224	31,279
General and administrative (includes related party of $559, $597 and $18 for the years ended December 31, 2015, 2014 and 2013, respectively)	36,046	17,564	7,465
Total operating expenses	249,108	95,788	38,744
Loss from operations	(219,067)	(64,682)	(35,993)
Interest expense (includes related party of $2,687 and $4,026 for the years ended December 31, 2014 and 2013, respectively)	(33)	(3,900)	(5,293)
Other expense, net	(4,838)	(18,595)	(12,349)
Net loss	(223,938)	(87,177)	(53,635)
Net loss attributable to non-controlling interest	678	44	—
Net loss attributable to Coherus	$ (223,260)	$ (87,133)	$ (53,635)
Net loss per share attributable to Coherus, basic and diluted	$ (6.01)	$ (10.64)	$ (16.10)
Weighted-average number of shares used in computing net loss per share attributable to Coherus, basic and diluted	37,122,008	8,186,529	3,332,020

(1) Represents revenue from Daiichi Sankyo through November 12, 2014 as a related party, a holder of more than 10% of our common stock until the closing of our initial public offering ("IPO").

See accompanying notes to consolidated financial statements.

Coherus BioSciences, Inc.

Consolidated Statements of Comprehensive Loss
(in thousands)

	Year Ended December 31,		
	2015	2014	2013
Net loss	$ (223,938)	$ (87,177)	$ (53,635)
Other comprehensive loss:			
Foreign currency translation adjustments, net of tax	124	(525)	—
Comprehensive loss	(223,814)	(87,702)	(53,635)
Comprehensive loss attributable to non-controlling interest	678	44	—
Comprehensive loss attributable to Coherus	$ (223,136)	$ (87,658)	$ (53,635)

See accompanying notes to consolidated financial statements.

Coherus BioSciences, Inc.

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

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Coherus Stockholders' Equity (Deficit)	Noncontrolling Interest	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount						
Balances at December 31, 2012	972,330	$ 1,191	8,181,576	$ 53,504	—	$ —	4,834,467	$ 1	$ 453	$ —	$ (45,957)	$ (45,503)	$ —	$ (45,503)
Issuance of common stock upon exercise of stock options	—	—	—	—	—	—	3,248	—	6	—	—	6	—	6
Vesting of restricted common stock issued to founders	—	—	—	—	—	—	—	—	10	—	—	10	—	10
Stock-based compensation expense	—	—	—	—	—	—	—	—	2,045	—	—	2,045	—	2,045
Net loss	—	—	—	—	—	—	—	—	—	—	(53,635)	(53,635)	—	(53,635)
Balances at December 31, 2013	972,330	1,191	8,181,576	53,504	—	—	4,837,715	1	2,514	—	(99,592)	(97,077)	—	(97,077)
Beneficial conversion feature related to convertible notes issued in 2013	—	—	—	—	—	—	—	—	(3,939)	—	—	(3,939)	—	(3,939)
Issuance of Series B convertible preferred stock for InteKrin acquisition	—	—	960,486	3,667	—	—	—	—	—	—	—	—	—	—
Issuance of Series B convertible preferred stock in exchange for services			8,185	57	—	—				—			—	—
Issuance of Series C convertible preferred stock at $6.00 per share, net	—	—	—	—	5,488,892	54,660	—	—	—	—	—	—	—	—
Issuance of Series C convertible preferred stock at $6.00 per share upon conversion of convertible notes issued in 2013	—	—	—	—	1,058,089	10,583	—	—	—	—	—	—	—	—
Issuance of Series C convertible preferred stock at $6.00 per share in exchange for services	—	—	—	—	9,997	100	—	—	—	—	—	—	—	—
Issuance of Series A and B convertible preferred stock upon exercise of warrants and reclassification of convertible preferred stock warrant liability	62,251	1,004	4,574,713	39,277	—	—	—	—	—	—	—	—	—	—
Issuance of common stock in connection with initial public offering, net	—	—	—	—	—	—	6,803,702	—	80,209	—	—	80,209	—	80,209
Conversion of convertible preferred stock to common stock in connection with initial public offering	(1,034,581)	(2,195)	(13,724,960)	(96,505)	(6,556,978)	(65,343)	21,316,519	2	164,041	—	—	164,043	—	164,043
Conversion of common stock warrants to common stock in connection with initial public offering	—	—	—	—	—	—	491,580	—	—	—	—	—	—	—
Issuance of common stock options in exchange for services	—	—	—	—	—	—	—	—	48	—	—	48	—	48
Issuance of common stock upon exercise of stock options	—	—	—	—	—	—	48,414	—	55	—	—	55	—	55
Repurchase of common stock							(239,952)	—	(2)			(2)		(2)
Vesting of restricted common stock issued to founders	—	—	—	—	—	—	—	—	5	—	—	5	—	5
Stock-based compensation expense	—	—	—	—	—	—	—	—	11,117	—	—	11,117	—	11,117
Cumulative translation adjustment	—	—	—	—	—	—	—	—	—	(525)	—	(525)	—	(525)

Distributions to non-controlling interest	—	—	—	—	—	—	—	—	—	—	—	—	(44)	(44)
Net loss	—	—	—	—	—	—	—	—	—	—	(87,133)	(87,133)	—	(87,133)
Balances at December 31, 2014	—	—	—	—	—	—	33,257,978	3	254,048	(525)	(186,725)	66,801	(44)	66,757
Issuance of common stock upon payment of InteKrin Earn Out contingency	—	—	—	—	—	—	358,384	—	9,849	—		9,849		9,849

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Coherus Stockholders' Equity (Deficit)	Noncontrolling Interest	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount						
Retired shares resulting from InteKrin escrow distribution in cash	—	—	—	—	—	—	(8)	—	—	—	—	—	—	—
Issuance of common stock in connection with follow-on public offering, net	—	—	—	—	—	—	4,137,931	1	112,198	—	—	112,199	—	112,199
Issuance of common stock in connection with private placement, net	—	—	—	—	—	—	390,167	—	9,930	—	—	9,930	—	9,930
Issuance of common stock upon exercise of stock options	—	—	—	—	—	—	861,137	—	1,429	—	—	1,429	—	1,429
Vesting of restricted common stock issued to founders	—	—	—	—	—	—	—	—	9	—	—	9	—	9
Stock-based compensation expense	—	—	—	—	—	—	—	—	16,712	—	—	16,712	—	16,712
Cumulative translation adjustment	—	—	—	—	—	—	—	—	—	124	—	124	—	124
Distributions to non-controlling interest	—	—	—	—	—	—	—	—	—	—	—	-	(678)	(678)
Net loss	—	—	—	—	—	—	—	—	—	—	(223,260)	(223,260)	—	(223,260)
Balances at December 31, 2015	—	$ —	—	$ —	—	$ —	39,005,589	$ 4	$ 404,175	$ (401)	$ (409,985)	$ (6,207)	$ (722)	$ (6,929)

See accompanying notes to consolidated financial statements.

Coherus BioSciences, Inc.

Consolidated Statements of Cash Flows
(in thousands)

	Years Ended December 31,		
	2015	2014	2013
Operating activities			
Net loss	$ (223,938)	$ (87,177)	$ (53,635)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:			
Depreciation and amortization	1,869	674	404
Remeasurement of contingent consideration	4,599	5,185	—
Remeasurement of convertible preferred stock warrant and embedded derivative liabilities	—	15,899	4,557
Fair value of warrants in excess of debt proceeds recognized at issuance	—	—	3,669
Fair value of embedded derivative in excess of debt proceeds recognized at issuance	—	—	4,096
Preferred stock issued in exchange for services	—	147	7,579
Non-cash interest (income) expense and amortization of (receivable) debt discount	(38)	3,897	5,293
Gain on extinguishment of 2013 Notes	—	(2,048)	—
Impairment of property and equipment	382	—	—
Provision for other receivables	1,300	—	—
Stock-based compensation expense	16,721	11,062	2,045
Changes in operating assets and liabilities:			
Receivables from collaboration and license agreement	857	(2,139)	(120)
Notes receivable	1,853	(1,815)	—
Notes receivable from related parties	—	107	16
Prepaid assets	(14,288)	(14,692)	(3,284)
Other assets	(3,329)	(2,046)	60
Other assets - related party	1,691	(1,691)	—
Other assets, non-current	42	(25)	(21)
Accounts payable	18,404	3,629	924
Accounts payable, related parties	1,528	1,637	(1,310)
Accrued liabilities	12,832	3,949	2,847
Other liabilities	(28)	31	(2)
Deferred revenue	32,294	19,848	34,749
Advance payments under license agreements	138	1,192	—
Contingent liability to collaborator	38,605	20,150	7,500
Other liabilities, non-current	516	299	56
Net cash (used in) provided by operating activities	(107,990)	(23,927)	15,423
Investing activities			
Net cash acquired from acquisition of InteKrin Therapeutics Inc.	—	2,334	—
Purchases of property and equipment	(6,164)	(2,849)	(373)
Increase in restricted cash	(785)	(10)	—
Net cash used in investing activities	(6,949)	(525)	(373)
Financing activities			
Proceeds from issuance of convertible preferred stock, net of issuance costs	—	54,660	—
Proceeds from issuance of convertible notes	—	—	2,900
Proceeds from issuance of convertible notes - related parties	—	—	7,050
Proceeds from issuance of convertible preferred stock upon exercise of warrants	—	131	—
Proceeds from initial public offering, net of underwriters discounts and commissions	—	85,419	—
Proceeds from follow-on offering, net of underwriters discounts and commissions	112,800	—	—
Proceeds from private placement	10,000	—	—
Payments of initial public offering costs	(855)	(4,307)	—
Payments of follow-on offering costs and private placement	(672)	—	—
Payment of costs related to future offerings	(13)	—	—
Proceeds from issuances of common stock upon exercise of stock options	1,429	55	6
Repurchase of restricted common stock	—	(2)	—
Net cash provided by financing activities	122,689	135,956	9,956
Effect of exchange rate changes in cash and cash equivalents	84	(666)	—
Net increase in cash and cash equivalents	7,834	110,838	25,006
Cash and cash equivalents at beginning of period	150,392	39,554	14,548
Cash and cash equivalents at end of period	$ 158,226	$ 150,392	$ 39,554
Supplemental disclosures of noncash investing and financing activities			
Issuance of Series B Preferred stock for acquisition	$ —	$ 3,667	$ —
Contingent consideration accrued in connection with acquisition	—	1,310	—
Conversion of 2013 Notes and accrued interest into Series C convertible preferred stock	—	10,583	—
Reclassification of fair value of convertible preferred stock warrants to preferred stock upon exercise	—	40,150	—
Vesting of restricted common stock	9	5	10
Purchase of property and equipment in accounts payable and accrued liabilities	1,684	726	169
Leasehold improvements allowance from landlord	1,239	—	—
Initial public offering costs in accounts payable	—	855	—
Costs related to future offerings in accounts payable and accrued liabilities	124	—	—
Accrued expenses settled in common stock warrants	—	55	—
Accrued expenses settled in preferred stock	—	10	—
Fair value of contingent consideration settled in common stock	9,849	—	—

See accompanying notes to consolidated financial statements.

1. Organization and Operations

Description of the Business

The Company is a late-stage clinical biologics platform company, focused on the global biosimilar market. The Company's headquarters and laboratories are located in Redwood City, California and in Camarillo, California, respectively. The Company operates in one segment.

The Company's clinical stage pipeline consists of a long-acting form of granulocyte colony-stimulating factor ("G-CSF"), and two anti-inflammatory agents targeting tumor necrosis factor ("TNF"):

- The Company's long-acting G-CSF product candidate, CHS-1701, is being developed as a pegfilgrastim (Neulasta) biosimilar. In October 2015, the Company has completed a pivotal pharmacokinetic (PK) and pharmacodynamics (PD) study for CHS-1701 in the United States (U.S.). Although it did not meet the PK AUC bioequivalence endpoint due to low, anomalous PK profile in the first period Neulasta group, the Company believes this study will support the planned filing of a biologics license application (BLA) in the U.S. as it met all the other co-primary endpoints including the PD endpoints. An immunogenicity study in healthy volunteers pursuant to this BLA met its primary endpoints. In February 2016, the Company initiated a follow-on PK/PD study, which is expected to read-out late in the first half of 2016. The Company expects to file a BLA in the United States directly thereafter.
- The Company's most clinically advanced anti-TNF product candidate, CHS-0214, is being developed as an etanercept (Enbrel) biosimilar that the Company has partnered with Baxalta Incorporated, Baxalta US Inc., and Baxalta GmbH, (collectively "Baxalta") and Daiichi Sankyo Company, Limited ("Daiichi Sankyo") to develop and commercialize in key markets outside of the U.S. In October 2015, the Company completed part 1 of a Phase 3 clinical study in psoriasis comparing CHS-0214 to Enbrel. The Company is currently conducting a Phase 3 clinical study in rheumatoid arthritis. This study met the primary endpoint at 24 weeks. The Company expects that results from these studies, combined with data from its Phase 1 studies will support the expected filing of a marketing application in Europe and Japan in 2016. The Company has retained the development and commercial rights to this product in the U.S. However, the therapeutic protein in etanercept is subject to certain originator-controlled U.S. patents expiring in 2028 and 2029. Assuming these patents are valid and enforceable, and that the Company would be unable to obtain a license to them, the Company does not expect to commercialize CHS-0214 in the U.S. prior to their expiration.
- The Company's second anti-TNF product candidate, CHS-1420, is being developed as an adalimumab (Humira) biosimilar. This product successfully completed a pivotal Phase 1 PK study in August 2014 by meeting the primary PK bioequivalence endpoint. The Company initiated a Phase 3 study in psoriasis in August 2015 to support the planned filing of a marketing application in the U.S. in 2016 and the E.U. in 2017. The Company initiated a bridging PK study comparing the Phase 3 CHS-1420 material to U.S. manufactured adalimumab (Humira) during the first quarter of 2016 and the Company plans to initiate a bridging PK study comparing the Phase 3 CHS-1420 material to E.U. manufactured adalimumab (Humira) in mid-2016.

Need to Raise Additional Capital

As of December 31, 2015, the Company had an accumulated deficit of $410.0 million and cash and cash equivalents of $158.2 million. In February 2016, we issued and sold $100.0 million aggregate principal amount of 8.2% senior convertible notes ("Notes") due March 31, 2022 (see Note 16). The Company believes that its current available cash and cash equivalents, together with proceeds from the issuance of the Notes and funding it expects to receive under its license agreements with Daiichi Sankyo and Baxalta, will be sufficient to fund its planned expenditures under its 2016 budget and meet the Company's obligations through at least December 31, 2016. The Company will need to raise additional funds in the future, however there can be no assurance that such efforts will be successful or that, in the event that they are successful, the terms and conditions of such financing will be favorable. If the Company is unable to obtain adequate financing when needed, it may have to delay, reduce the scope of or suspend one or more of its clinical trials, research and development programs or commercialization efforts.

2. Basis of Presentation and Summary of Significant Accounting Policies

Basis of Consolidation

The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP"). The accompanying consolidated financial statements include the accounts of Coherus and its wholly owned subsidiaries as of December 31, 2015: Coherus Intermediate Corp, Coherus Oncology, Inc., InteKrin Therapeutics Inc. ("InteKrin"), and InteKrin's 82.5% majority owned subsidiary of InteKrin Russia. Unless otherwise specified, references to the Company are references to Coherus and its consolidated subsidiaries. All intercompany transactions and balances have been eliminated upon consolidation.

Reclassification

To maintain comparability among the periods presented, the Company reclassified certain prior period amounts to a separate line item that was not included in the prior period presentation. Within Note 4, Accrued Liabilities, in the Notes to the Consolidated Financial Statements for the year ended December 31, 2014, the Company reclassified amounts that were recorded within accrued other to accrued clinical and manufacturing. The reclassification had no impact on the total current accrued liabilities for the periods presented.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts and disclosures reported in the financial statements. Management uses significant judgment when making estimates related to its stock-based compensation, valuation of deferred tax assets, impairment of goodwill and long-lived assets, the valuation of acquired intangible assets, clinical trial accruals, revenue recognition period, as well as certain accrued liabilities; and in prior years, common stock valuation, the valuations of the convertible preferred stock warrant liability and embedded derivative instruments. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ from these estimates.

Foreign Currency

The functional currency of InteKrin Russia, which the Company acquired in February 2014, is the Russian Ruble. Accordingly, the financial statements of this subsidiary are translated into U.S. dollars using appropriate exchange rates. Unrealized gains or losses on translation are recognized in accumulated other comprehensive loss in the consolidated balance sheet.

For the years ended December 31, 2015, 2014 and 2013, the foreign exchange gains and losses recorded in other expense, net in the consolidated statements of operations were a net loss of $386,000, a net gain of $671,000 and a net loss of $34,000, respectively.

Segment Reporting and Customer Concentration

The Company operates and manages its business as one reportable and operating segment, which is the business of developing and commercializing biosimilar products, and, as part of the InteKrin acquisition, small molecules (see Note 6). The Company's chief executive officer, who is the chief operating decision maker, reviews financial information on an aggregate basis for purposes of allocating resources and evaluating financial performance. Long-lived assets are primarily maintained in the United States of America.

The following table summarizes revenue by geographic region (in thousands):

	Year Ended December 31,		
	2015	2014	2013
United States	$ 27,802	$ 28,481	$ 726
Rest of world	2,239	2,625	2,025
Total revenue	$ 30,041	$ 31,106	$ 2,751

Customer Concentration

Customers whose collaboration and license revenue accounted for 10% or more of total revenues were as follows:

	Year Ended December 31,		
	2015	2014	2013
Daiichi Sankyo - related party (1)	*	*	74%
Baxalta	93%	92%	26%

* less than 10%

(1) Represents revenue from Daiichi Sankyo through November 12, 2014 as a related party, a holder of more than 10% of our common stock until the closing of our IPO.

Deferred Offering Costs

Deferred offering costs, which primarily consist of direct incremental legal and accounting fee, are capitalized in other assets until the completion of the offering. These deferred offering costs will be reclassified to additional paid-in capital upon the closing of the offering. There was $137,000 in deferred offering costs capitalized as of December 31, 2015 and none capitalized as of December 31, 2014.

Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of 90 days or less at the date of purchase to be cash and cash equivalents.

Restricted Cash

Restricted cash consists of cash held in money market accounts with a bank. The restricted cash that is used as collateral against the Company's corporate credit cards is classified as current and the restricted cash to cover the standby letter of credit issued for the Company's landlord to drawdown on if the facility lease is breached, is classified as non-current (see Note 8).

Concentration of Credit Risk

The Company's financial instruments that are exposed to concentration of credit risk consist primarily of cash and cash equivalents. The Company maintains its cash in bank accounts which at times exceed federally insured limits. The Company attempts to minimize the risks related to cash and cash equivalents by investing in money markets with a broad and diverse range of financial instruments. The investment portfolio is maintained in accordance with the Company's investment policy, which defines allowable investments, specifies credit quality standards and limits the credit exposure of any single issuer. The Company also maintains restricted cash in money market funds that invest primarily in U.S. Treasury securities. The Company has not recognized any losses from credit risks on such accounts during any of the periods presented. The Company believes it is not exposed to significant credit risk on its cash and money market funds.

Fair Value of Financial Instruments

Fair value accounting is applied for all financial assets and liabilities and non-financial assets and liabilities that are recognized or disclosed at fair value in the financial statements on a recurring basis.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation and amortization. Maintenance and repairs are charged to expense as incurred, and costs of improvements are capitalized. Depreciation and amortization is recognized using the straight-line method over the following estimated useful lives:

Computer equipment and software	3 years
Furniture and fixtures	5 years
Machinery and equipment	5 years
Leasehold improvements	Shorter of lease term or useful life

Impairment of Long Lived Assets and Acquired Intangible Asset

The Company reviews long-lived assets, including property and equipment, and indefinite-lived intangible, for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be fully recoverable. An impairment loss would be recognized when the estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition is less than its carrying amount. Impairment, if any, is measured as the amount by which the carrying amount of a long-lived asset exceeds its fair value. For the year ended December 31, 2015, the Company recorded a $382,000 impairment of property and equipment in research and development within the statement of operations.

Acquired in-process research and development ("IPR&D") represents the fair value assigned to research and development assets that have not reached technological feasibility. The Company reviews amounts capitalized as acquired IPR&D for impairment at least annually, and whenever events or changes in circumstances indicate that the carrying value of the assets might not be recoverable. If the carrying value of the acquired IPR&D exceeds its fair value, then the intangible asset is written-down to its fair value. As of December 31, 2015, there have been no such impairments. Once the product candidate derived from the indefinite-lived intangible asset has been developed and commercialized, the useful life will be determined, and the carrying value of the finite-lived asset will be amortized prospectively over that estimated useful life. Alternatively, if the product candidate is abandoned, the carrying value of the intangible will be charged to research and development expense.

Goodwill

Goodwill represents the excess of the purchase price over the fair value of the net tangible and intangible assets acquired. The Company tests goodwill for impairment at least annually or more frequently if events or changes in circumstances indicate that this asset may be impaired. The goodwill test is based on our single operating segment and reporting unit structure.

The Company compares the fair value of its reporting unit to its carrying value. If the carrying value of the net assets assigned to the reporting unit exceeds the fair value of the reporting unit, then the Company would need to determine the implied fair value of the reporting unit's goodwill. If the carrying value of the reporting unit's goodwill exceeds its implied fair value, then the Company would record an impairment loss equal to the difference. No goodwill impairment was identified through December 31, 2015.

Convertible Preferred Stock Warrant Liability

The Company classified warrants exercisable for shares of the Company's Series A and Series B convertible preferred stock as derivative liabilities and adjusted their carrying value to fair value at the end of each reporting period as long as such warrants were outstanding. At the end of each reporting period, changes in the fair value of the convertible preferred stock warrant liability during the period were recorded as a component of other expense, net, in the consolidated statements of operations.

Derivative Liability

The Company has a derivative liability related to the contingent consideration associated with the acquisition of InteKrin. There were two contingent payments payable upon the achievement of certain events: (i) the completion of the first dosing of a human subject in the first Phase 2 clinical trial for InteKrin, ("Earn-Out Payment") and (ii) upon the execution of any license, sublicense, development, collaboration, joint venture, partnering or similar agreement between the Company and the third party ("Compound Transaction Payment"). The derivative related to the contingent consideration is accounted for as a liability and remeasured to fair value as of each balance sheet date and the related remeasurement adjustment is recognized as other income (expense), net in the consolidated statements of operations. The Company determined the fair value of the two contingent consideration scenarios (the Earn-Out Payment and the Compound Transaction Payment) using a probability-weighted discounted cash flow approach. A probability-weighted value was determined by summing the probability of achieving a contingent payment threshold by the respective contingent payments. The expected cash flows were discounted at a rate selected to capture the risk of achieving the contingent payment thresholds and earning the contingent payment. This risk is comprised of InteKrin's continued development, a specific risk factor associated with meeting the contingent consideration threshold and related payout, and counterparty risk associated with the payment of the contingent consideration.

Embedded Derivative Liability

The Company recorded derivative instruments related to redemption features embedded within the convertible notes when such notes were outstanding. The embedded derivatives were accounted for as a liability and were remeasured to fair value as of each balance sheet date when such notes were outstanding, with the related remeasurement adjustment being recognized as a component of other income (expense), net in the consolidated statements of operations.

Accrued Research and Development Expenses

Clinical trial costs are a component of research and development expenses. The Company accrues and expenses clinical trial activities performed by third parties based upon actual work completed in accordance with agreements established with clinical research organizations and clinical sites. The Company determines the actual costs through monitoring patient enrollment, discussions with internal personnel and external service providers as to the progress or stage of completion of trials or services and the agreed-upon fee to be paid for such services.

Revenue Recognition

The Company recognizes revenue when persuasive evidence of an arrangement exists; transfer of technology has been completed, services have been performed or products have been delivered; the fee is fixed and determinable; and collection is reasonably assured.

For revenue agreements with multiple elements, the Company identifies the deliverables included within the agreement and evaluates which deliverables may represent separate units of accounting based on the achievement of certain criteria, including whether the delivered element has stand-alone value to the collaborator. Deliverables under the arrangement are a separate unit of accounting if (i) the delivered item has value to the customer on a standalone basis and (ii) if the arrangement includes a general right of return relative to the delivered item and delivery or performance of the undelivered items are considered probable and substantially within the Company's control.

The Company determines how to allocate arrangement consideration to identified units of accounting based on the selling price hierarchy provided under the relevant guidance. The selling price used for each unit of accounting is based on vendor-specific objective evidence, if available, third party evidence if vendor-specific objective evidence is not available or estimated selling price if neither vendor-specific nor third-party evidence is available. Management may be required to exercise considerable judgment in determining whether a deliverable is a separate unit of accounting and in estimating the selling prices of identified units of accounting under its agreements.

Upfront payments received in connection with licenses of the Company's technology rights are deferred if facts and circumstances dictate that the license does not have stand-alone value. Such payments are recognized as license revenue over the estimated period of performance that is generally consistent with the terms of the research and development obligations contained in the specific collaboration and license agreement. The Company regularly reviews the estimated period of performance based on the progress made under each arrangement. Amounts received as funding of research and development activities are recognized as revenue if the collaboration arrangement involves the sale of the Company's research or development services. However, such funding is recognized as a reduction in research and development expense when the Company engages in a research and development project jointly with another entity, with both entities participating in project activities and sharing costs and potential benefits of the arrangement.

Payments that are contingent upon the achievement of a substantive milestone are recognized in their entirety in the period in which the milestone is achieved, assuming all other revenue recognition criteria are met. A milestones is defined as an event that can only be achieved based on the Company's performance where there is substantive uncertainty about whether the event will be achieved at the inception of the arrangement. Events that are contingent only on the passage of time or only on counterparty performance are not considered milestones under accounting guidance. The Company's evaluation includes an assessment of whether (a) the consideration is commensurate with either (1) the Company's performance to achieve the milestone, or (2) the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the Company's performance to achieve the milestone, (b) the consideration relates solely to past performance and (c) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. The Company evaluates factors such as the scientific, regulatory, commercial and other risks that must be overcome to achieve the respective milestone, the level of effort and investment required to achieve the respective milestone and whether the milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement in making this assessment.

Other contingent payments in which a portion of the payment is refundable or adjusts based on future performance or non-performance (e.g., through a penalty or claw-back provision) are not considered to relate solely to the Company's past performance, and therefore, not considered substantive. Non-substantive contingent payments are classified as deferred revenue if they are ultimately expected to result in revenue recognition. The Company recognizes non-substantive contingent payments over the remaining estimated period of performance once the specific objective is achieved. Any portion of the non-substantive contingent payments which may be required to be refunded to the collaborator are not included in deferred revenue and instead are reflected as contingent liability to collaborator on the consolidated balance sheets.

Contingent payments associated with the achievement of specific objectives in certain contracts that are not considered substantive because the Company does not contribute effort to the achievement of such milestones are recognized as revenue upon achievement of the objective, as long as there are no undelivered elements remaining and no continuing performance obligations by the Company, assuming all other revenue recognition criteria are met.

Revenue from a government contract is recognized in the period during which the related costs are incurred and the related services are rendered, provided that the funds received are not refundable and applicable conditions under the government contract have been met. Funds received in advance are recorded as deferred revenue.

Research and Development Expenses

Research and development costs are charged to expenses as incurred. Research and development expenses include, among other costs, salaries and other personnel-related costs, consultant fees, preclinical costs, cost to manufacture drug candidates and clinical supplies, laboratory supplies costs and facility-related costs. Costs incurred under agreements with third parties are charged to expense as incurred in accordance with the specific contractual performance terms of such agreements. Costs of third parties include costs associated with preclinical and clinical support activities. In certain cases, amounts received as reimbursement of research and development activities from the Company's collaborators are recognized as a reduction in research and development expense when the Company engages in a research and development project jointly with another party, with both parties incurring costs while actively participating in project activities and both parties sharing costs and potential benefits of the arrangement. Costs incurred under the arrangements where the Company provides research services approximate the amount of revenues recorded. Advance payments for goods or services to be received in the future to be utilized in research and development activities are deferred and capitalized. The capitalized amounts are expensed as the related goods are delivered or the services are received.

Stock-Based Compensation

The Company measures the cost of equity-based service awards based on the grant-date fair value of the award, and recognizes the cost of such awards straight-line over the vesting period. Because non-cash stock compensation expense is based on awards ultimately expected to vest, it is reduced by an estimate for future forfeitures. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from estimates.

The Company accounts for equity instruments issued to nonemployees using the fair value approach. These equity instruments consist of stock options and restricted common stock, which are valued using the Black-Scholes option-pricing model. Stock-based compensation expense is recognized as the equity instruments are earned. The measurement of stock-based compensation is subject to periodic adjustments as the underlying equity instruments vest.

The Company utilizes the Black-Scholes option-pricing model for estimating fair value of its stock options and restricted stock granted. Option valuation models, including the Black-Scholes option-pricing model, require the input of highly subjective assumptions, and changes in the assumptions used can materially affect the grant-date fair value of an award. These assumptions include the risk-free rate of interest, expected dividend yield, expected volatility, the expected life of the award, and estimated forfeitures.

Income Taxes

The Company uses the liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and the tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. The Company must then assess the likelihood that the resulting deferred tax assets will be realized. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. Due to the Company's lack of earnings history, the net deferred tax assets have been fully offset by a valuation allowance.

The Company recognizes uncertain income tax positions at the largest amount that is more likely than not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. The Company does not expect its unrecognized tax benefits to change significantly over the next twelve months.

The Company's policy is to recognize interest and/or penalties related to income tax matters in income tax expense. The Company had accrued no amounts for interest and penalties related to income tax matters in the Company's consolidated balance sheets at December 31, 2015 and 2014.

Comprehensive Loss

Comprehensive loss is composed of two components: net loss and other comprehensive loss. Other comprehensive loss refers to gains and losses that under U.S. GAAP are recorded as an element of stockholders' equity, but are excluded from net loss. The Company's other comprehensive loss included foreign currency translation adjustments for the years ended December 31, 2015 and 2014.

Net Loss per Share Attributable to Coherus

Basic net loss per share attributable to Coherus is calculated by dividing the net loss attributable to Coherus by the weighted-average number of shares of common stock outstanding for the period, without consideration for potential dilutive common shares. Since the Company was in a loss position for all periods presented, basic net loss per share attributable to Coherus is the same as diluted net loss per share attributable to Coherus as the inclusion of all potential dilutive common shares would have been anti-dilutive for all periods presented. Shares of founders' common stock subject to repurchase are excluded from the calculation of weighted average shares as the vesting of such shares is contingent upon continued services being rendered by such holders.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2014-09, *Revenue from Contracts with Customers* ("ASU 2014-09"), which converges the FASB and the International Accounting Standards Board standards on revenue recognition. Areas of revenue recognition that will be affected include, but are not limited to, transfer of control, variable consideration, allocation of transfer pricing, licenses, time value of money, contract costs and disclosures. In August 2015, the FASB issued ASU 2015-14, *Revenue from Contracts with Customers: Deferral of the Effective Date* ("ASU 2015-14"). Under the amendments in ASU 2015-14, the FASB deferred the effective date of ASU 2014-09 for public business entities to fiscal years beginning after December 15, 2017, including interim reporting periods within that reporting period, with early adoption permitted on the original effective date of fiscal years beginning after December 15, 2016. The Company may adopt the new standard under the full retrospective method or the modified retrospective method. The Company is currently evaluating the impact that the adoption of ASU 2014-09 will have on its consolidated financial statements and related disclosures.

In August 2014, the FASB issued ASU No. 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. ASU 2014-15 is effective for the Company's annual reporting period ending December 31, 2016 and all annual and interim reporting periods thereafter, with early adoption permitted. The Company has not elected to early adopt this standard. When adopted, ASU 2014-15 will require management to evaluate whether there is substantial doubt about the Company's ability to continue as a going concern for at least 12 months from the issuance date of the financial statements and to provide related footnote disclosures.

In November 2015, the FASB issued ASU No. 2015-17, *Balance Sheet Classification of Deferred Taxes*. To simplify the presentation of deferred income taxes, the amendments in ASU 2015-17 requires that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. ASU 2015-17 is effective for our interim and annual reporting periods during the year ending December 31, 2017 and all annual and interim reporting periods thereafter, with early adoption permitted. The Company has elected to early adopt ASU 2015-17 prospectively. Such adoption did not have a material impact on the Company's consolidated balance sheet and related disclosures as of December 31, 2015, and did not adjust prior periods presented.

In January 2016, the FASB issued ASU No. 2016-1, *Recognition and Measurement of Financial Assets and Financial Liabilities.* ASU 2016-1 makes amendments to the classification and measurement of financial instruments and revises the accounting related to: (1) the classification and measurement of investments in equity securities, and (2) the presentation of certain fair value changes for financial liabilities measured at fair value. In addition, the update also amends certain disclosure requirements associated with the fair value of financial instruments. ASU 2016-1 is effective for the Company's interim and annual reporting periods during the year ending December 31, 2018, and all annual and interim reporting periods thereafter. Early adoptions of certain amendments within the update are permitted. The Company is currently evaluating the impact that the adoption of ASU 2016-1 will have on its consolidated financial statements and related disclosures.

In February 2016, the FASB issued ASU No. 2016-2, *Leases*. ASU 2016-2 is aimed at making leasing activities more transparent and comparable, and requires substantially all leases be recognized by lessees on their balance sheet as a right-of-use asset and corresponding lease liability, including leases currently accounted for as operating leases. ASU 2016-2 is effective for the Company's interim and annual reporting periods during the year ending December 31, 2019, and all annual and interim reporting periods thereafter. Early adoption is permitted. The Company is currently evaluating the impact that the adoption of ASU 2016-2 will have on its consolidated financial statements and related disclosures.

The Company has reviewed other recent accounting pronouncements and concluded they are either not applicable to the business or no material effect is expected on the consolidated financial statements as a result of future adoption.

3. Fair Value Measurements

Financial assets and liabilities are recorded at fair value. The carrying amounts of certain of the Company's financial instruments, including cash and cash equivalents, accounts receivable, accounts payable and other current liabilities approximate their fair value due to their short maturities. Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The accounting guidance describes a fair value hierarchy based on three levels of inputs that may be used to measure fair value, of which the first two are considered observable and the last is considered unobservable. These levels of inputs are the following:

Level 1 — Quoted prices in active markets for identical assets or liabilities.

Level 2 — Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The Company's financial instruments consist of Level 1 assets and Level 3 liabilities. Where quoted prices are available in an active market, securities are classified as Level 1. Level 1 assets consist of highly liquid money market funds that are included in cash and cash equivalents, and restricted cash. There were no unrealized gains and losses in the Company's investments in these money market funds.

In certain cases where there is limited activity or less transparency around inputs to valuation, securities are classified as Level 3. Level 3 liabilities consist of the contingent consideration.

Financial assets and liabilities subject to fair value measurements on a recurring basis and the level of inputs used in such measurements are as follows (in thousands):

	Fair Value Measurements December 31, 2015			
	Total	Level 1	Level 2	Level 3
Assets:				
Money market funds	$ 157,784	$ 157,784	$ —	$ —
Restricted cash (money market funds)	845	845	—	—
Total financial assets	$ 158,629	$ 158,629	$ —	$ —
Liabilities:				
Contingent consideration	$ 1,245	$ —	$ —	$ 1,245

	Fair Value Measurements December 31, 2014			
	Total	Level 1	Level 2	Level 3
Assets:				
Money market funds	$ 147,952	$ 147,952	$ —	$ —
Restricted cash (money market funds)	60	60	—	—
Total financial assets	$ 148,012	$ 148,012	$ —	$ —
Liabilities:				
Contingent consideration	$ 6,495	$ —	$ —	$ 6,495

There were no transfers between Level 1 and Level 3 during the periods presented.

Contingent Consideration

As part of the InteKrin acquisition, the Company recognized contingent consideration associated with potential payments to be made to the former InteKrin stockholders upon the achievement of certain events specified in the agreements (see Note 6). This fair value measurement is based on significant inputs not observable in the market and thus represents a Level 3 measurement within the fair value hierarchy. The InteKrin purchase agreement provides for contingent consideration to be paid upon (i) the first dosing of a human subject in the first Phase 2 Clinical Trial for CHS-131 (formerly INT-131) ("Earn-Out Payment") and (ii) per a compound transaction agreement as defined in the purchase agreement (the "Compound Transaction Payment"). The Company valued the two contingent consideration scenarios (the Earn-Out Payment and the Compound Transaction Payment) using a probability-weighted discounted cash flow approach. A probability of reaching each contingent consideration threshold was estimated by Company's management. As of December 31, 2014, the Earn-Out Payment was expected to occur in January 2015 with a 98% probability of occurrence. As part of that analysis, a 25% risk-adjusted discount rate was used to measure a present value. A separate credit spread was not applied to the Earn-Out Payment fair value since the consideration was to be made in common stock shares. The size of the contingent consideration was a fixed number of common stock shares, but the value fluctuated with the value of a common stock share. The Compound Transaction applied the same 25% risk-adjusted discount rate and also captured an additional 6% credit spread for counterparty credit risk given the cash payment. The Company's management estimates of probability of occurrence and timing were used to formulate an expected cash flow. The size of the consideration is tiered based on the size of a license or similar agreement with a third party and the timing of such agreement. The change in the fair value of the contingent consideration liability is recognized in other expense, net within the consolidated statement of operations.

On March 6, 2015, the Company achieved the first dosing of a human subject in a phase 2 clinical trial for CHS-131 in multiple sclerosis patients, triggering the obligation to settle the first contingent Earn-Out Payment to former InteKrin stockholders. As a result, the Company issued 358,384 shares of its common stock valued at $27.48 per share and cash of $1,000 for the aggregate amount value of $9.8 million to former InteKrin stockholders. Contemporaneously, the Company recognized the additional fair value of the Earn-Out Payment of $4.1 million to other expense, net, in the consolidated statement of operations on March 6, 2015 and reclassified the contingent consideration liability balance to equity in the consolidated balance sheet. For the years ended December 31, 2015 and 2014, the Company recognized $4.1 million and $5.0 million, respectively, in other expense, net in the consolidated statement of operations for the change in the fair value of the Earn-Out Payment.

The fair value measurement of the Compound Transaction Payment uses a probability-weighted discounted cash flow approach based on significant inputs not observable in the market and thus represents a Level 3 measurement within the fair value hierarchy. The Compound Transaction analysis applied a 25% risk-adjusted discount rate to measure present value and also captured an additional 6% credit spread for counterparty credit risk given the cash payment. The Company's management estimates of probability of occurrence and timing were used to formulate an expected cash flow. The value of the consideration is tiered based on the value of a license or similar agreement with a third party and the timing of such agreement. The change in the fair value of the Compound Transaction Payment was recognized in other expense, net in the consolidated statement of operations of $460,000 and $235,000 for the years ended December 31, 2015 and 2014, respectively.

The following table sets forth a summary of changes in the estimated fair value of the contingent consideration (in thousands):

Balance as of February 12, 2014 (acquisition date)	$ 1,310
Change in fair value of the contingent consideration liability	5,185
Balance as of December 31, 2014	6,495
Change in fair value of the contingent consideration liability	4,599
Fair value of Earn-Out Payment settled in common stock on March 6, 2015	(9,849)
Balance as of December 31, 2015	$ 1,245

4. Balance Sheet Components

Prepaid Assets

Prepaid assets are as follows (in thousands):

	December 31, 2015	December 31, 2014
Prepaid clinical, material, manufacturing and other - related parties (see Note 15)	$ 10,901	$ 5,990
Prepaid clinical, material and manufacturing	21,191	12,149
Prepaid other	2,651	2,346
Prepaid assets	$ 34,743	$ 20,485

Property and Equipment, Net

Property and equipment, net are as follows (in thousands):

	December 31, 2015	December 31, 2014
Machinery and equipment	$ 7,809	$ 4,317
Computer equipment and software	1,276	286
Furniture and fixtures	596	288
Leasehold improvements	4,343	399
Construction in progress	—	474
Total property and equipment	14,024	5,764
Accumulated depreciation and amortization	(3,520)	(1,292)
Property and equipment, net	$ 10,504	$ 4,472

Depreciation expense was $1.9 million, $674,000 and $404,000 for the years ended December 31, 2015, 2014 and 2013, respectively.

In July 2015, the Company entered into a new lease agreement with its landlord for its new headquarters facility in Redwood City, California (see Note 6). The Company moved into the new facility in December 2015 and recorded $3.1 million in leasehold improvements related to the new headquarters.

Accrued Liabilities

Accrued liabilities are as follows (in thousands):

	December 31, 2015	December 31, 2014
Accrued clinical, manufacturing and other - related parties (see Note 15)	$ 6,122	$ 2,997
Accrued clinical and manufacturing	11,681	2,396
Accrued compensation	4,666	3,435
Accrued professional and consulting fees	446	252
Accrued other	1,218	2,151
Accrued liabilities	$ 24,133	$ 11,231

5. Collaboration and License Agreement

The Company recognized revenue related to the collaboration and license agreements for the periods presented as follows (in thousands):

	Year Ended December 31,		
	2015	2014	2013
Baxalta	$ 27,802	$ 28,481	$ 726
Daiichi Sankyo - related party (1)	2,239	1,893	2,025
Total collaboration and license revenue	$ 30,041	$ 30,374	$ 2,751

(1) Represents revenue from Daiichi Sankyo through November 12, 2014 as a related party, a holder of more than 10% of our common stock until the closing of our initial public offering ("IPO").

Daiichi Sankyo

In January 2012, the Company entered into a license agreement with Daiichi Sankyo, under which the Company granted certain licenses to Daiichi Sankyo to develop and commercialize biosimilar forms of etanercept and rituximab in Japan, Taiwan, and South Korea with an option to develop in China. Under the terms of the agreement, the Company will be responsible for the manufacturing and supply of the products during the development activities and Daiichi Sankyo will conduct the development, regulatory approval filings, and commercialization activities of the biosimilar form of etanercept and rituximab products in Japan. Once the biosimilar forms of etanercept and rituximab are commercialized, the Company is entitled to royalties based on net sales by Daiichi Sankyo on a product-by-product basis in the licensed territories ranging from the low double digits to high teens, on a product-by-product basis. If the Company is manufacturing product, the Company is eligible to receive an incremental royalty reflecting the manufacturing costs for each licensed product which, when combined with the base royalty, will result in royalties equal to a percentage of net sales of licensed products ranging from the low to high-twenties, on a product-by-product basis.

Upon execution of the agreement, Daiichi Sankyo paid a non-refundable, upfront license fee of $10.0 million and purchased 2,867,426 shares of Series B convertible preferred stock at a price of $6.9749 per share, or $18.1 million in net cash proceeds. The Company concluded that there was no premium or discount associated with the purchase of the Series B convertible preferred stock since Daiichi Sankyo paid the same price paid by other investors at the close of the Series B convertible preferred stock offering. As such the Company recorded the $18.1 million as a convertible preferred stock transaction separate from the license agreement. The agreement has an initial term of ten years and contains provisions allowing Daiichi Sankyo to renew the agreement for an additional three years with respect to particular countries. Daiichi Sankyo also has the right to terminate the agreement, in its entirety or on a country-by country basis, at any time if the development and/or commercialization is deemed to not be commercially viable, there are material safety, efficacy or patient tolerability issues that cannot be remedied or overcome, or during the opt-out window after the achievement of specified objectives in the agreement. In May 2012, Daiichi Sankyo opted out of the development and commercialization of etanercept in Taiwan and South Korea, and in August 2012, Daiichi Sankyo chose not to exercise their option with respect to the development and commercialization of etanercept and rituximab in China.

The Company identified the following deliverables under the agreement: (1) the transfer of intellectual property rights (license), and (2) the manufacture of drug materials for clinical development purposes. The Company considered the provisions of the multiple-element arrangement guidance in determining how to recognize the total consideration of the agreement. The Company has concluded that the license is not a separate unit of accounting because Daiichi Sankyo cannot obtain benefit from the use of the license rights for their intended purpose without the products manufactured by the Company. Daiichi Sankyo must rely upon the Company to manufacture and supply the products necessary for Daiichi Sankyo's development because the related manufacturing know-how specific to the products is proprietary to the Company and Daiichi Sankyo does not have the right to manufacture the licensed product. The Company determined that neither of the deliverables have standalone value and, therefore, the deliverables are accounted for as a single unit of accounting with the upfront fee recognized as revenue on a straight-line basis over its estimated period of performance of approximately three years. The Company determined that there is no other method that is more appropriate than the straight-line method of revenue recognition for this agreement given there is no discernable pattern of its performance under the arrangement. The Company regularly evaluates the reasonableness of the estimated period of performance and revises the amortization of deferred revenue as deemed appropriate on a prospective basis. On September 30, 2014 and December 31, 2014, the Company extended the period of performance for two quarters and one quarter, respectively, through the fourth quarter of 2017. On September 2015, the Company revised the period of performance extending the period to November 2017.

In June 2013, the Company and Daiichi entered into a Memorandum of Understanding No. 1 (the "MOU 1") in which both parties agreed to cooperate and share costs to conduct a global Phase 1 study of a biosimilar form of etanercept. This program was not originally contemplated in the license agreement. Under the MOU 1, the Company will gather all clinical data, format it into a case study report, and conduct the final analysis. The Company will transfer the clinical data and other regulatory approval application documents for the product and post marketing to Daiichi Sankyo within 90 days after such documents are finalized. Under the MOU 1, Daiichi's Sankyo's overall cost sharing responsibility include (i) 33% of the total budgeted cost and (ii) 100% of the cost of the comparator drug (Enbrel) used for the Japanese volunteers. The amounts received from Daiichi Sankyo under this cost sharing responsibility are recognized as a reduction in research and development expense as the Company engages in a research and development project jointly with Daiichi Sankyo, with both parties incurring costs while actively participating in development activities and both parties sharing costs and potential benefits of the arrangement. The Company accounted for the MOU 1 as a separate arrangement which was not deemed to be a material modification of the original license agreement with Daiichi Sankyo.

In January 2014, the Company and Daiichi Sankyo entered into the Memorandum of Understanding No. 2 (the "MOU 2") in which both parties agreed to cooperate to conduct a global Phase 3 clinical trial in rheumatoid arthritis and that Daiichi Sankyo will be responsible for a minimum of 20% of the cost of the clinical trial. Also, both parties entered into a clinical supply agreement contemporaneously with the MOU 2 in which the Company will supply finished study drug and study comparator drug for Daiichi Sankyo's use in the Japanese portion of the product's clinical trial. Daiichi Sankyo reimburses these research and development costs in quarterly advance payments, for which the Company recorded $1.3 million and $1.2 million as advance payments under license agreement in the consolidated balance sheet as of December 31, 2015 and 2014, respectively. The Company will recognize the advance payment as a reduction in the research and development expense when the research and development activity has been performed.

In June 2015, the Company and Daiichi Sankyo entered into the Memorandum of Understanding No. 3 (the "MOU 3") in which both parties agreed to cooperate further on a global Phase 3 clinical trial in rheumatoid arthritis. Under the MOU 3, Daiichi Sankyo will be responsible for a minimum of 20% of the cost of an open label, safety extension study ("OLSES") in rheumatoid arthritis. The Company also entered into a clinical supply agreement as part of the MOU 3 in which the Company will supply finished study drug and study comparator drug for Daiichi Sankyo's use in the Japanese portion of the clinical trial. Daiichi Sankyo will pre-pay these research and development costs quarterly, and they are recorded by the Company as advance payments in the consolidated balance sheet. The Company recognizes the advance payments as a reduction of research and development expense when the research and development activity has been performed.

As of December 31, 2015, $2.8 million of revenue was deferred under all arrangements with Daiichi Sankyo, of which $1.5 million was included in current liabilities and $1.3 million was included in non-current liabilities in the consolidated balance sheet. As of December 31, 2014, $4.3 million of revenue was deferred under all arrangements with Daiichi Sankyo, of which $1.6 million was included in current liabilities and $2.7 million was included in non-current liabilities in the consolidated balance sheet.

The Company recognized in its consolidated statements of operations a reduction of research and development expense related to the costs reimbursed by Daiichi Sankyo of $16.1 million, $7.1 million and $1.3 million for the years ended December 31, 2015, 2014 and 2013, respectively.

Baxalta

In August 2013, the Company entered into a license agreement with Baxter, to develop and commercialize an etanercept biosimilar molecule, CHS-0214, worldwide, excluding the United States, Japan, Taiwan, South Korea, China and most of the Caribbean and South American nations. In the second quarter of 2015, Baxter assigned its rights and obligations under the license agreement to affiliated entities that are under common control of Baxalta. Under the terms of the license agreement, the Company will conduct the development and the regulatory activities, and Baxalta will conduct the commercialization of the etanercept biosimilar product.

Under the terms of the agreement, the Company will conduct the development and the regulatory activities, and Baxalta will conduct the commercialization of the etanercept biosimilar product. In consideration of the exclusive, royalty-bearing license to develop, commercialize and use the etanercept biosimilar product, Baxalta made an upfront payment of $30.0 million to the Company. Additionally, the Company is eligible to receive up to $216.0 million in contingent payments composed of $96.0 million in clinical development payments and up to $120.0 million in regulatory milestone payments. If the cumulative development costs exceed the cumulative contingent payments, Baxalta will reimburse the Company for the excess cost as set forth in the agreement up to predetermined limits. Once the etanercept biosimilar product is commercialized, the Company is entitled to tiered royalties, based on the manufacturing cost as a percentage of net sales of licensed products, ranging from the mid-single digits to the high teens on a country-by-country basis. These royalties are subject to certain offsets and reductions.

The agreement has an initial term of ten years and contains provisions allowing Baxalta to renew the agreement for another three years on a country-by-country basis. Baxalta also has the right to terminate the agreement, in its entirety or on a country-by country basis, at any time if the development and/or commercialization is deemed to not be commercially viable, there are material safety, efficacy or patient tolerability issues that cannot be remedied or overcome, if aggregate expenses exceed certain thresholds or after the first commercial sale upon 18 month prior written notice.

The Company identified the following deliverables under the license agreement with Baxalta: 1) the transfer of intellectual property rights (license), (2) the obligation to provide research and development services including the manufacturing and supply of clinical product, and (3) the obligation to participate on various committees.

The Company considered the provisions of the multiple-element arrangement guidance in determining how to recognize the total consideration of the agreement. The Company determined that the license does not have standalone value to Baxalta without the Company's technical expertise as it relates to the development of the product candidate and committee participation. Additionally, the license to Baxalta does not include the right to manufacture, or have manufactured the product during the development stage, or to conduct any process development activities. Therefore, the Company concluded that these deliverables represent a single unit of accounting under the multiple-element arrangement guidance.

The upfront payment of $30.0 million and clinical development payments of up to $96.0 million include $56.0 million of contingent payments that are intended to cover development related expenses incurred by the Company, but potentially reimbursable, in part, to Baxalta under certain limited circumstances. The Company concluded that the contingent payments that contain potentially reimbursable amounts to Baxalta are not substantive milestones under the relevant accounting guidance, since the guidance does not allow the substantive milestone components of a payment to be bifurcated from non-substantive milestone components. The amounts that are contingent payments also contain a claw-back feature that, in the event that the Company commercializes the etanercept biosimilar molecule in the U.S. without Baxalta, fifty percent (50%) of those contingent payments are refundable to Baxalta. Therefore, the Company will record the portion of the non-substantive contingent payment that contains the claw-back feature as a liability for the potential reimbursement of such funds to Baxalta until the earlier of: (1) expiration or termination of the license agreement, which is ten years, or (2) the determination of the party to commercialize the molecule in the U.S. These amounts are included in the contingent liability to collaborator on the consolidated balance sheets. The portion of the non-substantive milestone payment that does not contain the claw-back feature will be recorded as deferred revenue and recognized as license revenue on a straight-line basis over the remaining estimated performance period of approximately three years. The Company determined that there is no other method that is more appropriate than the straight-line method of revenue recognition for this agreement given there is no discernable pattern of performance under the arrangement. The Company regularly evaluates the reasonableness of the estimated period of performance and revises the amortization of deferred revenue as deemed appropriate on a prospective basis. On September 30, 2014 and December 31, 2014, the Company revised the period of performance extending the period of performance for two quarters and one quarter, respectively. On September 2015, the Company revised the period of performance extending the period to November 2017.

The $120.0 million of regulatory milestone payments are considered substantive as the achievement is subject to the significant uncertainty as to the outcome of the development efforts, by the Company, over an extended period of time, and the Company's substantive performance obligation under the license agreement which includes efforts associated with the clinical trials and filing and approval of drug applications by regulatory authorities in various countries. Therefore, the Company will recognize revenue associated with these respective contingent payments when each of the specific events is achieved.

In February 2014, the agreement was amended to increase the payment by $5.3 million therefore the Company is eligible to receive up to $221.3 million in contingent payments comprised of $101.3 million in clinical development payments, and up to $120.0 million in regulatory milestone payments.

In April 2015, the Company and Baxalta, entered into a second amendment (the "Second Amendment") to the license agreement. Under the terms of the Second Amendment, a revised milestone payment structure totaling $130.0 million replaced certain existing milestone and funding obligations under the license agreement as originally executed. Therefore the Company is eligible to receive up to $335.3 million in contingent payments comprised of $215.3 million in clinical development payments, and up to $120.0 million in regulatory milestone payments.

The Second Amendment does not provide for any change in the contracted deliverables set forth in the license agreement. As a result, the original assessment of the standalone value for the deliverables remains unchanged and the deferred revenue previously recorded prior to the Second Amendment continues to be recognized as revenue on a straight-line basis over the remaining expected performance period. Likewise, the contingent liability from the incremental milestones received under the license agreement prior to Second Amendment has not been adjusted.

If the Company commercializes CHS-0214, its etanercept biosimilar product, in the United States, the Company will be required to refund a portion of the milestone payments received from Baxalta as specified in the Second Amendment. A portion of each of the $130.0 million milestones would be subject to refund. The Company concluded that the payments that contain potentially reimbursable amounts to Baxalta are not substantive milestones under the relevant accounting guidance, since the guidance does not allow the substantive milestone components of a payment to be bifurcated from non-substantive milestone components. Therefore, the Company will record the portion of the contingent payment that contains the claw-back feature as a liability for the potential reimbursement of such funds to Baxalta until the earlier to occur of: (1) expiration of the license agreement pursuant to its terms in August 2023, (2) the earlier termination of the license agreement, or (3) the determination, pursuant to the terms of the license agreement, of the third party to commercialize CHS-0214 in the U.S. This liability is included in the contingent liability to collaborator on the consolidated balance sheets. The portion of the milestone payment that does not contain the claw-back feature will be recorded as deferred revenue and recognized as license revenue on a straight-line basis over the remaining estimated performance period as there is no discernable pattern of performance under the arrangement.

Pursuant to the Second Amendment, the Company received a total of $100 million in milestone payments in 2015 which are subject to the 50% claw-back feature. Therefore, the Company recorded $38.6 million as contingent liability to collaborator and $61.4 million as deferred revenue which is being amortized over the remaining estimated performance period using the straight line method.

The Second Amendment provides that Baxalta would purchase $10.0 million of the Company's common stock. As a result, on September 10, 2015, the Company sold Baxalta an aggregate of 390,167 shares of common stock at $25.63 per share (the fair value of the common stock on the day of pricing, September 9, 2015) for aggregate gross proceeds of approximately $10.0 million (see Note 11).

As of December 31, 2015, $92.0 million of revenue was deferred under the arrangements with Baxalta, of which $48.0 million was included in current liabilities and $44.0 million was included in non-current liabilities in the consolidated balance sheet. As of December 31, 2015, $66.3 million was recorded as contingent liability to collaborator in the consolidated balance sheet due to the potential refund to Baxalta.

As of December 31, 2014, $58.4 million of revenue was deferred under the arrangements with Baxalta, of which $21.2 million was included in current liabilities and $37.2 million was included in non-current liabilities in the consolidated balance sheet. As of December 31, 2014, $27.7 million was recorded as contingent liability to collaborator due to the potential refund of such amount to Baxalta in the future. Additionally in 2014, the Company received $10.0 million for the achievement of a substantive milestone pursuant to the license agreement and accordingly recognized the entire amount as collaboration and license revenue in its consolidated statements of operations in the third quarter of 2014.

6. Acquisition of InteKrin Therapeutics Inc.

On January 8, 2014, the Company entered into an Agreement and Plan of Merger (the "Merger Agreement") to acquire all of the outstanding shares of InteKrin and its 82.5% majority owned subsidiary, InteKrin Russia. On February 12, 2014, the Company completed the acquisition of InteKrin (the "Merger") for total consideration of $5.0 million. The acquisition was a related party transaction (see Note 15).

Prior to the Merger, InteKrin was a privately held, clinical-stage biopharmaceutical company focused on the development and commercialization of novel drugs for the treatment of immune diseases such as multiple sclerosis. InteKrin's primary product candidate is CHS-131, which is in the clinical stage of development. Although CHS-131 is a small molecule and not a protein, its therapeutic focus area was complementary to the Company's emerging multiple sclerosis biosimilar product pipeline which consists of broader level, central nervous system anti-inflammatory drug candidates. This in turn was complementary to the Company's systemic focus on anti-inflammatory drug candidates with the anti-tumor necrosis factor (TNF) portfolio composed of etanercept and adalimumab biosimilars. Additionally, the acquisition of InteKrin was a strategic transaction to obtain funding from new investors.

The Company accounted for the InteKrin acquisition as the purchase of a business. The Company expensed the related acquisition costs, consisting primarily of legal expenses in the amount of $134,000. These legal expenses are recorded in general and administrative expense in the consolidated statement of operations for the year ended December 31, 2014. The total consideration of $5.0 million consists of: (a) issuance of 716,645 shares of Series B preferred stock with a fair value of $2.7 million, (b) assumption of InteKrin's convertible promissory note payable to an InteKrin stockholder, which was concurrently paid off by issuing 243,841 shares of the Company's Series B convertible preferred stock with a fair value of $1.0 million (c) cash payment of $1,485, and (d) contingent consideration of $1.3 million. The Company determined the fair value of the Series B convertible preferred stock of $3.8174 per share using the PWERM. The non-controlling interest was not deemed to be significant at acquisition.

Pro forma results of operations for this acquisition have not been presented as such results are not material to the Company's results of operations for the years ended December 31, 2014 and 2013.

The following table summarizes the original fair value of the assets acquired and liabilities assumed (in thousands):

Cash	$	2,335
Prepaid and other assets		107
Accounts payable and other current liabilities		(1,027)
In-process research and development		2,620
Goodwill		943
Total	$	4,978

In connection with the acquisition of InteKrin, the Company recorded a deferred tax liability related to the acquired in-process research and development. This deferred tax liability represents a new source of future taxable income, which required the release of a portion of InteKrin's deferred tax asset valuation allowance equal to the deferred tax liability recorded. The deferred tax asset and liability are both classified as long term for purposes of the balance sheet presentation.

Intangible Asset — In-process Research and Development

The in-process research and development ("IPR&D") consists of InteKrin's CHS-131. The Company determined the fair value of the IPR&D based on the cost to recreate the asset to its current stage as the fair value is not determinable as a result of the lack of financial projections for this asset due to its early development stage. By applying this method, management estimated that $2.6 million of the acquisition consideration represents the fair value of the IPR&D. The IPR&D acquired through the InteKrin acquisition is treated as an indefinite-lived intangible asset and an annual impairment review is performed by management. As of December 31, 2015, there has been no impairment of this IPR&D.

Contingent Consideration

The contingent consideration is made up of two potential payments as discussed below.

Contingent Consideration — Earn-Out Payment: Upon completion of the first dosing of a human subject in the first Phase 2 clinical trial for InteKrin, InteKrin's stockholders could earn a minimal cash payment and 358,384 shares of the Company's Series B convertible preferred stock upon the successful achievement of this objective. At the acquisition date, the Company expected the first

dosing to be completed in September 2014 and assigned a 75% success probability to the achievement and timing of this event. As such, at the acquisition date, the fair value of the contingent consideration related to this earn-out payment was determined to be $0.8 million. As of the consummation of the IPO in November 2014, such contingent consideration was payable by issuing shares of common stock rather than shares of Series B convertible preferred stock.

C*ontingent Consideration — Compound Transaction Payment:* Upon the execution of any license, sublicense, development, collaboration, joint venture, partnering or similar agreement between the Company and a third-party or any agreement between the Company and such third-party to sell all of the assets related to the acquired InteKrin compound to such third-party, the Company will pay former InteKrin's stockholders cash based on a certain percentage of fees received pursuant to such compound transaction. That payment ranges from 60% of the fees received within one year to 10% after the third anniversary of the date of the final dose administered to the final patient in Phase 2 clinical trial.

At the time of the acquisition, the Company estimated that the probability of achieving the compound transaction agreement event was 7.5% of the fair value of this contingent consideration based on a probability weighted determination of both the range of the amount and the likelihood of achieving the estimated payouts. At the acquisition date, the fair value of this contingent consideration from the compound transaction payment was determined to be $0.5 million.

At the acquisition date, the Company valued the two contingent consideration scenarios using a probability-weighted discounted cash flow approach. A probability of reaching each contingent consideration threshold was estimated by management. A probability-weighted value was determined by multiplying the probability of achieving a contingent payment threshold by the respective contingent payment. The expected cash flows were discounted at a rate selected to capture the risk of achieving the contingent payment thresholds and earning the contingent payment. This risk is composed of InteKrin's continued development, a specific risk factor associated with meeting the contingent consideration threshold and related payout and counterparty risk associated with the payment of the contingent consideration.

As of December 31, 2014, the fair value of this contingent consideration liability increased to $6.5 million to reflect the updated fair value estimate of the liability and accordingly $5.2 million was recognized as an expense in the consolidated statement of operations during year ended December 31, 2014. The increase in the updated fair value of the contingent consideration is due to changes in the Company's estimate of reaching each contingent consideration threshold and the increase in the fair value of the Company's common stock (see Note 3).

On March 6, 2015, the Company achieved the first dosing of a human subject in a phase 2 clinical trial for CHS-131 in multiple sclerosis patients, triggering the obligation to settle the contingent Earn-Out Payment to former InteKrin stockholders. As a result, the Company issued 358,384 shares of its common stock valued at $27.48 per share and cash of $1,000 for the aggregate amount value of $9.8 million to former InteKrin stockholders (see Note 3).

As of December 31, 2015, the fair value of this contingent consideration liability decreased to $1.2 million to reflect the Earn-Out Payment settlement in March 2015 and the updated fair value estimate of the Compound Transaction Payment. Accordingly $4.6 million was recognized as an expense in the consolidated statement of operations during the year ended December 31, 2015 (see Note 3).

Goodwill

Goodwill resulting from this acquisition comprises the excess of the purchase price over the fair value of the underlying net assets acquired and primarily represents the strategic relationship acquired with InteKrin's investors. None of this goodwill will be deductible for tax purposes. Under the applicable accounting guidance, goodwill will not be amortized but will be tested for impairment on an annual basis or more frequently if certain indicators are present. As of December 31, 2015, there have been no such impairments.

Government Contract with the Russian Government

In 2012, InteKrin Russia, a subsidiary of InteKrin, was awarded a contract by the Ministry of Industry and Trade of the Russian Federation to perform scientific research and experimental development work for the treatment of multiple sclerosis and conducting its preclinical and clinical studies for a total aggregate amount of 147.9 million RUB ($2.6 million in US dollars as of December 31, 2014) which was expanded multiple years from 2012 to 2015. The contract amount related to the 2014 research period was expected to be 40.0 million RUB. Subsequent to the Company's acquisition of InteKrin in February 2014, the Company received 12.0 million RUB and 28.0 million RUB in the first and fourth quarter of 2014, respectively. These advance receipts of funding were deferred

until the Company met all the revenue recognition criteria in 2014. The Company recognized revenue of 40.0 million RUB ($732,000 based on the exchange rate on the date the revenue was recognized) as other revenue in the consolidated statement of operations for the year ended December 31, 2014. The remaining amount available under the government contract for 2015 is 39.4 million RUB, of which 11.8 million RUB ($162,000) was received in the first quarter of 2015 and reflected as deferred revenue in the consolidated balance sheet as of December 31, 2015.

7. Debt Obligations

From July 2013 to September 2013, the Company entered into convertible note agreements (the "Bridge Loans") with various stockholders, employees and institutions for an aggregate principal amount of $10.0 million. The Bridge Loans accrued interest of 8% per annum and would mature on July 15, 2014. The principal and the accrued interest on the Bridge Loans were converted into 5,488,892 shares of Series C convertible preferred stock in May 2014 (see note 11).

In connection with the Bridge Loans, the Company also issued warrants to purchase shares of its convertible preferred stock at an exercise price of $0.0167 per share. The determination of the number of shares issuable pursuant to the 2013 warrants was determined based on 300% of the principal amount of the Bridge Loans divided by the conversion price. In addition, at the issuance date of the notes, there was a beneficial conversion feature. The total aggregate Bridge Loans of $10.0 million were less than the initial fair value of the warrants of $13.6 million at the issuance date. Therefore $10.0 million was recognized as debt discount, and the difference of $3.6 million was immediately charged to other income (expense), net in the consolidated statement of operations and comprehensive loss as the carrying value of the debt could not be reduced to less than zero. No value was recorded initially for the beneficial conversion feature since the carrying value of the debt was zero. The debt discount of $10.0 million was accreted using the effective interest method as an additional interest expense over the term of the Bridge Loans.

The Bridge Loans redemption features were determined to be embedded derivatives requiring bifurcation and separate accounting. The fair value of the embedded derivative liability at issuance was determined to be $4.1 million. As a result of the fair value of the warrant debt discount reducing the debt to zero at the time of the issuance as discussed above, the estimated fair value of the derivative liability of $4.1 million was recognized within other income (expense), net, in the consolidated statement of operations and comprehensive loss and as a derivative liability on the consolidated balance sheet upon issuance. Changes in the fair value of the embedded derivative have also been recorded within other income (expense), net, in the consolidated statement of operations and comprehensive loss. The Company periodically remeasured the derivative liability to fair value.

In December 2013, following the receipt of the upfront license payment from Baxalta license agreement (see Note 5), the Company met the qualified licensing threshold ("QLT"). As a result, upon a change of control, a redemption feature related to the holders' option to receive a cash payment in lieu of conversion into Series B convertible preferred stock was reduced from 400% to 100% of the outstanding principal, plus accrued interest and the associated embedded derivative liability was reduced to zero.

The Bridge Loans were collateralized by a security interest in all assets, tangible and intangible, of the Company, subject to a prior security interest of Cook on the Company's property and equipment in Camarillo, California. Upon the issuance of Series C convertible preferred stock in May 2014, all security interests to the Company's asserts, tangible and intangible, were released.

In May 2014, the Company completed an equity financing of Series C convertible preferred stock and, as a result, the Bridge Loans and related accrued interest of $10.6 million automatically converted into 1,058,089 shares of Series C convertible preferred stock based on the price per share paid by other investors in the financing. In connection with the extinguishment of the Bridge Loans, the Company reacquired the beneficial conversion feature. The intrinsic value of the beneficial conversion feature at the date of the Bridge Loans extinguishment was $3.9 million. This amount is reflected in additional paid in capital. The Company recorded a gain from the extinguishment of the debt in the amount of $2.0 million which is reflected in other income (expense), net in the consolidated statement of operations in the year ended December 31, 2014.

In addition, as the warrants could be exercised for Series B convertible preferred stock any time after achieving a QLT, which was met on December 9, 2013 and before the Series C convertible preferred stock financing, in April and May 2014, all holders of these warrants elected to fully exercise warrants for 4,279,620 shares of Series B convertible preferred stock.

During the years ended December 31, 2014 and 2013, the Company recognized total interest expense of $3.9 million and 4.8 million, respectively, related to the accrued interest and amortization of the debt discount.

8. Commitments and Contingencies

Purchase Commitments

The Company enters into contracts in the normal course of business with contract research organizations for preclinical studies and clinical trials and contract manufacturing organizations ("CMOs") for the manufacture of drug materials. As of December 31, 2015, the Company had a commitment of $14.5 million with CMOs for the manufacture of clinical trial material due within a year. The Company has an agreement with Medpace, Inc. ("Medpace"), a related party (see Note 15) and, a CRO, which provides for a minimum fee commitment of $35.0 million in the aggregate for clinical trial services; however, the agreement is cancelable without cause by either party upon 30 days prior notification. As of December 31, 2015, the Company has fulfilled the minimum fee commitment related to this agreement.

Facility Leases

The Company leases office spaces for its corporate headquarters in Redwood City, California and for laboratory facilities in Camarillo, California under operating lease agreements. On July 6, 2015, the Company entered into a new office lease (the "New Lease") with Hudson 333 Twin Dolphin Plaza, LLC (the "Landlord") to lease approximately 27,532 square feet of office space located in Redwood City, California (the "Premises") for the Company's new corporate headquarters. The Company leased office space located in Redwood City, California, pursuant to a lease dated September 26, 2011 (as amended, the "Current Lease"), which expired pursuant to the terms described below under "Amendment to Current Lease." The New Lease commenced on December 1, 2015 and the Company moved into the new facility in December 2015.

The Company entered into the Seventh Amendment to the Current Lease (the "Seventh Amendment") with its current landlord when the New Lease was entered into. The Seventh Amendment provided early termination of the Current Lease which was effective in December 2015 when the New Leased commenced.

The New Lease provides for annual base rent of approximately $1.6 million in the first year of the Lease Term, which increases on an annual basis up to approximately $1.9 million for the final year of the Lease Term. The New Lease also provides for certain limited rent abatements in the second year of the Lease Term. The Company will be entitled to a one-time improvement allowance of approximately $1.2 million for costs related to the design and construction of Company improvements that are permanently affixed to the Premises. See the future minimum lease payment schedule for all facility leases below.

In addition, the Company obtained a standby letter of credit (the "Letter of Credit") in an amount of approximately $0.8 million, which may be drawn down by the Landlord to be applied for certain purposes upon the Company's breach of any provisions under the New Lease. Provided that no default occurs under the terms of the New Lease, the Company will be entitled to periodically reduce the amount of the Letter of Credit down to approximately $0.3 million as of the last day of the sixtieth full calendar month of the Lease Term. The Company has recorded the $0.8 million Letter of Credit in restricted cash, non-current within its consolidated balance sheet at December 31, 2015.

Rent expense is recognized on a straight-line basis over the term of the leases and accordingly, the Company records the difference between cash rent payments and the recognition of rent expense as a deferred rent liability. The corporate headquarters new lease expires in November 2022, and the Camarillo laboratory lease expires in June 2017 with an option to extend for three years.

The future minimum lease payments for these facilities as of December 31, 2015 are as follows (in thousands):

Year ending December 31,		
2016	$	1,692
2017		1,276
2018		1,669
2019		1,719
2020 and thereafter		5,315
Total minimum lease payments	$	11,671

Rent expense was $1.8 million, $0.8 million and $0.4 million for the years ended December 31, 2015, 2014 and 2013, respectively.

Guarantees and Indemnifications

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future, but have not yet been made. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. However, the Company may record charges in the future as a result of these indemnification obligations. The Company would assess the likelihood of any adverse judgments or related claims, as well as ranges of probable losses. In the cases where the Company believes that a reasonably possible or probable loss exists, it will disclose the facts and circumstances of the claims, including an estimate range, if possible. As of December 31, 2015, the Company is subject to one claim that is probable or reasonably possible and consequently has recorded a related liability of $50,000.

9. Convertible Preferred Stock Warrants

2011 Warrants A

In January 2011, in conjunction with the issuance of the 2011 convertible note agreements, the Company issued warrants to purchase shares of its newly authorized shares of preferred stock upon a financing event ("2011 Warrants A"). In March 2011, as a result of the Series A convertible preferred stock financing event, the 2011 Warrants A became exercisable warrants to purchase 63,923 shares of Series A convertible preferred stock with an exercise price of $1.2503 per share. Immediately prior to the closing of the Company's IPO in November 2014, all of the outstanding warrants were exercised, for cash or on a net cash basis for 62,251 shares of Series A convertible preferred stock resulting in cash proceeds of $55,000.

2011 Warrants B

From July to December 2011, the Company issued the 2011 Warrants B with an exercise price of $0.0167 per share in conjunction with the issuance of the 2011 convertible not agreements. In January 2012, as a result of the Series B convertible preferred stock financing event, the 2011 Warrants B became exercisable warrants to purchase 352,448 shares of Series B convertible preferred stock. In June 2012, warrants to purchase 57,347 of Series B preferred stock were exercised, resulting in cash proceeds of approximately $1,000. During April and May 2014, warrants to purchase 172,042 shares of Series B convertible preferred stock were cash exercised for $3,000 and the remaining outstanding warrants were exercised, for cash or on a net basis resulting in the issuance of 123,051 shares of Series B convertible preferred stock for $2,000 immediately prior to the closing of the Company's IPO in November 2014.

2013 Warrants

From July to September 2013, the Company issued the 2013 Warrants with the exercise price of $0.0167 per share in conjunction with the issuance of the Bridge Loans (see Note 7). The estimated fair value of the 2013 Warrants at issuance was $13.6 million based on probability-weighted values of the warrants under the qualifying event scenarios. The Company recognized the fair value of the 2013 Warrants up to the total aggregate Bridge Loans of $10.0 million as the debt cannot be reduced to less than zero. The remaining $3.6 million of the total fair value of the 2013 Warrants was recognized immediately within other income (expense), net, in the consolidated statement of operations. In December 2013, following the receipt of the upfront license payment from the Baxalta license agreement (see Note 5), the Company met the QLT criteria. As a result, the 2013 Warrants became exercisable to purchase 4,279,620 shares of Series B convertible preferred stock. During April and May 2014, warrants to purchase 4,279,620 shares of Series B convertible preferred stock were exercised for $71,000.

The 2011 Warrants A, 2011 Warrants B and 2013 Warrants were classified as convertible preferred stock warrant liabilities and subject to remeasurement at each balance sheet date. The fair value of the convertible preferred stock warrants was determined based on Level 3 inputs. The Company determined the fair value of the warrants by allocating the Company's equity value using a combination of the Probability-Weighted Expected Return Method ("PWERM") and the Option-Pricing Method ("OPM"). The Company's equity value was allocated among preferred stock, common stock, warrants and stock options expected to be outstanding at the expected future liquidity events based on the rights and preferences of each class. The OPM considers a distribution of future equity values based on the time to liquidity and the expected volatility in the total equity value. Inputs to the OPM include assumptions related to the fair value of the shares, the exercise price, expected volatility, expected term, risk-free interest rate, and the expected dividend yield. The estimated expected volatility was based on the volatility of common stock of a group of comparable, publicly-traded companies. The estimated expected term was based on the estimated time to liquidity event. The risk-free interest rate was based on the U.S. Treasury yield for a term consistent with the estimated expected term. The significant unobservable input used in the fair value measurement of the convertible preferred stock warrant liability is the fair value of the underlying preferred stock at

the valuation remeasurement date. The PWERM considers specific future equity values based on knowledge of a potential transaction or IPO. The range of future equity values is probability-weighted and discounted at a risk-adjusted rate. Some of the valuations applied a combination of the two allocation methods to capture the fair value of the warrants. During 2014, the warrants were valued using the PWERM exclusively based on the expectation for an IPO in November 2014. The size of the IPO and the implied pre-money total equity values were used to support the warrants value. Generally, increases (decreases) in the fair value of the underlying preferred stock would result in a directionally similar impact to the fair value measurement.

The change in the fair value of the convertible preferred stock warrant liability was recognized in other expense, net within the consolidated statements of operations. The net change in the fair value of the warrant liability was an increase of $15.9 million and an increase of $8.9 million for the years ended December 31, 2014 and 2013, respectively. The Company adjusted the liability for changes in fair value at the time of the exercise and then reclassified the liability to the respective series of preferred stock. Any remaining warrants outstanding immediately prior to the Company's IPO in November 2014 were exercised, for cash or on a net basis, and the fair value of the warrants were recorded to the respective series of convertible preferred. As the result of all of the outstanding warrant exercises during 2014, the Company reclassified $1.0 million and $39.3 million to Series A and Series B preferred stock, respectively, reducing the preferred stock warrant liability to zero by December 31, 2014.

The following table sets forth a summary of the changes in the estimated fair value of the convertible preferred stock warrants for the year ended December 31, 2014 (in thousands):

	December 31, 2014
Balance, beginning of year	$ 24,251
Warrants issued in connection with notes payable	—
Initial fair value of the warrants issued in excess of debt proceeds recognized in other income (expense), net	—
Warrants exercised	(40,150)
Change in fair value of convertible preferred stock warrant liability	15,899
Balance, end of year	$ —

10. Common Stock Warrants

In March 2014, the Company issued warrants to purchase 553,274 shares of common stock with the exercise price of $1.667 per share to two employees and one consultant for past services. The warrants were vested and exercisable upon issuance and would have expired at the earlier of: (i) March 28, 2024, (ii) an IPO or (iii) the consummation of a liquidation event. If the holders had not exercised these warrants prior to the closing of a liquidation event or the IPO, these warrants would have automatically been net exercised. The Company valued the warrants at $2.7 million using the Black-Scholes option-pricing model with the following assumptions on the date of grant: exercise price of $1.667 per share, fair value of the common stock of $5.73 per share, expected volatility of 93% and 96% for the employee and consultant warrants, respectively, risk-free interest rate of 1.74% and 2.73% for the employee and consultant warrants, respectively, expected terms of 5 and 10 years for the employee and consultant warrants, respectively, and dividend yield of zero. The grant date fair value per warrant share was $4.95 for employees and $5.42 for the consultant, resulting in warrant valuations of $2.6 million and $144,000 for the employees and consultant, respectively. Due to the immediate vesting and exercisability of the warrants upon issuance, the Company immediately recognized $1.3 million and $1.4 million of stock-based compensation in research and development expense and general and administrative expense, respectively, in the consolidated statement of operations. In November 2014, all of the warrants outstanding to purchase common stock were net exercised, which resulted in the issuance of 491,580 shares of common stock upon the closing of the IPO.

11. Stockholders' Equity (Deficit)

Common Stock

In October 2014, the Company's board of directors and stockholders approved the amendment and restatement of the Company's certificate of incorporation to be effective immediately prior to the consummation of the IPO. The Amended and Restated Certificate of Incorporation was filed on November 12, 2014, which provides for 300,000,000 authorized shares of common stock with a par value of $0.0001 per share and 5,000,000 authorized shares of preferred stock with a par value of $0.0001 per share.

Initial Public Offering

On November 6, 2014, the Company's registration statement on Form S-1 (File No. 333-198936) relating to the IPO of its common stock was declared effective by the Securities and Exchange Commission ("SEC") and the shares began trading on The NASDAQ Global Market on November 6, 2014. The price of the shares sold in the IPO was $13.50 per share. The IPO closed on November 12, 2014, pursuant to which the Company sold 6,803,702 shares of common stock, including the sale of 507,402 shares of common stock to the underwriters upon their partial exercise of their over-allotment option. The Company received total gross proceeds from the offering of $91.8 million, after deducting underwriting discounts and commissions of $6.4 million and offering expenses of $5.2 million, the net proceeds were $80.2 million. In connection with the closing of the IPO, all shares of convertible preferred stock then outstanding converted into 21,316,519 shares of common stock, including 185,302 outstanding convertible preferred stock warrants were exercised, for cash or on a net basis. Also, all outstanding warrants for common stock were exercised, on a net basis, into 491,580 shares of common stock in connection with the IPO.

Follow-on Offering

In March 2015, the Company's registration statement on Form S-1 (File No. 333-202936) relating to its follow-on offering of its common stock was declared effective by the SEC. The price of the shares sold in the follow-on offering was $29.00 per share. The follow-on offering closed on April 7, 2015, pursuant to which the Company sold 4,137,931 shares of common stock. The Company received total gross proceeds from the offering of $120.0 million. After deducting underwriting discounts and commissions of $7.2 million and offering expenses of $0.6 million, the net proceeds were $112.2 million.

Private Placement with Baxalta

On September 10, 2015, the Company completed a private placement and entered into a Purchase Agreement with Baxalta. Pursuant to the Purchase Agreement, the Company sold Baxalta an aggregate of 390,167 shares of common stock for aggregate gross proceeds of approximately $10 million. The purchase price for each share was $25.63, which was equal to the closing trading price of the Company's common stock on the NASDAQ Global Market on the day of pricing, September 9, 2015. The securities sold and issued in connection with the private placement are not registered under the Securities Act or any state securities laws and may not be offered or sold in the United States absent registration with the SEC or an applicable exemption from the registration requirements. In connection with the Purchase Agreement, the Company entered into a Registration Rights Agreement (the "Registration Rights Agreement") with Baxalta GmbH. Pursuant to the Registration Rights Agreement, the Company filed a registration statement on Form S-3 (File No. 333-208625) with the SEC on December 18, 2015 for purposes of registering the resale of the shares. The Registration Statement on Form S-3 was declared effective by the SEC on January 21, 2016.

Convertible Preferred Stock

In May 2014, the Company completed a financing resulting in the issuance of 5,488,892 shares of Series C convertible preferred stock, for net cash proceeds of $54.7 million. In conjunction with the Series C convertible preferred stock financing, the Bridge Loans and the related accrued interest were automatically converted into 1,058,089 shares of Series C convertible preferred stock at the price per share of such financing, and the collateralized security interest of the Company's assets, tangible and intangible, under the Bridge Loans was released. In addition, the Company issued 9,997 shares of Series C convertible preferred stock in exchange for consulting services.

The Company recorded the convertible preferred stock at fair value on the dates of issuance. The Company classified the convertible preferred stock outside of stockholders' deficit because the shares contained liquidation features that were not solely within the Company's control.

During April and May 2014, warrants to purchase 4,451,662 shares of Series B convertible preferred stock were exercised into Series B convertible preferred stock for $74,000, which included the 4,279,620 shares of Series B convertible preferred stock warrants related to the Bridge Loan (see Note 9).). In November 2014, in connection with the closing of the IPO, warrants to purchase 62,251 shares and 123,051 shares of Series A and B convertible preferred stock, respectively, were exercised on a cash or net basis for $57,000.

In connection with the closing of the IPO in November 2014, all outstanding shares of Series A, Series B and Series C convertible preferred stock shares were converted into 21,316,519 shares of common stock on a one-for-one basis. As such, no convertible preferred stock shares were outstanding as of December 31, 2014.

12. Stock Option Plans and Stock-Based Compensation

Restricted Common Stock ("Founders Shares")

In October 2010 and January 2011, the Company issued 4,130,173 shares and 968,804 shares of common stock, respectively, with a purchase price of $0.0083 per share to its founders under the Founder Shares agreements. Under the Founders Shares agreements, the Company has the right to repurchase the common stock which right lapses monthly in equal installments over four years. In order to vest, the holders are required to provide continued service to the Company. Upon vesting, the appropriate amounts are transferred from liabilities to additional paid in capital. If the holder of any unvested restricted common stock is terminated for any reason, the Company has the right to repurchase the unvested shares at the stockholder's original purchase price. As such, the shares subject to future vesting were not deemed outstanding for accounting purposes until the shares vested. In July 2012 and March 2014, the Company repurchased 286,817 and 239,952 shares of founders' common stock from founders at $0.0083 per share, respectively.

A summary of the Company's non-vested restricted stock for the periods is as follows:

	Number of Shares
Non-vested as of December 31, 2014	21,245
Vested	(21,245)
Non-vested as of December 31, 2015	—

The Company recognized stock-based compensation over the vesting term of four years based on the fair value of the common stock on the dates of issuance. The restricted common stock granted to an employee is valued using the Black-Scholes options pricing model based on the common stock fair value at the time of the grant. For restricted common stock issued to consultants, the Company remeasured the fair value of the restricted shares as they vest at each reporting period using the Black-Scholes option-pricing model reflecting the remaining vesting period.

The stock-based compensation expense recorded related to the founder's shares was as follows (in thousands):

	Year Ended December 31,		
	2015	2014	2013
Research and development	$ 9	$ 1,547	$ 227
General and administrative	—	4	1,054
	$ 9	$ 1,551	$ 1,281

2010 Stock Plan

In 2010, the Company adopted the 2010 Stock Plan (the "2010 Plan") and granted options under this plan until November 2014 which is when it was terminated as to future awards, although it continues to govern the terms of options that remain outstanding under the 2010 Plan. The 2010 Plan provided for the Company to grant shares and/or options to purchase shares of common stock to employees, directors, consultants, and other service providers at prices not less than the fair value at the date of grant for incentive stock options and nonstatutory options. These options were granted to generally vest over four years, expire ten years from the date of grant, and are generally exercisable after vesting. Unvested options exercised are subject to the Company's repurchase right that lapses as the options vest. As of December 31, 2015 and 2014, no shares were subject to repurchase under the 2010 Plan.

In November 2014, the board of directors adopted the Company's 2014 Equity Incentive Award Plan (the "2014 Plan") and any remaining unissued shares available under the 2010 Plan were transferred into the 2014 Plan. As such, no more options may be issued under the 2010 Plan.

As of December 31, 2015, a total of 4,560,904 shares of common stock are subject to options outstanding under the 2010 plan, which shares will become available under the 2014 Plan to the extent the options are forfeited or lapse unexercised.

2014 Equity Incentive Award Plan

In October 2014, the Company's board of directors and its stockholders approved the establishment of the 2014 Equity Incentive Plan (the "2014 Plan"), effective upon the date upon which the registration statement for the IPO was declared effective, which was November 6, 2014. As of the date of the IPO, the Company reserved for issuance under the 2014 Plan a total of 2,300,000 shares of its common stock, plus any additional shares that would otherwise return to the 2010 Plan as a result of forfeiture, termination or expiration of awards previously granted under the 2010 Plan. In addition, the 2014 Plan provides for annual increases in the number of shares available for issuance thereunder on the first business day of each fiscal year, beginning with 2015, equal to four percent (4%) of the number of shares of the Company's common stock outstanding as of such date or a lesser number of shares as determined by the Company's board of directors.

Employee Stock Purchase Plan

In October 2014, the Company's board of directors and its stockholders approved the establishment of the 2014 Employee Stock Purchase Plan ("ESPP"). The Company will reserve for issuance 320,000 shares of its common stock and provide for annual increases in the number of shares available for issuance on the first business day of each fiscal year, beginning with the Company's fiscal year following the year of this offering, equal to the lesser of one percent (1%) of the number of shares of the Company's common stock outstanding as of such date, 320,000 shares of common stock, or a number of shares as determined by the Company's board of directors.

The following table sets forth the summary of option activities under the 2014 and 2010 Plans:

		Options Outstanding	
	Shares Available for Grant	Number of Options	Weighted-Average Exercise Price
Balances at December 31, 2014	2,652,500	5,770,307	$ 2.909
Authorized	1,330,319	—	—
Granted - at fair value	(3,217,313)	3,217,313	28.020
Exercised	—	(861,137)	1.660
Forfeited	317,641	(317,641)	15.066
Balances at December 31, 2015	1,083,147	7,808,842	$ 12.898

Additional information related to the status of options as of December 31, 2015 is summarized as follows:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Contractual Terms (Years)	Aggregate Intrinsic Value (in thousands)
Options outstanding	7,808,842	$ 12.898	8.27	$ 94,220
Options vested and expected to vest	7,747,817	$ 12.839	8.26	$ 93,860
Options vested and exercisable	3,054,854	$ 4.956	7.34	$ 56,696

Valuation of Awards Granted to Employees

The Company estimated the fair value of each stock award on the date of grant using the Black-Scholes option-pricing model. The weighted average assumptions used to value options granted to employees under the Plan during the years ended December 31, 2015, 2014 and 2013 were as follows:

	Year Ended December 31,		
	2015	2014	2013
Expected term (years)	6.00	6.50	5.51
Expected volatility	78%	99%	108%
Risk-free interest rate	1.62%	2.05%	1.23%
Expected dividend yield	0%	0%	0%

Expected Term

The expected term represents the period for which the stock-based awards are expected to be outstanding and is based on the options' vesting term, contractual term and industry peers. The Company did not have sufficient historical information to develop reasonable expectations about future exercise patterns and post vesting employment termination behavior.

Expected Volatility

The Company used an average historical stock price volatility of industry peers as representative of future stock price volatility since the Company does not have any trading history for its common stock.

Risk-Free Interest Rate

The Company based the risk-free interest rate by using an equivalent to the expected term based on the U.S. Treasury constant maturity rate as of the date of grant.

Expected Dividends

The Company has not paid and does not anticipate paying any dividends in the near future, and therefore used an expected dividend yield of zero in the valuation model.

The stock-based compensation expense recorded related to options granted to employees was as follows (in thousands):

	Year Ended December 31,		
	2015	2014	2013
Research and development	$ 6,460	$ 1,580	$ 431
General and administrative	8,289	3,934	309
	$ 14,749	$ 5,514	$ 740

During the years ended December 31, 2015, 2014 and 2013, the total estimated fair value of the options vested was $14.6 million, $4.2 million and $0.7 million, respectively and the estimated weighted-average grant-date fair value of options granted was $18.42, $6.65 and $1.88 per share, respectively. The aggregate intrinsic value of options exercised during the years ended December 31, 2015, 2014 and 2013 was $1.4 million, $0.4 million and $0, respectively.

As of December 31, 2015, total unrecognized stock-based compensation expenses related to unvested employee stock options was $55.2 million, which is expected to be recognized on a straight-line basis over a weighted-average period of approximately 3.15 years.

In November 2014, the Company entered into a separation agreement with its former CFO and granted accelerated vesting of options and extended the exercise period for those vested options. In connection with the option modification, the Company recognized stock-based compensation expense of $1.2 million to general and administrative expense in its consolidated statements of operations for the year ended December 31, 2014, which is included in the $3.9 million in the above stock-based compensation table.

Nonemployees Stock-Based Compensation

The Company granted 198,750, 113,913 and 74,983 stock options to purchase shares of common stock to nonemployees during the years ended December 31, 2015, 2014 and 2013. The weighted-average exercise price of the options granted in 2015, 2014 and 2013 was $ 26.51, $4.42 and $1.42 per share, respectively. For the years ended December 31, 2015, 2014 and 2013, the Company recorded stock-based compensation expense related to options granted to nonemployees of $2.0 million, $1.3 million and $24,000, respectively. The Company remeasures the fair value of the unvested nonemployee options at each period using the Black-Scholes option-pricing model reflecting the same assumptions as applied to employee options in each of the reported years, other than the expected life, which is assumed to be the remaining contractual life of the options.

13. Income Taxes

The Company utilizes the liability method of accounting for deferred income taxes. Under this method, deferred tax liabilities and assets are recognized for the expected future tax consequences of temporary differences between the carrying amounts and the tax basis of assets and liabilities. A valuation allowance is established against deferred tax assets because, based on the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. The Company's policy is to record interest and penalties on uncertain tax positions as income tax expense.

A reconciliation of the statutory U.S. federal rate to the Company's effective tax rate is as follows:

	Year Ended December 31,		
	2015	2014	2013
Percent of pre-tax income:			
U.S. federal statutory income tax rate	34.00%	34.00%	34.00%
State taxes, net of federal benefit	0.70	(1.65)	3.97
Permanent items	(1.25)	(10.80)	(12.40)
Research and development credit	2.46	3.11	4.53
Net operating loss	(0.01)	0.01	—
InteKrin purchase price allocation	—	0.73	—
Other	0.09	0.02	—
Change in valuation allowance	(35.99)	(25.42)	(30.10)
Effective income tax rate	—%	—%	—%

Significant components of the Company's net deferred tax assets as of December 31, 2015 and 2014 consist of the following (in thousands):

	December 31,	
	2015	2014
Net operating loss carryforwards	$ 91,334	$ 34,463
Research and development credits	12,980	6,032
Depreciation and amortization	778	854
Stock-based compensation	5,111	1,428
Other accruals	2,236	940
Deferred revenue	23,237	12,762
Gross deferred tax assets	135,676	56,479
In-process research and development	(891)	(892)
Gross deferred tax liabilities	(891)	(892)
Total net deferred tax asset	134,785	55,587
Less valuation allowance	(134,785)	(55,587)
Net deferred tax assets	$ —	$ —

The valuation allowance increased $79.2 million, $22.1 million and $16.1 million during the years ended December 31, 2015, 2014 and 2013, respectively.

As of December 31, 2015, the Company had federal net operating loss carryforwards of approximately $281.6 million, which will start to expire beginning in 2031, and various state net operating loss carryforwards of approximately $94.8 million, which have various expiration dates beginning in 2031. Utilization of the net operating loss carryforwards and credits may be subject to a substantial annual limitation due to the ownership change limitations provided by Section 382 of the Internal Revenue Code of 1986, as amended, and similar state provisions. The annual limitation may result in the expiration of net operating losses and credits before utilization.

As of December 31, 2015, the Company had federal research and development credit carryforwards of approximately $15.1 million, which will start to expire in 2031, and state research and development credit carryforwards of approximately $5.2 million, which can be carried forward indefinitely.

In assessing the realizability of deferred tax assets, the Company considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which the temporary differences representing net future deductible amounts become deductible. Due to the Company's history of losses, and lack of other positive evidence, the Company has determined that it is more likely than not that its deferred tax assets will not be realized, and therefore, the deferred tax assets are fully offset by a valuation allowance at December 31, 2015 and 2014.

At December 31, 2015, the portion of the federal net operating loss carryforwards related to stock option deductions is approximately $21.7 million, which is not included in the Company's gross or net deferred tax assets. Pursuant to ASC 718-740-25-10, the tax effect of the stock option benefit of approximately $7.4 million will be recorded to equity when they reduce cash taxes payable in the future.

The Company files U.S, California, and other state income tax returns with varying statutes of limitations. The tax years from 2011 forward remain open to examination due to the carryover of unused net operating losses and tax credits.

A reconciliation of the Company's unrecognized tax benefits for the years ended December 31, 2015 and 2014 is as follows (in thousands):

	Year Ended December 31,		
	2015	2014	2013
Balance at beginning of year	$ 3,816	$ 749	$ 73
Additions based on tax positions related to current year	3,633	861	319
Additions for tax positions of prior years	3,156	2,206	357
Balance at end of year	$ 10,605	$ 3,816	$ 749

As of December 31, 2015 and 2014, the Company had approximately $10.6 million and $3.8 million, respectively, of unrecognized benefits, none of which would currently affect the Company's effective tax rate if recognized due to the Company's deferred tax assets being fully offset by a valuation allowance. The Company does not believe there will be any material changes in its unrecognized tax positions over the next twelve months. During the years ended December 31, 2015, 2014 and 2013, the Company did not recognize accrued interest and penalties related to unrecognized tax benefits. The Company does not anticipate that the amount of existing unrecognized tax benefits will significantly increase or decrease during the next 12 months.

14. Net Loss Per Share Attributable to Coherus

The following table sets forth the computation of the basic and diluted net loss per share attributable to Coherus (in thousands, except share and per share data):

	Years Ended December 31,		
	2015	2014	2013
Numerator:			
Net loss attributable to Coherus	$ (223,260)	$ (87,133)	$ (53,635)
Denominator:			
Weighted-average common shares outstanding	37,125,617	8,520,100	4,828,214
Less: weighted-average unvested common shares subject to repurchase (1)	(3,609)	(333,571)	(1,496,194)
Weighted-average number of shares used in computing net loss per share attributable to Coherus, basic and diluted	37,122,008	8,186,529	3,332,020
Net loss per share attributable to Coherus, basic and diluted	$ (6.01)	$ (10.64)	$ (16.10)

(1) Shares were excluded as such shares represent restricted common stock (founders' shares) which is vesting contingently upon the holders' continued services to the Company.

The following outstanding dilutive potential shares have been excluded from the calculation of diluted net loss per share attributable to Coherus due to their anti-dilutive effect:

	Outstanding as of December 31,		
	2015	2014	2013
Stock options outstanding	7,808,842	5,770,307	3,047,396
Convertible preferred stock	—	—	9,153,906
Convertible preferred stock warrants	—	—	4,638,644
Total	7,808,842	5,770,307	16,839,946

In addition, 358,384 shares of common stock contingently issuable upon the successful achievement of an objective associated with contingent consideration payable to former InteKrin stockholders have been excluded from the calculation of diluted net loss per share attributable to Coherus for the year ended December 31, 2014. On March 6, 2015, the contingent issuable shares were settled (see Note 3).

15. Related Party Transactions

Notes Receivable from Founders

In December 2011, the Company entered into unsecured promissory notes ("Notes Receivable") agreement with the four founders of the Company. Of the four founders, three are members of the executive team of the Company. The aggregate amount of Notes Receivable was $133,000 at the issuance date and the Notes Receivable bore interest at 0.2% per annum. In May 2014, the Company forgave the outstanding balance of Notes Receivable of $111,000 and the related accrued interest of approximately $1,000, which is reflected in the Company's consolidated statement of operations for the year ended December 31, 2014, as interest expense.

Daiichi Sankyo

In January 2012, Company entered into a license agreement with Daiichi Sankyo (see Note 5), under which the Company issued 2,867,426 shares of Series B convertible preferred stock. As such, Daiichi Sankyo was deemed to be a related party by ownership of more than 10% of the Company's equity. Upon the consummation of the Company's IPO, Daiichi Sankyo's ownership percentage decreased to less than 10% of the Company's equity; therefore, as of November 2014, Daiichi Sankyo was no longer considered a related party. As a result, the consolidated balance sheets as of December 31, 2015 and 2014 no longer reflects these balances as related party amounts, and the consolidated statement of operations for the year ended December 31, 2015 does not reflect any transactions with Daiichi Sankyo as related party. For the years ended December 31, 2014 and 2013, the Company recognized related party transactions of $1.9 million and $2.0 million as collaboration and license revenue–related party in the Company's consolidated statements of operations, respectively. In addition, the Company recognized $7.1 million and $1.3 million as a reduction of research and development expense related to the costs reimbursed by Daiichi Sankyo in the Company's consolidated statements of operations for the years ended December 31, 2014 and 2013, respectively.

Transactions Associated with Cook

In January and December 2012, the Company issued a total of 2,150,569 shares of Series B convertible preferred stock to Cook as consideration for past and future services. As such, Cook was deemed to be a related party by ownership of more than 10% of the Company's equity. During the second quarter of 2014, Cook divested a majority of its shares of the Company's Series B convertible preferred stock; therefore, as of December 31, 2014, Cook was no longer considered a related party. As a result, the consolidated balance sheets as of December 31, 2015 and 2014 no longer reflects these balances as related party amounts, and the consolidated statement of operations for the year ended December 31, 2015 no longer reflect transactions with Cook as related party transactions. For the years ended December 31, 2014 and 2013, the Company recognized $4.5 million and $6.1 million, respectively, of services rendered by Cook within research and development in the consolidated statements of operations.

Transactions Associated with Medpace Agreement

One member of the Company's board of directors is also the chief executive officer of Medpace. As such, Medpace was deemed to be a related party. As of December 31, 2015, the Company had $10.9 million in prepaid assets (prepaid clinical, material, manufacturing and other–related parties), $3.5 million in accounts payable–related parties, and $6.1 million in accrued and other liabilities (accrued clinical, manufacturing and other–related parties), all reflected on the Company's consolidated balance sheet associated with Medpace. As of December 31, 2014, the Company had $6.0 million in prepaid assets (prepaid clinical, material, manufacturing and other–related parties), $1.9 million in accounts payable–related parties, and $3.0 million in accrued and other liabilities (accrued clinical, manufacturing and other–related parties), all reflected on the Company's consolidated balance sheet associated with Medpace. The Company recognized $42.5 million, $24.1 million and $4.7 million during years ended December 31, 2015, 2014 and 2013, respectively, for services rendered by Medpace within research and development expense in the consolidated statements of operations. Additionally, the Company recognized $0.5 million of interest expense for the year ended December 31, 2013 associated with extended payment arrangement with Medpace. The Company also has an agreement with Medpace which provides for a minimum fee commitment of $35.0 million for clinical trial services which is further discussed in Note 8. As of December 31, 2015, the Company has fulfilled the minimum fee commitment related to this agreement.

Recruiting Services

One member of the Company's board of directors is the chief executive officer of a company that provides recruiting services to the Company. As such, the recruiting services provided were deemed to be related party transactions. As of December 31, 2014, the Company had $90,000 in accounts payable-related parties reflected on the Company's consolidated balance sheet. As of December 31, 2015, there were no such balances in the Company's consolidated balance sheet. The Company recorded in research and development expense in its consolidated statements of operations, $258,000, $241,000 and $35,000 for the years ended December 31, 2015, 2014 and 2013, respectively, for services rendered by the recruiting company. The Company recorded in general and administrative expense in its consolidated statements of operations, $559,000, $597,000 and $18,000 for the year ended December 31, 2015, 2014 and 2013, respectively, for services rendered by the recruiting company.

Convertible Notes — Related Parties

In the third quarter of 2013, the Company entered into Bridge Loans with certain investors, including existing stockholders, some members of the Company's board of directors and their affiliated companies and some members of management, for a total aggregate amount of $10.0 million and issued the 2013 Warrants to purchase shares of the Company's preferred stock at an exercise price of $0.0167 per share (see Note 9). In May 2014, the Company completed a preferred stock financing and contemporaneously the Bridge Loans and the related accrued interest were automatically converted into Series C preferred stock (see Note 7). For the years ended December 31, 2014 and 2013, the Company recognized $2.7 million and $3.3 million, respectively, of interest expense related to the debt and the amortization of the debt discount in the Company's consolidated statements of operations.

InteKrin Acquisition

In February 2014, the Company completed the acquisition of the InteKrin for total consideration of $5.0 million (see Note 6). Mr. Dennis M. Lanfear, the chief executive officer of the Company, was the chairman of the board and acting president of InteKrin at the time of the acquisition. As such, the InteKrin acquisition was a related party transaction. Mr. Lanfear also owns 10% of the outstanding securities of InteKrin Russia, a majority owned subsidiary of InteKrin.

Other Assets – Related Party

In December 2014, the Company entered into an agreement with an officer of the Company, in which the officer irrevocably transferred his rights to a certain number of shares with an aggregate value of $1.7 million. This amount is reflected in the Company's consolidated balance sheet at December 31, 2014 as "other assets-related party". This transaction was settled in July 2015.

16. Subsequent Events

In February 2016, the Company issued and sold $100.0 million aggregate principal amount of its 8.2% senior convertible notes due 2022 ("the Notes"). These Notes require quarterly interest distributions at a fixed coupon rate of 8.2% until maturity, redemption or conversion, which will be no later than March 31, 2022. The Notes are convertible into shares of common stock at an initial conversion rate of 44.7387 shares of common stock per $1,000 principal amount of the Notes (equivalent to a conversion price of approximately $22.35 per share of common stock, representing a 60% premium over the average last reported sale price of the Company's common stock over the 15 trading days preceding the date the notes were issued), subject to adjustment in certain events. After March 31, 2020, the full amounts of the Notes not previously converted are redeemable for cash at the Company's option if the last reported sale price per share of the Company's common stock exceeds 160% of the conversion price on 20 or more trading days during the 30 consecutive trading days preceding the date on which the Company sends notice of such redemption to the holders of the Notes. Upon conversion of the Notes by a holder, the holder will receive shares of the Company's common stock, together, if applicable, with cash in lieu of any fractional share. At maturity or redemption, if not earlier converted, the Company will pay 109% of the par value of the Notes, together with accrued and unpaid interest, in cash.

The holders of the Notes are Healthcare Royalty Partners III, L.P., which holds $75.0 million in aggregate principal amount, and three related party investors, KKR Biosimilar L.P., which holds $20.0 million, MX II Associates LLC, which holds $4.0 million, and KMG Capital Partners, LLC, which holds $1.0 million.

17. Supplementary Data – Quarterly Financial Data (Unaudited)

The following table presents certain unaudited consolidated quarterly financial information for each of the quarters ended December 31, 2015 and 2014:

	2015 Quarter End			
(in thousands, except per share data)	March 31	June 30	September 30	December 31
Total revenue	$ 5,810	$ 6,866	$ 7,167	$ 10,198
Total operating expenses	42,558	65,761	78,384	62,405
Net loss	(40,839)	(59,034)	(71,485)	(52,580)
Net loss attributable to Coherus	(40,725)	(58,810)	(71,334)	(52,391)
Net loss per share attributable to Coherus, basic and diluted	(1.22)	(1.56)	(1.86)	(1.35)

	2014 Quarter End			
	March 31	June 30	September 30	December 31
Total revenue	$ 3,596	$ 4,965	$ 16,052	$ 6,493
Total operating expenses	17,357	22,903	22,475	33,053
Net loss	(25,170)	(25,070)	(7,914)	(29,023)
Net loss attributable to Coherus	(25,170)	(24,957)	(7,872)	(29,134)
Net loss per share attributable to Coherus, basic and diluted	(6.04)	(5.96)	(1.79)	(1.47)

Item 9. ***Changes in and Disagreements with Accountants on Accounting and Financial Disclosure***

None

Item 9A. ***Controls and Procedures***

(a) Evaluation of Effectiveness of Disclosure Controls and Procedures

We carried out an evaluation, under the supervision of our Chief Executive Officer and our Chief Financial Officer, and evaluated the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of the end of the period covered by this Annual Report on Form 10-K. Based on that evaluation, our President and Chief Executive Officer and our Chief Financial Officer have concluded that, as of the end of the period covered by this Annual Report on Form 10-K, our disclosure controls and procedures were, in design and operation, effective.

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and that such information is accumulated and communicated to our management, including our chief executive officer, principal financial officer and principal accounting officer, as appropriate, to allow for timely decisions regarding required disclosure.

We intend to review and evaluate the design and effectiveness of our disclosure controls and procedures on an ongoing basis and to correct any material deficiencies that we may discover. Our goal is to ensure that our management has timely access to material information that could affect our business. While we believe the present design of our disclosure controls and procedures is effective to achieve our goal, future events affecting our business may cause us to modify our disclosure controls and procedures. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

(b) Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f). Under the supervision and with the participation of our management, including our principal executive officer, principal financial officer and principal accounting officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 Framework). Based on our evaluation under the framework in *Internal Control—Integrated Framework*, our management concluded that our internal control over financial reporting was effective as of December 31, 2015. Ernst & Young LLP, our independent registered public accounting firm, has attested to and issued a report on the effectiveness of our internal control over financial reporting, which is included herein.

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of Coherus BioSciences, Inc.

We have audited Coherus BioSciences, Inc.'s internal control over financial reporting as of December 31, 2015, 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). Coherus BioSciences Inc.'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 Management's Report 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 conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). 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.

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.

In our opinion, Coherus BioSciences Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2015, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Coherus BioSciences Inc. as of December 31, 2015 and 2014, and the related consolidated statements of operations, comprehensive loss, convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2015 of Coherus BioSciences, Inc. and our report dated February 29, 2016 expressed an unqualified opinion thereon.

/s/ Ernst & Young, LLP

Redwood City, California
February 29, 2016

Changes in Internal Control Over Financial Reporting.

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended December 31, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. ***Other Information***

Not applicable.

PART III

Certain information required by PART III is omitted from this Annual Report on From 10-K because the Company will file a Definitive Proxy Statement with the Securities and Exchange Commission within 120 days after the end of our year ended December 31, 2015.

Item 10. ***Directors, Executive Officers and Corporate Governance***

The information required by this item is incorporated herein by reference to the Proxy Statement.

Item 11. ***Executive Compensation***

The information required by this item is incorporated herein by reference to the Proxy Statement.

Item 12. ***Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters***

The information required by this item is incorporated herein by reference to the Proxy Statement.

Item 13. ***Certain Relationships and Related Transactions, and Director Independence***

The information required by this item is incorporated herein by reference to the Proxy Statement.

Item 14. ***Principal Accounting Fees and Services***

The information required by this item is incorporated herein by reference to the Proxy Statement.

PART IV

Item 15. ***Exhibits and Financial Statement Schedules***

(a) (1) The financial statements required by Item 15(a) are filed in Item 8 of this Annual Report on Form 10-K.

(2) The financial statement schedules required by Item 15(a) are omitted because they are not applicable, not required or the required information is included in the financial statements or notes thereto as filed in Item 8 of this Annual Report on Form 10-K.

(3) We have filed, or incorporated into this report by reference, the exhibits listed on the accompanying Index to Exhibits immediately following the signature page of this Annual Report on Form 10-K.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) the Securities Exchange Act of 1934, the registrant has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized.

COHERUS BIOSCIENCES, INC.

Date: February 29, 2016

By: /s/ Dennis M. Lanfear
Name: Dennis M. Lanfear
Title: President and Chief Executive Officer
(Principal Executive Officer)

POWER OF ATTORNEY

KNOW ALL MEN AND WOMEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Dennis M Lanfear and Jean-Frédéric Viret, his attorneys-in-fact, for him or her in any and all capacities, to sign any amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the U.S. Securities and Exchange Commission, hereby ratifying and confirming all that said attorney-in-fact, or his substitute, may do or cause to be done by virtue thereof.

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.

/s/ Dennis M. Lanfear Dennis M. Lanfear	Chairman, President and Chief Executive Officer *(Principal Executive Officer)*	February 29, 2016
/s/ Jean-Frédéric Viret, Ph.D. Jean-Frédéric Viret, Ph.D.	Chief Financial Officer *(Principal Financial and Accounting Officer)*	February 29, 2016
/s/ James I. Healy, M.D., Ph.D. James I. Healy, M.D., Ph.D.	Director	February 29, 2016
/s/ V. Bryan Lawlis, Ph.D. V. Bryan Lawlis, Ph.D.	Director	February 29, 2016
/s/ Christos Richards Christos Richards	Director	February 29, 2016
/s/ Ali J. Satvat Ali J. Satvat	Director	February 29, 2016
/s/ August J. Troendle, M.D. August J. Troendle, M.D.	Director	February 29, 2016
/s/ Mats Wahlström Mats Wahlström	Director	February 29, 2016
/s/ Mary T. Szela Mary T. Szela	Director	February 29, 2016

INDEX TO EXHIBITS

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
3.1	Amended and Restated Certificate of Incorporation.	8-K	11/12/2014	3.1	
3.2	Amended and Restated Bylaws.	8-K	11/12/2014	3.2	
4.1	Reference is made to exhibits 3.1 and 3.2.				
4.2	Registration Rights Agreement, dated as of September 10, 2015, by and between Baxalta GmbH and Coherus BioSciences, Inc.	8-K	9/14/2015	4.1	
4.3	Form of Common Stock Certificate.	S-1/A	10/24/2014	4.2	
4.4	Third Amended and Restated Investor Rights Agreement, dated as of May 9, 2014 by and among Coherus BioSciences, Inc. and certain investors named therein.	S-1	9/25/2014	4.3	
10.1†	License Agreement, effective January 23, 2012, by and between Daiichi Sankyo Company, Limited and BioGenerics, Inc.	S-1/A	10/20/2014	10.1	
10.2(a)†	License Agreement, effective August 30, 2013, by and among Baxter International Inc., Baxter Healthcare Corporation, and Baxter Healthcare SA and Coherus BioSciences, Inc.	S-1/A	10/20/2014	10.2(a)	
10.2(b)†	First Amendment to License Agreement, effective February 7, 2014, by and among Baxter International Inc., Baxter Healthcare Corporation, and Baxter Healthcare SA and Coherus BioSciences, Inc.	S-1	9/25/2014	10.2(b)	
10.3†	Distribution Agreement, effective December 26, 2012, by and between Orox Pharmaceuticals B.V. and Coherus BioSciences, Inc.	S-1	9/25/2014	10.3	
10.4†	Non-Exclusive License Agreement, effective July 10, 2013, by and between Genentech, Inc. and Coherus BioSciences, Inc.	S-1	9/25/2014	10.4	
10.5†	Commercial License Agreement, effective April 8, 2011, by and between Selexis SA and BioGenerics, Inc.	S-1	9/25/2014	10.5	
10.6†	Commercial License Agreement, effective June 25, 2012, by and between Selexis SA and Coherus BioSciences, Inc.	S-1	9/25/2014	10.6	
10.7	Agreement and Plan of Merger, dated January 8, 2014, by and among Coherus BioSciences, Inc., Coherus Intermediate Corp., Coherus Acquisition Corp., InteKrin Therapeutics Inc., and Fortis Advisors LLC.	S-1	9/25/2014	10.7	
10.8(a)	Office Lease, effective September 26, 2011, by and between CA-Towers at Shores Center Limited Partnership and BioGenerics, Inc.	S-1	9/25/2014	10.8(a)	
10.8(b)	First Amendment to the Office Lease, effective May 17, 2012, by and between CA-Towers at Shores Center Limited Partnership and Coherus BioSciences, Inc.	S-1	9/25/2014	10.8(b)	
10.8(c)	Second Amendment to the Office Lease, effective September 11, 2013, by and between CA-Towers at Shores Center Limited Partnership and Coherus BioSciences, Inc.	S-1	9/25/2014	10.8(c)	
10.8(d)	Third Amendment to the Office Lease, effective February 4, 2014, by and between CA-Towers at Shores Center Limited Partnership and Coherus BioSciences, Inc.	S-1	9/25/2014	10.8(d)	
10.8(e)	Fourth Amendment to the Office Lease, effective May 1, 2014, by and between CA-Towers at Shores Center Limited Partnership and Coherus BioSciences, Inc.	S-1	9/25/2014	10.8(e)	

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
10.8(f)	Fifth Amendment to the Office Lease, effective December 10, 2014, by and between CA-Towers at Shores Center Limited Partnership and Coherus BioSciences, Inc.	8-K	12/11/2014	10.1	
10.9(a)	Standard Industrial/Commercial Multi-tenant Lease-Gross, effective December 5, 2011, by and between Howard California Property Camarillo 5 and BioGenerics, Inc.	S-1	9/25/2014	10.9(a)	
10.9(b)	First Amendment to Lease, effective December 21, 2013, by and between Howard California Property Camarillo 5 and Coherus BioSciences, Inc.	S-1	9/25/2014	10.9(b)	
10.10(a)#	BioGenerics, Inc. 2010 Equity Incentive Plan, as amended.	S-1	9/25/2014	10.10(a)	
10.10(b)#	Form of Stock Option Grant Notice and Stock Option Agreement under the 2010 Equity Incentive Plan, as amended.	S-1	9/25/2014	10.10(b)	
10.11(a)#	Coherus BioSciences, Inc. 2014 Equity Incentive Award Plan.	S-1/A	10/24/2014	10.11	
10.11(b)#	Form of Stock Option Grant Notice and Stock Option Agreement under the 2014 Equity Incentive Award Plan.	S-1/A	11/4/2014	10.11(b)	
10.11(c)#	Form of Restricted Stock Award Grant Notice and Restricted Stock Award Agreement under the 2014 Equity Incentive Award Plan.	S-1/A	11/4/2014	10.11(c)	
10.11(d)#	Form of Restricted Stock Unit Award Grant Notice and Restricted Stock Unit Award Agreement under the 2014 Equity Incentive Award Plan.	S-1/A	11/4/2014	10.11(d)	
10.12#	Coherus BioSciences, Inc. 2014 Employee Stock Purchase Plan.	S-1/A	10/24/2014	10.12	
10.13#	Form of Indemnification Agreement between Coherus BioSciences, Inc. and each of its directors, officers and certain employees.	S-1/A	10/24/2014	10.13	
10.14#	Separation Agreement, effective June 30, 2014, by and between Stephen C. Glover and Coherus BioSciences, Inc.	S-1	9/25/2014	10.14	
10.15†	Master Services Agreement, effective January 23, 2012, by and between Medpace, Inc. and BioGenerics, Inc.	S-1	9/25/2014	10.15	
10.16(a)†	Task Order Number 13, effective October 18, 2013, by and between Medpace, Inc. and Coherus BioSciences, Inc.	S-1	9/25/2014	10.16(a)	
10.16(b)†	Amendment Number 1 to Task Order Number 13, effective April 23, 2014, by and between Medpace, Inc. and Coherus BioSciences, Inc.	S-1	9/25/2014	10.16(b)	
10.16(c)†	Amendment Number 2 to Task Order Number 13, effective May 21, 2014, by and between Medpace, Inc. and Coherus BioSciences, Inc.	S-1	9/25/2014	10.16(c)	
10.16(d)†	Amendment Number 3 to Task Order Number 13, effective May 30, 2014, by and between Medpace, Inc. and Coherus BioSciences, Inc.	S-1	9/25/2014	10.16(d)	
10.16(e)†	Amendment Number 4 to Task Order Number 13, effective August 19, 2014, by and between Medpace, Inc. and Coherus BioSciences, Inc.	S-1	9/25/2014	10.16(e)	
10.17(a)†	Task Order Number 20, effective November 8, 2013, by and between Medpace, Inc. and Coherus BioSciences, Inc.	S-1/A	10/24/2014	10.17(a)	
10.17(b)†	Amendment Number 1 to Task Order Number 20, effective April 23, 2014, by and between Medpace, Inc. and Coherus BioSciences, Inc.	S-1/A	10/24/2014	10.17(b)	
10.17(c)†	Amendment Number 2 to Task Order Number 20, effective June 27, 2014, by and between Medpace, Inc. and Coherus BioSciences, Inc.	S-1/A	10/24/2014	10.17(c)	
10.17(d)†	Amendment Number 3 to Task Order Number 20, effective September 5, 2014, by and between Medpace, Inc. and Coherus BioSciences, Inc.	S-1/A	10/24/2014	10.17(d)	

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
10.18†	Amended and Restated License Agreement, effective April 10, 2015, by and among Baxter International Inc., Baxter Healthcare Corporation, and Baxter Healthcare SA and Coherus BioSciences, Inc.	10-Q	5/11/2015	10.1	
10.19(a)†	Master Services Agreement, effective February 27, 2015, by and between a contract research organization and Coherus BioSciences, Inc.	10-Q	5/11/2015	10.2(a)	
10.19(b)†	Work Order #1, effective March 31, 2015, by and between a contract research organization and Coherus BioSciences, Inc.	10-Q	5/11/2015	10.2(b)	
10.20	Task Order Number 23, effective November 12, 2014, by and between Medpace, Inc. and Coherus BioSciences, Inc.	10-Q	8/10/2015	10.1	
10.21	Seventh Amendment to the Office Lease, effective July 6, 2015 by and between Hudson Towers at Shore Center, LLC, successor in interest to CA-Towers at Shores Center Limited Partnership, and Coherus BioSciences, Inc.	10-Q	8/10/2015	10.2	
10.22	New Office Lease, effective July 6, 2015, by and between Hudson 333 Twin Dolphin Plaza, LLC and Coherus BioSciences, Inc.	10-Q	8/10/2015	10.3	
10.23	First Amendment, effective August 10, 2015, by and between Hudson 333 Twin Dolphin Plaza, LLC and Coherus BioSciences, Inc.	10-Q	8/10/2015	10.4	
10.24	Stock Purchase Agreement dated as of September 10, 2015 by and among Baxalta Incorporated, Baxalta US Inc. and Baxalta GmbH and Coherus BioSciences, Inc.	8-K	9/14/2015	10.1	
23.1	Consent of Independent Registered Public Accounting Firm				X
31.1	Certification of Principal Executive Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.				X
31.2	Certification of Principal Financial Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.				X
32.1	Certification of Principal Executive Officer and Principal Financial Officer Required Under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C §1350.				X
101.INS*	XBRL Instance Document				X
101.SCH*	XBRL Taxonomy Extension Schema Document				X
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document				X
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document				X
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document				X
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document				X

† Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment and this exhibit has been filed separately with the SEC.

# Indicates management contract or compensatory plan.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statement (Form S-3 No. 333-208625) of Coherus BioSciences, Inc. and in the related Prospectus for the registration of common stock, preferred stock, debt securities and warrants and in the Registration Statement (Form S-8 No. 333-200593) pertaining to the BioGenerics, Inc. 2010 Equity Incentive Plan, as amended, the Coherus BioSciences, Inc. 2014 Equity Incentive Award Plan, and the Coherus BioSciences, Inc. 2014 Employee Stock Purchase Plan of Coherus BioSciences, Inc. of our reports dated February 29, 2016, with respect to the consolidated financial statements of Coherus BioSciences, Inc., and the effectiveness of internal control over financial reporting of Coherus BioSciences, Inc., included in this Annual Report (Form 10-K) for the year ended December 31, 2015.

/s/ERNST & YOUNG LLP

Redwood City, California
February 29, 2016

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO
SECTION 13(a) OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Dennis M. Lanfear, certify that:

1. I have reviewed this Annual Report on Form 10-K of Coherus BioSciences, Inc. (the "registrant"); and

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

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

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

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

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

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

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

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

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

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

Date: February 29, 2016

/s/ Dennis M. Lanfear
Dennis M. Lanfear
President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO
SECTION 13(a) OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jean-Frédéric Viret, certify that:

1. I have reviewed this Annual Report on Form 10-K of Coherus BioSciences, Inc. (the "registrant"); and

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

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

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

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

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

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

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

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

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

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

Date: February 29, 2016

/s/ Jean-Frédéric Viret
Jean-Frédéric Viret, Ph.D.
Chief Financial Officer

Exhibit 32.1

CERTIFICATIONS OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officers of Coherus BioSciences, Inc. (the "Registrant") certify that the Annual Report of Coherus BioSciences, Inc. on Form 10-K for the year ended December 31, 2015 (the "Report") fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended, and that information contained in the Report fairly presents in all material respects the financial condition and results of operations of the Registrant.

Date: February 29, 2016

By: /s/ Dennis M. Lanfear
Name: Dennis M. Lanfear
Title: President and Chief Executive Officer

Date: February 29, 2016

By: /s/ Jean-Frédéric Viret
Name: Jean-Frédéric Viret
Title: Chief Financial Officer

A signed original of this written statement required by Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350 has been provided to the Registrant and will be retained by the Registrant and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.