

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

**FORM S-1**

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

**COHERUS BIOSCIENCES, INC.**

*(Exact name of Registrant as specified in its charter)*

**Delaware**  
*(State or other jurisdiction of  
incorporation or organization)*

**2836**  
*(Primary Standard Industrial  
Classification Code Number)*

**27-3615821**  
*(I.R.S. Employer  
Identification Number)*

**201 Redwood Shores Parkway, Suite 200  
Redwood City, CA 94065  
(650) 649-3530**

*(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)*

**Dennis M. Lanfear  
President and Chief Executive Officer  
Coherus BioSciences, Inc.**

**201 Redwood Shores Parkway, Suite 200  
Redwood City, CA 94065  
(650) 649-3530**

*(Name, address, including zip code, and telephone number, including area code, of agent for service)*

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**Approximate date of commencement of proposed sale to the public:**

As soon as practicable after the effective date of this Registration Statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

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

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

(Do not check if a smaller reporting company)

**CALCULATION OF REGISTRATION FEE**

Title of securities to be registered	Proposed maximum aggregate offering price <sup>(1)(2)</sup>	Amount of registration fee
Common stock, \$0.0001 par value per share	\$115,000,000	\$13,363

(1) Includes \$15,000,000 of shares of common stock that may be purchased by the underwriters pursuant to an option to purchase additional shares.

(2) Estimated solely for the purpose of computing the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended, on the basis of the maximum aggregate offering price.

**The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.**

The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

Subject to completion, dated March 23, 2015

**\$100,000,000**



## Common Stock

We are offering \$100,000,000 of shares of our common stock. Our common stock is listed on The NASDAQ Global Market under the symbol "CHRS." At an assumed offering price of \$ \_\_\_\_\_, the last reported sale price of our common stock on \_\_\_\_\_, 2015, we would be offering \_\_\_\_\_ shares of our common stock.

We are an emerging growth company under the federal securities laws and are subject to reduced public company reporting requirements.

Investing in our common stock involves a high degree of risk. See "[Risk Factors](#)" beginning on page 11.

	<u>Per Share</u>	<u>Total</u>
Public offering price	\$ _____	\$ _____
Underwriting discounts and commissions <sup>(1)</sup>	\$ _____	\$ _____
Proceeds, before expenses, to us	\$ _____	\$ _____

(1) See "Underwriting" for additional disclosure regarding underwriting discounts, commissions and estimated offering expenses.

We intend to grant the underwriters the option to purchase up to an additional \$15,000,000 of shares of our common stock from us at the public offering price less underwriting discounts and commissions. The underwriters can exercise this option at any time within 30 days after the date of this prospectus.

The underwriters expect to deliver the shares of common stock to investors on \_\_\_\_\_, 2015.

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

**J.P. Morgan**

**Credit Suisse**

**Cowen and Company**

, 2015

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Neither we nor the underwriters have authorized anyone to provide you with information that is different from that contained in this prospectus, the documents incorporated by reference herein or in any free writing prospectus we may authorize to be delivered or made available to you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We and the underwriters are offering to sell shares of common stock and seeking offers to buy shares of common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus and the documents incorporated by reference herein is accurate only as of the date on the front of this prospectus, or such documents, as applicable, regardless of the time of delivery of this prospectus, such documents or any sale of shares of our common stock.

Coherus BioSciences® and our logo are some of our trademarks used in this prospectus. This prospectus and the documents incorporated by reference herein also include trademarks, tradenames and service marks that are the property of other organizations. Solely for convenience, our trademarks and tradenames referred to in this prospectus appear without the ® and ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the right of the applicable licensor to these trademarks and tradenames.

**PROSPECTUS SUMMARY**

The items in the following summary are described in more detail later in this prospectus. This summary provides an overview of selected information and does not contain all of the information you should consider before buying our common stock. Therefore, you should read the entire prospectus carefully, especially the “Risk Factors” section beginning on page 11 and our consolidated financial statements and the related notes appearing at the end of this prospectus, before deciding to invest in our common stock. In this prospectus, unless the context otherwise requires, references to “we,” “us,” “our,” “Coherus,” or “Coherus BioSciences,” refer to Coherus BioSciences, Inc. and its subsidiaries.

**Our Company**

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 one product candidate into Phase 3 clinical development, two others into or through Phase 1 clinical development and entered into partnerships with two global pharmaceutical companies.

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

Candidate	Originator Product	Originator Approved Indications	Pre-clinical	Phase 1	Phase 3 / BLA-enabling	Status / Anticipated Milestones	Coherus Commercial Rights
<b>Anti-TNF Pipeline</b>							
CHS - 0214	etanercept (Enbrel)	Ankylosing Spondylitis Juvenile Idiopathic Arthritis Psoriasis (PsO) Psoriatic Arthritis Rheumatoid Arthritis (RA)		→		Phase 3 clinical trials in RA and in PsO in progress / File MAA in E.U. in 2016	US only <sup>1</sup>
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 / Initiate PK bioequivalence bridging study in 2015 with Phase 3 drug material / Initiate Phase 3 clinical study in PsO in 2015 / File BLA in U.S. in 2016	Worldwide
<b>Long Acting G-CSF Pipeline</b>							
CHS-1701	pegfilgrastim (Neulasta)	Febrile neutropenia		→		Phase 1 (351 (a)) completed / Initiated pivotal PK/PD BLA-enabling trial / Initiate immunogenicity and safety study in 2 <sup>nd</sup> quarter 2015 / Expect to file 351 (k) BLA 4 <sup>th</sup> quarter 2015 or 1 <sup>st</sup> quarter 2016	Worldwide

<sup>1</sup> Assuming validity and enforceability, certain originator-controlled patents may preclude commercialization of CHS-0214 in the United States until 2029.

Our clinical stage pipeline consists of two anti-inflammatory agents targeting tumor necrosis factor, or TNF, and a long-acting form of granulocyte colony-stimulating factor, or G-CSF. Our most clinically advanced anti-TNF product candidate, CHS-0214, is being developed as an etanercept (Enbrel) biosimilar that we have partnered with Baxter International Inc., Baxter Healthcare Corporation and Baxter Healthcare SA and Daiichi Sankyo Company, Limited to develop and commercialize in key markets outside of the United States. We are currently enrolling two Phase 3 clinical trials with CHS-0214 to support the planned filing of a marketing application in Europe in 2016. 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 study endpoint. We plan to initiate a Phase 3 trial during the first half of 2015 to support the planned filing of a marketing application in the United States in 2016 and the European Union, or E.U., in 2017. Our long-acting G-CSF product candidate, CHS-1701, is being developed as a pegfilgrastim (Neulasta) biosimilar. On October 9, 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) pathway. We believe the 351(k) (biosimilar) approval pathway may enable us to file for U.S. regulatory approval for CHS-1701 in the 4th quarter of 2015 or 1st quarter of 2016, approximately 6 to 12 months earlier than we project under a 351(a) (novel biologic) 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-1701 in the United States, which, if positive, we believe will support the planned filing of a biologics license application, or BLA, in the United States. An additional immunogenicity study is planned in healthy volunteers pursuant to this BLA and is projected to conclude in 2015. 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. We have retained full U.S. commercial rights to all of our product candidates and plan to seek strategic partnerships in territories outside of the United States.

Our team includes industry veterans with decades of experience in pioneering biologics companies, such as Amgen Inc., or Amgen, and Genentech Inc., or 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. 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. 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.

#### **Background on Biosimilars**

The global market opportunity for biosimilars is emerging as a result of several factors. Through 2020, 31 "blockbuster" biologics, each with annual sales in excess of \$1 billion, face loss of patent exclusivity in at least one major pharmaceutical market. In response, regulatory agencies around the world have begun to define new approval pathways which we believe will help streamline the biosimilar approval process. Escalating healthcare costs and healthcare reforms have also been major drivers of the advancement of the biosimilar market, as governments and insurers are in search of mechanisms to contain costs and expand patient access without sacrificing quality of care. Consequently, we believe there is tremendous interest in bringing high-quality, lower-priced biologic therapeutics to market.

While the potential market opportunity is significant, biosimilar product development poses a number of challenges that distinguish it from traditional, small-molecule generic product development. Heterogeneity arising from the physicochemical complexity of biologic therapeutics creates significant technical and scientific challenges in the context of their replication as biosimilar products. An example of such variability is related to

glycosylation, or the attachment of sugars at certain amino acids, which can be critical to the half-life, efficacy and safety of the therapeutic. Accordingly, heterogeneity and inherent variation is a fundamental consideration with respect to establishing biosimilarity to an originator product to support regulatory approval.

### Our Approach

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. We have invested a substantial part of our capital budget in this area.
- **Molecular tuning to achieve biosimilarity.** Accurately reproducing the glycosylation pattern of the originator protein is particularly critical to successful development of a biosimilar, as this profile can substantially impact pharmacokinetics and biologic activity. By conducting a number of critical steps in a parallel fashion, we have been able to complete this process for our etanercept (Enbrel) biosimilar product candidate in an extremely short period of time while achieving a high degree of biosimilarity. The same parallel process has been applied to our other biosimilar product candidates.
- **Process science.** We 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 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 protein's ability to maintain its 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 innovator products. We and our global partners have met with competent authorities in the United States, the E.U. and Japan and have gained deep insight into the regulatory rationale and nuanced approach required to successfully navigate global requirements.

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 approval of our product candidates. We have had meetings with regulatory agencies in several of the major regulated markets to discuss our three most advanced product candidates and the data that will be required to support marketing approval. The outcomes of these discussions have informed our clinical designs, product development and regulatory strategies.

## Development Portfolio

### *Anti-TNF pipeline: CHS-0214 and CHS-1420*

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. 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. Our anti-TNF product candidates, CHS-0214 and CHS-1420, are based on two of the leading products in this category, etanercept (Enbrel) and adalimumab (Humira), respectively. We selected these originator products as biosimilar development targets for the following reasons:

- *Large market opportunity.* Global sales of Enbrel and Humira are projected to exceed \$24 billion in 2017, representing over 60% of the combined estimated global sales in the anti-TNF monoclonal antibody and TNF inhibitor markets in 2017. Approximately \$19 billion of this estimated market is in territories in which we or our partners currently intend to commercialize our anti-TNF products.
- *Receptivity to biosimilars.* Because anti-TNF agents are typically used to treat diseases where there is a 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.
- *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 many major markets offers us a near-term opportunity to introduce biosimilar competitors in these markets. 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:* Etanercept (Enbrel), the reference product for CHS-0214, is a complex fusion protein that links the protein for tumor necrosis factor receptor 2, or TNFR-2, to the immunoglobulin Fc fragment protein, or IgG1 Fc. We announced the dosing of the first patient in our Phase 3 rheumatoid arthritis clinical trial in June 2014, and in July 2014 initiated a separate Phase 3 clinical trial in psoriasis. The design of each Phase 3 clinical trial reflects guidance from regulatory agencies regarding key study parameters. If data are positive, we expect to file a marketing application for CHS-0214 with the European Medicines Agency, or EMA, and with the Japanese Pharmaceutical and Medical Devices Agency, or PMDA, in 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 of the indications included in the label for Enbrel.

*CHS-1420:* Adalimumab (Humira), the reference product for CHS-1420, is a fully humanized monoclonal antibody that binds TNF and interferes with its binding to receptors on the cell surface. Monoclonal antibodies are identical antibodies that have an affinity for the same antigen and are produced by a specific clone or cell line. We have completed a pivotal Phase 1 pharmacokinetics, or PK, and pharmacodynamics, or PD, study comparing CHS-1420 to Humira in healthy volunteers, and the trial met the primary endpoint demonstrating PK similarity of CHS-1420 to Humira. We plan to initiate a Phase 3 clinical trial in the first half of 2015 to support the expected filing of a Biologics License Application, or BLA, in the United States in 2016 and the expected filing of a marketing application in the E.U. in 2017. We are in the process of reaching concurrence with regulatory authorities in the United States, Europe and Japan with the objective of designing a harmonized global Phase 3 clinical trial program to support registration in these territories. 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-1420 in all the indications included in the label for Humira.

On October 29, 2014, as part of our quality process and upon routine visual inspection during storage, four syringes containing CHS-0214 from a production lot (Lot 5) in use in the ongoing 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 the follow-on production lot (Lot 6). None of the approximately 8,000 unlabeled syringes inspected exhibited any such particulate.

We also reviewed our clinical trials for injection site reactions reported directly by patients and observed by staff, since particulates in subcutaneously injected drug may cause injection site reactions. We found these to be no more frequent or worse in intensity than those normally reported for Enbrel (i.e., mild to moderate intensity and resolving without medical intervention over hours to days). We also reviewed the adverse events reported in the ongoing clinical trials and found that no serious or significant adverse events have been reported in either clinical trial.

However, in the interest of patient safety we immediately stopped dosing of the ongoing Phase 3 clinical trials and initiated an investigation to determine the cause and incidence of the observed particulate. A chemical analysis of the particulate impurity by an independent laboratory subsequently determined that the particles found in the four syringes were not the result of any instability in the CHS-0214 protein product or its formulation. We have concluded that the particulate impurity is most likely a result of a non-recurring anomaly related to first use of new process equipment with Lot 5. The dosing of the Phase 3 clinical trials resumed in November 2014 for the rheumatoid arthritis trial and in December 2014 for the psoriasis trial.

#### ***Long-acting G-CSF pipeline: CHS-1701***

G-CSF is a protein that promotes the survival, proliferation (an increase in the number of cells due to cell growth and cell division) and differentiation of certain types of white blood cells known as neutrophils. Recombinant G-CSF therapies, such as filgrastim (Neupogen) and pegfilgrastim (Neulasta), are commonly used in the prevention of chemotherapy-induced neutropenia in cancer, which is characterized by an abnormally low level of neutrophils and other white blood cells that aid in the defense against infections. We selected pegfilgrastim (Neulasta) as the development target for our biosimilar G-CSF product candidate for the following reasons:

- *Large market opportunity.* The combined opportunity for both short- and long-acting G-CSF therapies worldwide is estimated to exceed \$5 billion in 2017, and pegfilgrastim therapies are expected to capture over 70% of the worldwide G-CSF market. It is estimated that the worldwide opportunity for Neulasta, the reference product for CHS-1701, will exceed \$3.9 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 a 52% share of the short-acting G-CSF market and a 77% share of the filgrastim market by the third quarter of 2013.
- *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 February 2018.

Under the 351(a) (novel biologic) pathway, we have successfully advanced CHS-1701 through completion of a Phase 1 PK / PD study in healthy volunteers. However, on October 9, 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) 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 in the United States, which, if positive, we believe will support the planned filing of a BLA in the United States. An additional immunogenicity study is planned in healthy volunteers pursuant to this BLA and is projected to be concluded in 2015.

### **Our Strategy**

Our goal is to become a leading global biosimilar company. The five 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;
- advance our lead programs through clinical development to secure approvals in major markets;
- continue to advance our early-stage product pipeline;
- maximize the value of our portfolio and pipeline by retaining commercial rights to our products in the United States and by selectively partnering with leading pharmaceutical companies to commercialize our products in other geographies; and
- attract and retain exceptionally capable team members who share our vision of bringing high quality, lower cost biologic therapeutics to patients.

### **Risks Associated with Our Business**

Our business is subject to the risks and uncertainties discussed more fully in the section entitled “Risk Factors” immediately following this summary. These risks include, among others:

- 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.
- Even if this offering is successful, we expect that we will need to raise substantial additional funding. This additional financing 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 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.
- The development, manufacture and commercialization of biosimilar products under various global regulatory pathways pose unique risks. Regulations for biosimilar approval differ across jurisdictions such that we may obtain approval in some jurisdictions, and not in others. The evolving legal and regulatory climate for biosimilars in the U.S. and abroad could result in legislative or regulatory requirements that could restrict our ability to commercialize our products. Even if our biosimilar products are approved, they may not be approved for all of the indications of the originator drug and the extent to which they will achieve marketplace acceptance in terms of quality, safety and efficacy is unclear.
- 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.

- 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.
- 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.
- Our ability to market our products in the United States may be significantly delayed or prevented by the patent dispute mechanism established under the Biologics Price Competition and Innovation Act of 2009. This mechanism requires us to disclose our biosimilar regulatory approval application to the originator. As a result of such disclosure, the originator could initiate patent infringement litigation against us which may delay or block our ability to commercialize our products.

### **Corporate Information**

We were incorporated in the State of Delaware in September 2010 under the name BioGenerics, Inc. We subsequently changed the name of the corporation to Coherus BioSciences, Inc. in April 2012. Our principal executive offices are located at 201 Redwood Shores Parkway, Suite 200, Redwood City, California 94065, and our telephone number is (650) 649-3530. Our website address is <http://www.coherus.com>. The information contained in or that can be accessed through our website is not part of this prospectus.

We are an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our initial public offering, which was completed on November 12, 2014, (b) in which we have total annual gross revenue of at least \$1.0 billion or (c) in which we are deemed to be a large accelerated filer (this means the market value of our common stock that is held by non-affiliates exceeds \$700 million as of the end of the second quarter of that fiscal year), or (2) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period. An emerging growth company may take advantage of specified reduced reporting requirements and is relieved of certain other significant requirements that are otherwise generally applicable to public companies. As an emerging growth company:

- we have availed ourselves of the exemption from the requirement to obtain an attestation and report from our auditors on the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002;
- we will provide less extensive disclosure about our executive compensation arrangements; and
- we will not require shareholder non-binding advisory votes on executive compensation or golden parachute arrangements.

However, we have irrevocably elected to “opt out” of the extended transition periods available under the JOBS Act for complying with new or revised accounting standards.

**THE OFFERING**

Issuer	Coherus BioSciences, Inc.
Common stock we are offering	\$100,000,000 of shares of common stock
Common stock to be outstanding after the offering	shares
Underwriters' option to purchase additional shares	Up to \$15,000,000 of shares of common stock
Use of proceeds	We expect to use the substantial majority of the net proceeds from this offering to fund the development through regulatory submission of one biosimilar currently in the pre-clinical stage, as well as the proof-of-concept Phase 2 study of INT-131, and the remainder for working capital and other corporate purposes. See "Use of Proceeds" on page 62 for a more complete description of the intended use of proceeds from this offering.
Risk factors	See "Risk Factors" beginning on page 11 and other information included in this prospectus for a discussion of factors that you should consider carefully before deciding to invest in our common stock.
Symbol on The NASDAQ Global Market	"CHRS"

The number of shares of common stock to be outstanding after this offering is based on 33,257,978 shares of common stock outstanding as of December 31, 2014, and assumes the sale of \$100.0 million of shares of common stock at an assumed offering price of \$ per share, the last reported sale price of our common stock on The NASDAQ Global Market on , 2015, and excludes the following:

- 5,560,345 shares of common stock issuable upon the exercise of outstanding stock options under our 2010 Equity Incentive Plan, as amended, as of December 31, 2014 having a weighted-average exercise price of \$2.46 per share;
- 209,962 shares of common stock issuable upon the exercise of outstanding stock options under our 2014 Equity Incentive Award Plan as of December 31, 2014 having a weighted-average exercise price of \$14.69 per share;
- 2,652,500 shares of common stock reserved for issuance pursuant to future awards under our 2014 Equity Incentive Award Plan, as well as any future increases in the number of shares of our common stock reserved for future issuance under this plan; and
- 320,000 shares of common stock reserved for future issuance under our 2014 Employee Stock Purchase Plan, as well as any future increases in the number of shares of our common stock reserved for future issuance under this plan.

Unless otherwise indicated, the number of shares of our common stock described above assumes no exercise of the underwriters' option to purchase additional shares.

**SUMMARY CONSOLIDATED FINANCIAL DATA**

The following tables set forth a summary of our consolidated financial data as of, and for the period ended on, the dates indicated. The consolidated statement of operations data for the years ended December 31, 2012, 2013 and 2014, as well as the consolidated balance sheet data as of December 31, 2014, are derived from our audited consolidated financial statements incorporated by reference in this prospectus from our Annual Report on Form 10-K for the fiscal year ended December 31, 2014. You should read this data together with our audited consolidated financial statements and related notes, as well as the information under the captions “Selected Financial Data” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2014 and incorporated by reference herein. Our historical results are not necessarily indicative of our future results.

	<u>Year Ended December 31,</u>		
	<u>2012</u>	<u>2013</u>	<u>2014</u>
<b>(in thousands, except share and per share data)</b>			
<b>Consolidated Statement of Operations Data:</b>			
Revenue:			
Collaboration and license revenue — related party <sup>(1)</sup>	\$ 1,899	\$ 2,025	\$ 1,893
Collaboration and license revenue	—	726	28,481
Other revenue	—	—	732
Total revenue	<u>1,899</u>	<u>2,751</u>	<u>31,106</u>
Operating expenses:			
Research and development <sup>(2)</sup>	34,886	31,279	78,224
General and administrative <sup>(2)</sup>	5,531	7,465	17,564
Total operating expenses	<u>40,417</u>	<u>38,744</u>	<u>95,788</u>
Loss from operations	<u>(38,518)</u>	<u>(35,993)</u>	<u>(64,682)</u>
Interest expense	(1,514)	(5,293)	(3,900)
Other income (expense), net	7,014	(12,349)	(18,595)
Net loss	<u>(33,018)</u>	<u>(53,635)</u>	<u>(87,177)</u>
Net loss attributable to non-controlling interest	—	—	44
Net loss attributable to Coherus	<u>\$ (33,018)</u>	<u>\$ (53,635)</u>	<u>\$ (87,133)</u>
Net loss per share attributable to Coherus, basic and diluted <sup>(3)</sup>	<u>\$ (15.85)</u>	<u>\$ (16.10)</u>	<u>\$ (10.64)</u>
Weighted-average number of shares used in computing net loss per share attributable to Coherus, basic and diluted <sup>(3)</sup>	<u>2,082,622</u>	<u>3,332,020</u>	<u>8,186,529</u>

- (1) Represents revenue from Daiichi Sankyo Company, Limited, a holder of more than 10% of our common stock for the period presented until the closing of our IPO on November 12, 2014.  
(2) Includes stock-based compensation expense as follows:  
(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.

	<u>Year Ended December 31,</u>		
	<u>2012</u>	<u>2013</u>	<u>2014</u>
Research and development	\$268	\$ 682	\$ 5,625
General and administrative	175	1,363	5,437
Total stock-based compensation expense	<u>\$443</u>	<u>\$2,045</u>	<u>\$11,062</u>

The table below presents our balance sheet data as of December 31, 2014:

- on an actual basis; and

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- on an as adjusted basis to give effect to (i) the reclassification of our contingent consideration liability to stockholders' equity upon the issuance of 358,384 shares of common stock to former InteKrin stockholders to satisfy a contingent consideration obligation upon the achievement of the first dosing of a human subject in the phase 2 clinical trial for INT 131 on March 6, 2015; and (ii) the sale of \$100,000,000 of shares of common stock in this offering based on an assumed public offering price of \$ per share, the last reported sale price of our common stock on The NASDAQ Global Market on , 2015 and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

	December 31, 2014	
	Actual	As Adjusted <sup>(1)</sup> (unaudited)
<b>Consolidated Balance Sheet Data:</b>		
Cash and cash equivalents	\$ 150,392	\$
Working capital	127,353	
Total assets	187,221	
Contingent consideration	5,710	
Accumulated deficit	(186,725)	
Total stockholders' equity	66,757	

- (1) Each \$1.00 increase (decrease) in the assumed public offering price of \$ per share, the last reported sale price of our common stock on The NASDAQ Global Market on , 2015, would increase (decrease) the number of shares of common stock to be issued by us in this offering by , assuming the aggregate dollar amount of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the aggregate dollar amount of shares we are offering. Each increase (decrease) of \$ million of shares offered by us would increase (decrease) the as adjusted amount of cash, working capital, total assets and total stockholders' equity by approximately \$ million, assuming that the assumed public offering price remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. The as adjusted information discussed above is illustrative only and will be adjusted based on the actual public offering price and other terms of this offering determined at pricing.

## RISK FACTORS

*Investing in our common stock involves a high degree of risk. Before investing in our common stock, you should consider carefully the risks described below, together with the other information contained in this prospectus or incorporated by reference in this prospectus. If any of the risks set forth below occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you may lose all or part of your investment.*

### **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 \$87.2 million and \$53.6 million for the years ended December 31, 2014 and 2013, respectively. As of December 31, 2014, we had an accumulated deficit of \$186.7 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 manufacture, 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 Baxter International, Inc., Baxter Healthcare Corporation and Baxter Healthcare SA, or together, Baxter, and Daiichi Sankyo Company, Limited, or Daiichi Sankyo. 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 clinical development with one of our lead products, CHS-0214 (our etanercept (Enbrel) biosimilar candidate). We are in earlier stages of clinical development with our other lead product candidates, namely CHS-1420 (our adalimumab (Humira) biosimilar candidate) and CHS-1701 (our pegfilgrastim (Neulasta) biosimilar candidate) for which we have not commenced Phase 3 clinical trials. It may be several years, if ever, before we complete Phase 3 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;

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- 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 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., Baxter 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;

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- 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.

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 lead products, namely CHS-0214, CHS-1420 and CHS-1701, 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.

***Even if this offering is successful, 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 our CHS-0214, CHS-1420 and CHS-1701 product candidates through clinical development. Developing our product candidates is expensive, and we expect our research and development expenses to increase substantially in connection with our ongoing activities, particularly as we advance our product candidates through late-stage clinical studies.

As of December 31, 2014, our cash and cash equivalents were \$150.4 million. We expect that our existing cash and cash equivalents, together with funding we expect to receive under our license agreements with Daiichi Sankyo and Baxter, will be sufficient to fund our current operations for the next 12 months; however, we expect that 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;



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- 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 business, 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-0214 has entered Phase 3 clinical development, and both CHS-1420 and CHS-1701 are expected to advance into a biologics license application, or BLA, enabling studies in 2015. CHS-0214 is our only product candidate that has advanced into a pivotal study. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates.

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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;

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- 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 lengthy 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. Moreover, 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.

In addition, if we change the regulatory pathway through which we intend to seek approval of any of our product candidates, we may have to conduct additional clinical trials, which may delay our ability to submit a marketing application for the product. Even if we or our collaboration partners were to obtain approval for any of our product candidates, regulatory agencies may limit the scope of such approval for fewer or more limited indications than we request, may grant approval contingent on the completion of costly additional clinical trials or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

***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 data 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. For example, a determination of biosimilarity for CHS-0214 will be based on our demonstration of its high similarity to Enbrel.

Although our Phase 1 PK / PD trial for CHS-1701 met its primary endpoint and was satisfactory for purposes of pursuing a 351(a) (novel biologic) approval pathway (which does not require bioequivalence to the originator drug), we believe the results of the trial are indicative of the challenges in developing biosimilar drugs insofar as the data from the trial did not establish bioequivalence to Neulasta sufficient to support a 351(k) (biosimilar) approval pathway. However, on October 9, 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) pathway. We believe the 351(k) (biosimilar) approval pathway may enable us to file for U.S. regulatory approval for CHS-1701 in the 4th quarter of 2015 or 1st quarter of 2016, approximately 6 to 12 months earlier than we project under a 351(a) (novel biologic) 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-1701 in the United States, which, if positive, we believe

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will support the planned filing of a BLA in the United States. An additional immunogenicity study is planned in healthy volunteers pursuant to this BLA and is projected to conclude in 2015. While we believe it may be possible to advance CHS-1701 to such 351(k) approval application without a collaboration or licensing partner, it remains uncertain whether execution of our development plan will result in data supporting our planned 351(k) approval application for CHS-1701.

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 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 (attachment of sugars to the protein) critical to therapeutic efficacy, 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.

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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. For example, results generated to date in clinical studies for our CHS-0214 product candidate do not ensure that later clinical studies will demonstrate similar positive results. 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. Moreover, nonclinical and clinical data are 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.

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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 process for CHS-0214 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;

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- 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, EMA, EEA Competent Authorities and other foreign regulatory agency 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, the EMA, EEA Competent Authorities or other 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 PHS Act. 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 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. For example, the FDA would not be able to grant approval of any application submitted for an etanercept (Enbrel) biosimilar, an adalimumab (Humira) biosimilar or a pegfilgrastim (Neulasta) biosimilar, until 12 years after the original BLAs for these drugs were approved, which occurred on September 12, 2002 in the case of Enbrel, December 31, 2002 in the case of Humira and January 31, 2002 in the case of Neulasta.

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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.

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 local (national) level on a country-by-country basis. 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.



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

We expect other companies to seek approval to manufacture and market biosimilar versions of Enbrel, Neulasta or Humira. If other biosimilars of Enbrel, Humira or Neulasta 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 etanercept (Enbrel), adalimumab (Humira) or pegfilgrastim (Neulasta) are determined to be interchangeable and our biosimilar 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

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etanercept (Enbrel) biosimilar product, CHS-0214 in Japan (through our licensee Daiichi Sankyo), Europe (through our licensee Baxter) and certain Latin American countries (through our licensee, Orox). We intend to market our pegfilgrastim (Neulasta) biosimilar product, CHS-1701 and our adalimumab (Humira) biosimilar in the United States without collaboration partners, and have not decided on whether to enter into collaborations for marketing of CHS-1701 or CHS-1420 outside the United States.

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.

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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.

***We may elect to seek licensure of our biosimilar products under the 351(a) (novel biologic) approval pathway instead of the 351(k) (biosimilar) approval pathway. This approval pathway may require us to undertake more expensive clinical trials and may present greater risk of failure than the 351(k) (biosimilar) approval pathway.***

While we have elected to proceed under the 351(k) (biosimilar) approval pathway for CHS-0214, our etanercept (Enbrel) biosimilar, CHS-1420, our adalimumab (Humira) biosimilar and for CHS-1701, our pegfilgrastim (Neulasta) biosimilar, we may elect for future products to pursue a 351(a) (novel biologic) approval pathway for a variety of clinical, regulatory and business reasons. The 351(a) (novel biologic) approval pathway generally requires three study phases (as contrasted with the two study phases required under the 351(k) (biosimilar) pathway). Moreover, the 351(a) pathway generally does not allow for the possibility that a clinical trial in one indication can be extrapolated to multiple indications as is generally the case under the 351(k) (biosimilar) approval pathway. Pursuing licensure under the 351(a) (novel biologic) approval pathway may present disadvantages in terms of the requirements for additional clinical and nonclinical studies, clinical trial cost and failure risk, as well as the likelihood that multiple clinical trials would be required to obtain approval for all of the indications approved for the originator biologic.

***Adverse events involving an originator product, or other biosimilars of such originator product, may adversely 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.

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. Our industry has experienced a high rate of turnover of management personnel in recent years. 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.

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 our organization and we may experience difficulties in managing this growth, which could disrupt our operations.***

As of December 31, 2014, we had 66 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 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, there is a natural transition period when a new CRO commences work. As a result, delays occur, 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, financial condition and prospects.

***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

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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 produce our product candidates in sufficient quantities to meet the requirements for the launch of these products 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 products 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;

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- 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 M923, an adalimumab (Humira) biosimilar being developed by Momenta in collaboration with Baxter;
- 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, Baxter and Orox for the commercialization of our biosimilar products 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, Baxter, 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-0214, CHS-1420 and CHS-1701, 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 legal costs to fund 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

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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 trial was resumed in December 2014 and is 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-0214, CHS-1701 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



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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 biologic product, 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 higher 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;

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- 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-0214, CHS-1420 and CHS-1701 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, Sandoz International GmbH, or Sandoz, Hospira, Inc., or Hospira, 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 etanercept (Enbrel), adalimumab (Humira) and pegfilgrastim (Neulasta). For example, we understand that Sandoz, Samsung Group and Hanwha are each currently engaged in the development of competing biosimilar product candidates for etanercept (Enbrel). Each of Sandoz, Bioepis and Hanwha appear to have ongoing Phase 3 clinical trials for an etanercept (Enbrel) biosimilar product candidate which they initiated earlier than our own Phase 3 clinical trials. Similarly, we understand that Sandoz is engaged in the development of a pegfilgrastim (Neulasta) biosimilar product candidate and believe such development has completed two Phase 3 clinical trials. Boehringer, Amgen, and Pfizer are examples of companies engaged in development of biosimilar product candidates for adalimumab (Humira). We understand Boehringer Ingelheim's program is in Phase 1, Pfizer's program is in Phase 3, and that Amgen's program has successfully completed Phase 3.

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

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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, Teva, Boehringer, Hospira, 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 Baxter 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.

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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 and reduce their competitiveness even if they reach the market. As a result, our business and operating results may be adversely affected.

***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 more or less 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;

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- 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.

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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.

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.

Moreover, 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

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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 and AbbVie Inc., or AbbVie, as well as other competitors (including other companies developing biosimilars) have developed 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. There may be third-party patents or patent applications with claims 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. We have not yet completed freedom to operate analysis on products we are evaluating for inclusion in our future biosimilar product pipeline and therefore we do not know whether or to what extent these products may be subject to unexpired patents.

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. Moreover, we 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



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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.

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. The Brockhaus patents are presently subject to litigation in which Sandoz is seeking to invalidate the patents. If challenges to the scope, validity or enforceability of the Brockhaus patents 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.

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***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 Baxter, 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

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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.

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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. Furthermore, even if they are unchallenged, our patents and patent applications 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.

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. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. 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. 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.

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.

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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. Rather than wait for the expiration of these formulation patents, we have developed our own proprietary formulations for these products which we believe are not covered by third party patents, including Amgen or AbbVie's formulation patents; and we have filed patent applications covering our formulations. 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. For example, we are aware that Sandoz is developing biosimilar versions of etanercept (Enbrel) and adalimumab (Humira) and has filed patent applications directed to formulations of etanercept (Enbrel) and adalimumab (Humira). We are also aware that Boehringer-Ingelheim is developing a biosimilar version of adalimumab (Humira) and has filed a patent application directed to formulations of adalimumab (Humira). We have also filed patent applications, none of which have yet issued, directed to aspects of our manufacturing processes for CHS-0214. In contrast to our patent applications directed to formulations of CHS-0214 and CHS-1420, the proprietary technologies embodied in our process-related patent filings, while directed to inventions we believe may provide us with competitive advantage, were not developed by us to avoid third party patents. 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.

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 Baxter or Daiichi Sankyo may choose 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

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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 some 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.

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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 (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;

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- 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 rights to 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 could prevent us from launching our product candidates in the United States or could substantially delay such launches. The BPCIA mechanism required for 351(k) biosimilar applicants may pose greater risk that patent infringement litigation will disrupt our activities, as compared to the litigation risk to which we might be exposed under a traditional 351(a) BLA regulatory pathway.

The BPCIA mandates patent disclosure and briefing requirements that are demanding, time-sensitive and, to date, untested. The following is an overview of the patent exchange and patent briefing procedures required by the BPCIA:

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 must provide a copy of its application to the originator.
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



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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.

Biosimilar companies such as ours have the option of applying for U.S. regulatory approval for our products under either a traditional 351(a) BLA approval route, or under the recently enacted streamlined 351(k) approval route established by the BPCIA. The factors underpinning such a decision are extremely complex and involve, among other things, balancing legal risk (in terms of, e.g., the degree and timing of exposure to potential patent litigation by the originator) versus regulatory risks (in terms of, e.g., the development costs and the differing scope of regulatory approval that may be afforded under 351(a) versus 351(k)).

A significant legal risk in pursuing regulatory approval under the 351(k) regulatory approval route is that the above-summarized patent exchange process established by the BPCIA 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 our products. In particular, while the 351(k) route is more attractive to us (versus 351(a)) for reasons related to development time and costs and the potential broader scope of eventual regulatory approval for our proposed biosimilar candidates, the countervailing risk in such a regulatory choice is that the complex patent exchange process mandated by the BPCIA could ultimately prevent or substantially delay us from launching our products in the United States.

Moreover, the disclosure process required in Step 1 of the process outlined above, which requires the biosimilar applicant to disclose not only the regulatory application but also the applicant's manufacturing process, has the potential to afford originators an easier path than traditional infringement litigation for developing any factual grounds they may require to support allegations of infringement. The rules established in

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the BPCIA's patent dispute procedures (versus the rules governing traditional patent infringement litigation) place biosimilar firms at a significant disadvantage by affording originators a much easier mechanism for factual discovery, thereby increasing the risk that a biosimilar product could be blocked from the market more quickly than under traditional patent infringement litigation processes.

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 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.

We are aware that some biosimilar companies, namely Sandoz and Celltrion, Inc., or Celltrion, have engaged in legal challenges against originators to establish their right to bring declaratory judgment actions against such originators outside the complex framework of the BPCIA patent exchange rules in order to challenge the validity of the originators' patents *prior* to the filing of any biosimilar regulatory application. For example, in the Sandoz case against the originator Amgen (relating to Sandoz' proposed etanercept (Enbrel) biosimilar) the Federal District Court ruled that Sandoz did not have the right to bring a declaratory judgment action against Amgen to challenge the validity of certain Amgen-controlled patents directed to Enbrel, but instead determined that Sandoz must use the patent exchange mechanism established in the BPCIA. Sandoz appealed this decision to the United States Court of Appeals for the Federal Circuit, and on December 5, 2014 the Federal Circuit Court ruled that Sandoz had not met the legal requirements to pursue a declaratory judgment action against Amgen. The Federal Circuit Court did not address whether the patent resolution mechanism established in the BPCIA would preclude Sandoz from filing its declaratory judgment action against Amgen if and when it files an FDA application under the BCPIA for its etanercept biosimilar.

In October 2014, Amgen filed suit in federal district court against Sandoz alleging that Sandoz unlawfully refused to follow the patent resolution provisions of the BPCIA in connection with Sandoz' July 2014 regulatory approval application under 351(k) for its Neupogen (filgrastim) biosimilar, Zarxio. Amgen is seeking declaratory and injunctive relief. In October 2014 Amgen also filed a Citizen's Petition with the FDA asking that the FDA require biosimilar applicants to comply with the BCPIA by providing to the reference product sponsor a copy of the biosimilar application accepted for review, together with information that fully describes the manufacture of the proposed biosimilar product, within 20 days after being informed by the FDA that the biosimilar application has been accepted for review. On March 19, 2015, the district court refused Amgen's request to enjoin Sandoz' launch of Zarxio and ruled that the patent resolution provisions of the BPCIA (summarized above in paragraphs 1 through 8) are optional insofar as it is permissible for a 351(k) applicant to decide not to provide its BLA and/or manufacturing information to the originator. The court also held that a biosimilar applicant need not wait until it receives BLA approval to provide the 180 prior day notice of commercial marketing set forth in the BPCIA provisions (see paragraph 8 above), but instead may provide such notice to the originator, if at all, prior to receiving FDA approval. The FDA has not yet ruled on Amgen's Citizen's Petition.

While the ability to file declaratory judgment actions outside the framework of the BPCIA, or to treat the patent resolution mechanism of this framework as optional, may be attractive to us for addressing and resolving patent infringement risks prior to the expenditure of substantial development and regulatory costs, we see substantial risk that the Federal Appeals Court could reverse the District Court's decision in the Amgen v. Sandoz case and instead rule that the patent resolution framework of the BCPIA is mandatory, and that Sandoz violated this framework by refusing to follow it. These pending court cases may ultimately require biosimilar applicants to test (or defend against) originator patents *only* in the BPCIA process, *after* they have filed for regulatory approval under 351(k). We believe this required order of events may expose biosimilar applicants to more patent litigation risk than they might otherwise be exposed to in litigation conducted outside

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the BPCIA framework, such as (i) under a regulatory application that we might choose to pursue under 351(a), where an originator would not be able to use the BPCIA procedures to potentially block the launch of a biosimilar product candidate; or (ii) under a 351(k) application in which federal court rulings may conclude it is permissible for biosimilar applicants to “opt out” of the BPCIA patent resolution mechanism, as has Sandoz in its 351(k) application for Zarxio.

Whether courts will ultimately view the BPCIA process as the *sole* and mandatory framework for a biosimilar entity and the originator to identify and potentially initiate patent litigation prior to launch of a biosimilar product remains highly uncertain. We see substantial risk that a final outcome to that effect in the Sandoz and Celltrion cases could increase patent infringement risks for companies, including ours, seeking to introduce biosimilar versions of originator products.

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; but we may ultimately not be successful in that strategy and could be prevented from marketing the product in the United States.

Under the complex, untested 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.

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

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, as well as rules subsequently implemented by the Securities and Exchange Commission, or SEC, and The NASDAQ Global Market, or NASDAQ, have imposed various requirements on public companies. In July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as “say on pay” and pay parity. Recent legislation permits smaller “emerging growth companies” such as us to implement many of these requirements over a longer period and up to five years from the pricing of our IPO on November 6, 2014. We intend to take advantage of this new legislation but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate. 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.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. In particular, we will be required to perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report, commencing in our annual report on Form 10-K for the year ending December 31, 2015, on the effectiveness of our internal controls over financial reporting, if then required by Section 404 of the Sarbanes-Oxley Act. Our testing may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses. Our compliance with Section 404 will require that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group and rely on independent contractors for control monitoring and for the preparation and review of our consolidated financial statements. We are actively seeking additional accounting and financial staff with appropriate public company experience and technical accounting knowledge to augment our current staff. Moreover, if we are not able to comply with the requirements of Section 404 in a timely manner or if we identify or our independent registered public accounting firm identifies deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by NASDAQ, the SEC or other regulatory authorities, which would require additional financial and management resources.

New laws and regulations as well as changes to existing laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act and rules adopted by the SEC and by NASDAQ, would likely result in increased costs to us as we respond to their requirements.

### ***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

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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 audit of our financial statements for the year ended December 31, 2014, 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.

***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,

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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;

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- 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 \$2.2 million of cash in Russian banks as of December 31, 2014. 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 the Company is currently evaluating for inclusion in its 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

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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 initial public offering and the intraday sales price per share has ranged from \$12.27 to \$33.30 per share during the period from November 6, 2014 to March 20, 2015, 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 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;



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- 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 February 28, 2015, our executive officers, directors, five percent stockholders and their affiliates beneficially owned approximately 58% of our voting stock. 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.

***We are an “emerging growth company” and, due to the reduced reporting requirements applicable to emerging growth companies, certain investors may find investing in our common stock less attractive.***

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years, although circumstances could cause us to lose that status earlier, including if the market value of our common stock held by non-affiliates exceeds \$700.0 million as of any June 30 before that time or if we have total annual gross revenue of \$1.0 billion or more during any fiscal year before that time, in which cases we would no longer be an emerging growth company as of the following December 31 or, if we issue more than \$1.0 billion in non-convertible debt during any three-year period before that time, we would cease to be an emerging growth company immediately. We cannot predict if investors will find our common stock less attractive because we may rely on this exemption. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

***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 February 28, 2015, there were 33,324,459 shares of common stock outstanding. Of these shares, approximately 15,504,589 shares of our common stock are currently subject to contractual lock-up agreements entered into by certain of our stockholders with the underwriters in connection with our IPO and will become freely tradeable on May 5, 2015, subject to volume limitations under Rule 144 of the Securities Act of 1933, as amended (the “Securities Act”). In addition, in connection with this offering, our officers, directors and certain stockholders affiliated with our directors, collectively holding approximately 11,016,168 shares, entered into lock-up agreements that will expire 60 days after the date of this prospectus. J.P. Morgan Securities LLC and Credit Suisse Securities (USA) LLC, however, may, in their sole discretion, permit our officers, directors and other stockholders who are subject to these lock-up agreements to sell shares prior to the expiration of the lock-up agreements.

In addition, as of February 28, 2015, approximately 8.7 million shares of common stock that are either subject to outstanding options or reserved for future issuance under our equity incentive plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements 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.

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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;

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- 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.

### **Risks Related to this Offering**

***If you purchase our common stock in this offering, you will incur immediate and substantial dilution in the book value of your shares.***

Investors purchasing shares of common stock in this offering will pay a price per share that substantially exceeds the as-adjusted book value per share of our tangible assets after subtracting our liabilities. As a result, investors purchasing shares of common stock in this offering will incur immediate dilution of \$        per share, based on an assumed offering price of \$        per share, the last reported sale price of our common stock on       , 2015, and our as-adjusted net tangible book value as of December 31, 2014 after giving effect to this offering. For information on how the foregoing amounts were calculated, see “Dilution.”

This dilution is due to the substantially lower price paid by our investors who purchased shares prior to this offering as compared to the price offered to the public in this offering, and the exercise of stock options granted to our employees. In addition, as of December 31, 2014, we had outstanding options to purchase 5.8 million shares of our common stock; the exercise of any of these options would result in additional dilution. As a result of the dilution to investors purchasing shares in this offering, investors may receive significantly less than the purchase price paid in this offering, if anything, in the event of our liquidation.

***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 discussed in this prospectus lapse, the market price of our common stock could decline. Based upon the number of shares of common stock outstanding as of December 31, 2014 and the sale by us of \$100,000,000 of shares of our common stock, which would be \_\_\_\_\_ shares based on an assumed offering price of \$ \_\_\_\_\_ per share, the last reported sale price of our common stock on \_\_\_\_\_, 2015, upon the closing of this offering we will have outstanding a total of approximately \_\_\_\_\_ shares of common stock. Of these shares, the shares of our common stock sold in our initial public offering (other than any shares purchased by our then-existing investors and directors and executive officers), which was completed in November 2014, are currently freely tradable, and the shares to be sold in this offering, plus any shares sold upon exercise of the underwriters' option to purchase additional shares, will be freely tradable, without restriction, in the public market immediately following this offering.

The lock-up agreements pertaining to our initial public offering will expire on May 5, 2015, following which up to approximately 15,504,589 shares of common stock will be eligible for sale in the public market, subject to any additional restrictions. The lock-up agreements pertaining to this offering will expire 60 days from the date of this prospectus for our officers, directors and certain stockholders affiliated with our directors, following which approximately 11,016,168 shares of common stock will be eligible for sale in the public market, all 11,016,168 of which shares are held or beneficially owned by current directors and executive officers or their affiliates and may be subject to Rule 144 limitations under the Securities Act.

In addition, as of December 31, 2014, approximately 8.7 million shares of common stock that are either subject to outstanding options or reserved for future issuance under our equity incentive plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements, 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.

After this offering, the holders of approximately 21.3 million shares of our common stock will be entitled to rights with respect to the registration of their shares under the Securities Act, subject to the vesting schedules and lock-up agreements described above. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares purchased by affiliates. Any sales of securities by these stockholders could have a material adverse effect on the market price of our common stock.

***We will have broad discretion in the use of the net proceeds to us from this offering and we may not use the offering proceeds that we receive effectively.***

We will receive net proceeds of \$ \_\_\_\_\_ million from this offering, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. Our management will have broad discretion in the application of the net proceeds to us from this offering, including for any of the purposes described in the section entitled "Use of Proceeds," and you will not have the opportunity as part of your investment decision to assess whether the net proceeds are being used appropriately. Because of the number and variability of factors that will determine our use of the net proceeds to us from this offering, their ultimate use may vary from their currently intended use. The failure by our management to apply these funds effectively could harm our business. Pending their use, we may invest the net proceeds to us from this offering in investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders.

## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated by reference herein contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that involve substantial risks and uncertainties concerning our business, operations and financial performance and condition, as well as our plans, objectives and expectations for our business operations and financial performance and condition. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “aim,” “anticipate,” “assume,” “believe,” “contemplate,” “continue,” “could,” “due,” “estimate,” “expect,” “goal,” “intend,” “may,” “objective,” “plan,” “predict,” “positioned,” “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-0214 (our etanercept (Enbrel) biosimilar candidate), CHS-1420 (our adalimumab (Humira) biosimilar candidate) and CHS-1701 (our pegfilgrastim (Neulasta) biosimilar candidate);
- whether the results of our trials will be sufficient to support domestic or global regulatory approvals for CHS-0214, CHS-1420 and CHS-1701;
- our ability to obtain and maintain regulatory approval of CHS-0214, CHS-1420 and CHS-1701 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 Baxter International, Inc. and the net proceeds from this offering will be sufficient to fund our operations for at least the next 12 months;
- the implementation of our business model and strategic plans for our business and product candidates;
- 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 manufacture and supply our product candidates for us;
- our reliance on third-party contract research organizations to conduct clinical trials of our product candidates for us;
- the benefits of the use of CHS-0214, CHS-1420 and CHS-1701;
- the rate and degree of market acceptance of CHS-0214, CHS-1420 and CHS-1701 or any future product candidates;
- our expectations regarding government and third-party payor coverage and reimbursement;
- our ability to manufacture CHS-0214, CHS-1420 and CHS-1701 in conformity with regulatory requirements and to scale up manufacturing capacity of these products for commercial supply;

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- our ability to compete with companies currently producing the reference products, including Enbrel, Humira and Neulasta;
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act;
- our expected uses of the net proceeds to us from this offering;
- our financial performance; and
- developments and projections relating to our competitors and our industry.

These forward-looking statements are based on management's current expectations, estimates, forecasts and projections about our business and the industry in which we operate and management's beliefs and assumptions and are not guarantees of future performance or development and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control. As a result, any or all of our forward-looking statements in this prospectus may turn out to be inaccurate. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under "Risk Factors" and elsewhere in this prospectus. Potential investors are urged to consider these factors carefully in evaluating the forward-looking statements. These forward-looking statements speak only as of the date of this prospectus. 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. You should, however, review the factors and risks we describe in the reports we will file from time to time with the Securities and Exchange Commission, or SEC, after the date of this prospectus. See "Where You Can Find More Information."

This prospectus and the documents incorporated by reference herein also contain 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.

## **MARKET, INDUSTRY AND OTHER DATA**

This prospectus and the documents incorporated by reference herein contain estimates, projections and other information concerning our industry, our business and the markets for certain drugs, including data regarding the estimated size of those markets, their projected growth rates, the incidence of certain medical conditions and the perceptions and preferences of customers regarding certain therapies, as well as data regarding market research, estimates and forecasts prepared by our management. 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 that are assumed 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. In some cases, we do not expressly refer to the sources from which this data are derived. In that regard, when we refer to one or more sources of this type of data in any paragraph, you should assume that other data of this type appearing in the same paragraph are derived from the same sources, unless otherwise expressly stated or the context otherwise requires.



## USE OF PROCEEDS

We estimate that the net proceeds from the sale of \$100,000,000 of common stock in this offering will be approximately \$ \_\_\_\_\_ million, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters exercise in full their option to purchase \$15,000,000 of additional shares of common stock, we estimate that the net proceeds will be approximately \$ \_\_\_\_\_ million after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. Each \$1.00 increase (decrease) in the assumed public offering price of \$ \_\_\_\_\_ per share, the last reported sale price of our common stock on The NASDAQ Global Market on \_\_\_\_\_, 2015, would increase (decrease) the number of shares of common stock to be issued by us in this offering by \_\_\_\_\_, assuming the aggregate dollar amount of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the aggregate dollar amount of shares we are offering. Each increase (decrease) of \$ \_\_\_\_\_ million of shares offered by us would increase (decrease) the as adjusted amount of cash, working capital, total assets and total stockholders' equity by approximately \$ \_\_\_\_\_ million, assuming that the assumed public offering price remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. The as adjusted information discussed above is illustrative only and will be adjusted based on the actual public offering price and other terms of this offering determined at pricing.

We expect to use substantially all of the net proceeds from this offering as follows:

- approximately \$85.0 million to fund the development through regulatory submission of one biosimilar currently in the pre-clinical stage;
- approximately \$7.0 million to fund the proof-of-concept Phase 2 study of INT-131; and
- the remainder for working capital and other corporate purposes, which may include the licensing of other products or technologies.

However, due to the uncertainties inherent in the product development and commercialization process, it is difficult to estimate with certainty the exact amounts of the net proceeds from this offering that may be used for the above purposes. Our management will have broad discretion over the use of the net proceeds from this offering. The amounts and timing of our expenditures will depend upon numerous factors, including the timing and success of preclinical studies and any ongoing clinical trials or clinical trials we may commence in the future, the timing of regulatory submissions, any unforeseen delays or problems in the development of our manufacturing capabilities and supply chain, and the timing and amount of our future revenue, our future expenses as well as any collaborations or licensing that we may enter into with third parties for our product candidates, and any unforeseen cash needs.

Based on our planned use of the net proceeds from this offering and our existing cash and expected funding under our license agreements, we expect that such funds will be sufficient to enable us to complete clinical studies that we are currently undertaking in respect of CHS-0214, CHS-1420 and CHS-1701. We will require substantial capital in order to complete the remaining clinical development and to potentially commercialize these product candidates. See "Risk Factors — Risks Related to Our Financial Condition and Capital Requirements — Even if this offering is successful, 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."

Pending the use of the proceeds from this offering, we intend to invest the net proceeds in interest-bearing, investment-grade securities, certificates of deposit or government securities.

**PRICE RANGE OF COMMON STOCK**

Our common stock has been publicly traded on The NASDAQ Global Market under the symbol “CHRS” since our initial public offering on November 6, 2014. Prior to that time, there was no public market for our common stock. The following table sets forth on a per share basis, for the periods indicated, the low and high sale prices of our common stock as reported by The NASDAQ Global Market.

	<u>High</u>	<u>Low</u>
<b>2014</b>		
Fourth Quarter (from November 6, 2014)	\$17.31	\$12.27
<b>2015</b>		
First Quarter (through March 20, 2015)	\$33.30	\$15.50

On March 20, 2015, the last reported sale price of our common stock on The NASDAQ Global Market was \$26.46 per share. As of December 31, 2014, there were approximately 90 holders 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 cash dividends on our capital stock. We intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination related to dividend policy will be made at the discretion of our board of directors.

## CAPITALIZATION

The following table sets forth our cash and cash equivalents, and capitalization as of December 31, 2014:

- on an actual basis;
- on an as adjusted basis to give effect to (i) the reclassification of our contingent consideration liability to stockholders' equity upon the issuance of 358,384 shares of common stock to former InteKrin stockholders to satisfy a contingent consideration obligation upon the achievement of the first dosing of a human subject in the phase 2 clinical trial for INT 131 on March 6, 2015; and (ii) the issuance and sale by us of \$100.0 million of shares of our common stock assuming the underwriters' option to purchase additional shares is not exercised and assuming a public offering price of \$ \_\_\_\_\_ per share, the last reported sale price of our common stock on The NASDAQ Global Market on \_\_\_\_\_, 2015, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

You should read this information together with our audited financial statements and related notes incorporated by reference in this prospectus. For more details on how you can obtain our SEC reports and other information, you should read the section of the prospectus entitled "Where You Can Find More Information."

	December 31, 2014	
	Actual	As Adjusted <sup>(1)</sup> (unaudited)
	(in thousands, except share and per share data)	
Cash and cash equivalents	\$ 150,392	\$ _____
Contingent consideration	\$ 5,710	\$ _____
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 5,000,000 shares authorized, no shares issued and outstanding, actual and as adjusted	—	—
Common stock, \$0.0001 par value; 300,000,000 shares authorized, 33,257,978 shares issued and outstanding, actual; 300,000,000 shares authorized, _____ shares issued and outstanding, as adjusted	3	3
Additional paid-in capital	254,048	254,048
Accumulated other comprehensive loss	(525)	(525)
Accumulated deficit	(186,725)	(186,725)
Total Coherus stockholders' equity	66,801	66,801
Non-controlling interest	(44)	(44)
Total stockholders' equity	66,757	66,757
Total capitalization	\$ 72,467	\$ _____

(1) Each \$1.00 increase (decrease) in the assumed public offering price of \$ \_\_\_\_\_ per share, the last reported sale price of our common stock on The NASDAQ Global Market on \_\_\_\_\_, 2015, would increase (decrease) the number of shares of common stock to be issued by us in this offering by \_\_\_\_\_, assuming the aggregate dollar amount of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the aggregate dollar amount of shares we are offering. Each increase (decrease) of \$ \_\_\_\_\_ million of shares offered by us would increase (decrease) the as adjusted amount of cash, working capital, total assets and total stockholders' equity by approximately \$ \_\_\_\_\_ million, assuming that the assumed public offering price remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. The as adjusted information discussed above is illustrative only and will be adjusted based on the actual public offering price and other terms of this offering determined at pricing.

The number of shares of common stock to be outstanding after this offering is based on 33,257,978 shares of common stock outstanding as of December 31, 2014, and assumes the sale of \$100.0 million of shares of common stock at an assumed offering price of \$ \_\_\_\_\_ per share, the last reported sale price of our common

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stock on The NASDAQ Global Market on \_\_\_\_\_, 2015. The outstanding share information in the table above excludes the following:

- 5,560,345 shares of common stock issuable upon the exercise of outstanding stock options under our 2010 Stock Incentive Plan, as amended, as of December 31, 2014 having a weighted-average exercise price of \$2.46 per share;
- 209,962 shares of common stock issuable upon the exercise of outstanding stock options under our 2014 Equity Incentive Award Plan as of December 31, 2014 having a weighted-average exercise price of \$14.69 per share;
- 2,652,500 shares of common stock reserved for issuance pursuant to future awards under our 2014 Equity Incentive Award Plan, as well as any automatic increases in the number of shares of our common stock reserved for future issuance under this plan; and
- 320,000 shares of common stock reserved for future issuance under our 2014 Employee Stock Purchase Plan, as well as any automatic increases in the number of shares of our common stock reserved for future issuance under this plan.

Unless otherwise indicated, the number of shares of our common stock described above assumes no exercise of the underwriters' option to purchase additional shares.

## DILUTION

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

Our historical net tangible book value per share is determined by dividing our total tangible assets less our total liabilities by the number of shares of common stock outstanding. Our historical net tangible book value as of December 31, 2014 was \$62.2 million, or \$1.90 per share, based on 33,257,978 shares of common stock outstanding as of December 31, 2014.

Net tangible book value dilution per share to new investors represents the difference between the amount per share paid by purchasers of shares of common stock in this offering and the as adjusted net tangible book value per share of common stock immediately after completion of this offering. After giving effect to our sale of \$100.0 million of shares of common stock offered at an assumed public offering price of \$ \_\_\_\_\_ per share, the last reported sale price of our common stock on The NASDAQ Global Market on \_\_\_\_\_, 2015, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our as adjusted net tangible book value as of December 31, 2014 would have been \$ \_\_\_\_\_ million, or \$ \_\_\_\_\_ per share. This represents an immediate increase in net tangible book value of \$ \_\_\_\_\_ per share to existing stockholders and an immediate dilution in net tangible book value of \$ \_\_\_\_\_ per share to purchasers of common stock in this offering, as illustrated in the following table:

Assumed public offering price per share		\$
Historical net tangible book value per share as of December 31, 2014	\$ 1.90	
As adjusted increase in a net tangible book value per share attributable to new investors in this offering	\$	
As adjusted net tangible book value per share after this offering		\$
Dilution per share to investors participating in this offering		\$

Each \$1.00 increase (decrease) in the assumed public offering price of \$ \_\_\_\_\_ per share, the last reported sale price of our common stock on The NASDAQ Global Market on \_\_\_\_\_, 2015, would increase (decrease the number of shares of common stock to be issued by us in this offering by \_\_\_\_\_, assuming the aggregate dollar amount of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the aggregate dollar amount of shares we are offering. Each increase (decrease) of \_\_\_\_\_ million shares in the number of shares offered by us would increase (decrease) the as adjusted amount of cash, working capital, total assets and total stockholders' equity by approximately \$ \_\_\_\_\_ million, assuming that the assumed public offering price remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. The as adjusted information discussed above is illustrative only and will be adjusted based on the actual public offering price and other terms of this offering determined at pricing.

The number of shares of common stock to be outstanding after this offering is based on 33,257,978 shares of common stock outstanding as of December 31, 2014, and assumes the sale of \$100.0 million of shares of common stock at an assumed offering price of \$ \_\_\_\_\_ per share, the last reported sale price of our common stock on The NASDAQ Global Market on \_\_\_\_\_, 2015, and excludes the following:

- 5,560,345 shares of common stock issuable upon the exercise of outstanding stock options under our 2010 Stock Incentive Plan, as amended, as of December 31, 2014 having a weighted-average exercise price of \$2.46 per share;
- 209,962 shares of common stock issuable upon the exercise of outstanding stock options under our 2014 Equity Incentive Award Plan as of December 31, 2014 having a weighted-average exercise price of \$14.69 per share;

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- 2,652,500 shares of common stock reserved for issuance pursuant to future awards under our 2014 Equity Incentive Award Plan, as well as any automatic increases in the number of shares of our common stock reserved for future issuance under this plan; and
- 320,000 shares of common stock reserved for future issuance under our 2014 Employee Stock Purchase Plan, as well as any automatic increases in the number of shares of our common stock reserved for future issuance under this plan.

## PRINCIPAL STOCKHOLDERS

The following table sets forth information relating to the beneficial ownership of our common stock as of March 20, 2015, by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our outstanding shares of common stock;
- each of our directors;
- each of our named executive officers; and
- all directors and executive officers as a group.

The number of shares beneficially owned by each entity, person, director or executive officer is determined in accordance with the rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rules, beneficial ownership includes any shares over which the individual has sole or shared voting power or investment power as well as any shares that the individual has the right to acquire within 60 days of March 20, 2015 through the exercise of any stock options or other rights. Except as otherwise indicated, and subject to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all shares of common stock held by that person. Unless otherwise indicated below, the address for each beneficial owner listed is c/o Coherus BioSciences, Inc., at 201 Redwood Shores Parkway, Suite 200, Redwood City, California.

Our calculation of the percentage of beneficial ownership prior to this offering is based on 33,682,843 shares of common stock outstanding as of March 20, 2015. Our calculation of the percentage of beneficial ownership after this offering is based on \_\_\_\_\_ shares of common stock outstanding immediately after the closing of this offering, assuming the sale of \$100.0 million of shares of common stock at an assumed offering price of \$ \_\_\_\_\_ per share, the last reported sale price of our common stock on The NASDAQ Global Market on \_\_\_\_\_, 2015, no exercise of outstanding options and no exercise of the underwriters' option to purchase additional shares of our common stock.

Name of Beneficial Owner	Beneficial Ownership Prior to this Offering				Beneficial Ownership After this Offering	
	Number of Shares Beneficially Owned	Number of Shares Exercisable Within 60 Days	Number of Shares Beneficially Owned	Percentage of Beneficial Ownership	Number of Shares Beneficially Owned	Percentage of Beneficial Ownership
<b>5% and Greater Stockholders</b>						
KKR Biosimilar L.P. <sup>(1)</sup>	3,055,055	—	3,055,055	9.07%		
Lilly Ventures Fund I, LLC <sup>(2)</sup>	3,042,019	—	3,042,019	9.03%		
Sofinnova Venture Partners VII, L.P. <sup>(3)</sup>	2,893,221	—	2,893,221	8.59%		
Daiichi Sankyo Company, Limited <sup>(4)</sup>	2,867,426	—	2,867,426	8.51%		
Entities affiliated with MX II Associates, LLC <sup>(5)</sup>	2,500,920	—	2,500,920	7.42%		
Entities affiliated with Venrock Associates VI, L.P. <sup>(6)</sup>	2,341,882	—	2,341,882	6.95%		
<b>Named Executive Officers and Directors</b>						
Barbara K. Finck, M.D. <sup>(7)</sup>	26,791	125,198	151,989	*		
James I. Healy, M.D., Ph.D. <sup>(8)</sup>	2,893,313	9,373	2,902,686	8.62%		
Alan C. Herman, Ph.D. <sup>(9)</sup>	514,863	173,335	688,198	2.03%		
Dennis M. Lanfear <sup>(10)</sup>	1,503,526	754,588	2,258,114	6.56%		
V. Bryan Lawlis, Ph.D. <sup>(11)</sup>	—	19,683	19,683	*		
Christos Richards <sup>(12)</sup>	78,836	44,991	123,827	*		
Ali J. Satvat <sup>(13)</sup>	3,055,055	6,874	3,061,929	9.09%		
Mary T. Szela <sup>(14)</sup>	—	3,124	3,124	*		
August J. Troendle, M.D. <sup>(15)</sup>	2,522,790	8,124	2,530,914	7.51%		
Mats Wahlström <sup>(16)</sup>	763,065	68,111	831,176	2.46%		
Jean- Frédéric Viret, Ph.D.	—	—	—	*		
Peter K. Watler, Ph.D. <sup>(17)</sup>	—	138,738	138,738	*		
All directors and executive officers as a group (12 persons) <sup>(18)</sup>	11,358,239	1,352,139	12,710,378	36.28%		



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\* Indicates beneficial ownership of less than 1% of the total outstanding shares of common stock.

- (1) The shares are owned directly by KKR Biosimilar L.P. KKR Biosimilar GP LLC is the sole general partner of KKR Biosimilar L.P. KKR Fund Holdings L.P. is the sole member of KKR Biosimilar GP LLC. The general partners of KKR Fund Holdings L.P. are KKR Fund Holdings GP Limited and KKR Group Holdings L.P. The sole shareholder of KKR Fund Holdings GP Limited is KKR Group Holdings L.P. The sole general partner of KKR Group Holdings L.P. is KKR Group Limited. The sole shareholder of KKR Group Limited is KKR & Co. L.P. The sole general partner of KKR & Co. L.P. is KKR Management LLC. The designated members of KKR Management LLC are Messrs. Kravis and Roberts. Each of KKR Biosimilar GP LLC, KKR Fund Holdings L.P., KKR Fund Holdings GP Limited, KKR Group Holdings L.P., KKR Group Limited, KKR & Co. L.P., KKR Management LLC, and Messrs. Kravis and Roberts disclaim beneficial ownership over all shares held by KKR Biosimilar L.P. except to the extent of their indirect pecuniary interests therein. Ali J. Satvat, who is a member of our board of directors, is an executive of Kohlberg Kravis Roberts & Co. L.P. and/or one or more of its affiliates. Mr. Satvat disclaims beneficial ownership of all shares held by KKR Biosimilar L.P. except to the extent of his indirect pecuniary interests therein. The address of the entities affiliated with Kohlberg Kravis Roberts & Co. L.P. and Mr. Kravis is c/o Kohlberg Kravis Roberts & Co. L.P., 9 West 57th Street, New York, NY 10019. The address of Messrs. Roberts and Satvat is c/o Kohlberg Kravis Roberts & Co. L.P., 2800 Sand Hill Road, Suite 200, Menlo Park, CA 94025.
- (2) The shares are owned directly by Lilly Ventures Fund I, LLC. Eli Lilly and Company, as Sole Managing Member of Lilly Ventures Fund I, LLC, and pursuant to the LLC Agreement of Lilly Ventures Fund I, LLC, has voting authority with respect to shares owned by Lilly Ventures Fund I, LLC. The address of Lilly Ventures Fund I, LLC is 115 West Washington Street, Suite 1680 — South, Indianapolis, IN 46204.
- (3) The shares are owned directly by Sofinnova Venture Partners VII, L.P., or SV VII. Sofinnova Management VII, L.L.C., or SV VII LLC, the general partner of SV VII, and Dr. Healy, Michael Powell and Eric Buatois, the managing members of SV VII LLC, may be deemed to have shared voting and dispositive power over the shares owned by SV VII. Such persons and entities disclaim beneficial ownership over the shares owned by SV VII except to the extent of any pecuniary interest therein. The address of SV VII is c/o Sofinnova Ventures, 3000 Sand Hill Road, Suite 4-250, Menlo Park, CA 94025.
- (4) The shares are owned directly by Daiichi Sankyo Company, Limited, or Daiichi Sankyo. Daiichi Sankyo is a publicly traded company on the Tokyo Stock Exchange. As of March 31, 2014, Daiichi Sankyo had 110,851 shareholders (none of whom owned or beneficially owned more than 10% of Daiichi Sankyo's outstanding shares of common stock) and approximately 703,959,767 shares (excluding treasury shares held by Daiichi Sankyo and its consolidated subsidiaries) of common stock outstanding. This beneficial ownership information includes information contained in publicly available records of the filings made by Daiichi Sankyo shareholders regarding their ownership of Daiichi Sankyo's common stock under the Securities and Exchange Law of Japan. The address of Daiichi Sankyo is 3-5-1 Nihonbashi Honcho, Chuo-Ku, Tokyo 103-8426 Japan.
- (5) Includes (i) 358,428 shares of common stock held by Medpace Investors, LLC, or Medpace Investors, and (ii) 2,142,492 shares of common stock held by MX II Associates LLC, or MX II Associates. August J. Troendle, M.D., is the President of Medpace Investors and the Managing Member of MX II Associates. Voting and dispositive decisions with respect to shares held by Medpace Investors and MX II Associates are made by Dr. Troendle; however, he disclaims beneficial ownership of the shares held by these entities, except to the extent of any pecuniary interest therein. The address of MX II Associates and affiliated entity is c/o Medpace, Inc., 5375 Medpace Way, Cincinnati, OH 45227.
- (6) Consists of (i) 1,364,481 shares of common stock by Venrock Associates VI, L.P., or VA VI, (ii) 370,370 shares of common stock by affiliates of Venrock Associates VI, L.P., or VA VI, (iii) 107,132 shares of common stock by Venrock Partners VI, L.P., or VP VI, (iv) 422,595 shares of common stock held by Venrock Healthcare Capital Partners, L.P., or VHCP, and (v) 77,304 shares of common stock held by VHCP Co-Investment Holdings, LLC, or VHCP Co. Venrock Management VI, LLC, or VM VI, is the sole general partner of VA IV. Venrock Partners Management VI, LLC, or VPM VI, is the sole general partner of VP IV. VHCP Management, LLC, or VHCPM, is the sole general partner of each of VHCP and VHCP Co. VM VI, VPM VI and VHCPM expressly disclaim beneficial ownership over all shares held by VA VI, VP VI, VHCP and VHCP Co, except to the extent of their indirect pecuniary interest therein. Anders D. Hove and Bryan E. Roberts are members of VI VI, VP VI and VHCPM and disclaim beneficial ownership over all shares held by VA VI, VP VI, VHCP and VHCP Co, except to the extent of their indirect pecuniary interests therein. The address of each of the entities is c/o Venrock, 3340 Hillview Avenue, Palo Alto, CA 94304.
- (7) Consists of (i) 26,791 shares of common stock, and (ii) 125,198 shares that may be acquired pursuant to the exercise of stock options within 60 days of March 20, 2015 by Dr. Finck.
- (8) Consists of the shares held by Sofinnova Venture Partners VII, L.P. Dr. Healy is a managing member of Sofinnova Management VII, L.L.C., the general partner of Sofinnova Venture Partners VII, L.P., and disclaims beneficial ownership of the shares held by Sofinnova Venture Partners VII, L.P., except to the extent of his pecuniary interest therein. Also includes (i) 92 shares of common stock and (ii) 9,373 shares that may be acquired pursuant to the exercise of stock options within 60 days of March 20, 2015.
- (9) Consists of (i) 300,164 shares of common stock held by Alan C. Herman, Ph.D. and Margaret R. Herman, Trustees of the Herman Trust dated March 16, 2001, (ii) 214,699 common stock held by Alan C. Herman, Ph.D., and (iii) 173,355 shares that may be acquired pursuant to the exercise of stock options within 60 days of March 20, 2015 by Dr. Herman.
- (10) Consists of (i) 1,344,926 shares of common stock held by Dennis M. Lanfear, as Trustee of the Lanfear Revocable Trust, dated January 27, 2004, as restated, (ii) 86,965 shares of common stock held by offering by Lanfear Capital Advisors, LLC, (iii) 71,635 shares of common stock held by Dennis M. Lanfear, and (iv) 754,588 shares that may be acquired pursuant to the exercise of stock options within 60 days of March 20, 2015 by Mr. Lanfear.
- (11) Consists of 19,683 shares that may be acquired pursuant to the exercise of stock options within 60 days of March 20, 2015 by Dr. Lawlis.

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- (12) Consists of (i) 78,836 shares of common stock held, and (ii) 44,991 shares that may be acquired pursuant to the exercise of stock options within 60 days of March 20, 2014 by Mr. Richards.
- (13) Consists of the shares held by KKR Biosimilar L.P. Mr. Satvat disclaims beneficial ownership of the shares held by KKR Biosimilar L.P., except to the extent of his pecuniary interest therein. Also, includes 6,874 shares that may be acquired pursuant to the exercise of stock options within 60 days of March 20, 2015.
- (14) Consists of 3,124 shares that may be acquired pursuant to the exercise of stock options within 60 days of March 20, 2014 by Ms. Szela.
- (15) Consists of the shares described in Note (5) above. Dr. Troendle disclaims beneficial ownership of the shares held by Medpace Investors, LLC and MX II Associates, LLC as described in Note (5) above, except to the extent of his pecuniary interest therein. Also includes (i) 21,870 shares of common stock, and (ii) 8,124 shares that may be acquired pursuant to the exercise of stock options within 60 days of March 20, 2015 by Dr. Troendle.
- (16) Consists of the shares held by KMG Capital Partners, LLC and Leonard Capital, LLC. Mr. Wahlström disclaims beneficial ownership of the shares held by KMG Capital Partners, LLC and Leonard Capital, LLC, except to the extent of his pecuniary interest therein. Also includes 68,111 shares that may be acquired pursuant to the exercise of stock options within 60 days of March 20, 2015 by Mr. Wahlström.
- (17) Consists of 138,783 shares that may be acquired pursuant to the exercise of stock options within 60 days of September 30, 2014 by Dr. Watler.
- (18) Includes (i) 8,449,196 shares held by entities affiliated with certain of our directors and (ii) 12,710,378 shares beneficially owned by our executive officers and directors, which includes the 11,358,239 shares held by such entities and 1,352,139 shares that may be acquired pursuant to the exercise of stock options within 60 days of March 20, 2015.

## DESCRIPTION OF CAPITAL STOCK

*The following summary describes our capital stock and the material provisions of our amended and restated certificate of incorporation and our amended and restated bylaws, the third amended and restated investor rights agreement to which we and certain of our stockholders are parties and of the Delaware General Corporation Law. Because the following is only a summary, it does not contain all of the information that may be important to you. For a complete description, you should refer to our amended and restated certificate of incorporation, amended and restated bylaws and third amended and restated investor rights agreement, copies of which are incorporated by reference as exhibits to the registration statement of which this prospectus is part.*

### General

Our amended and restated certificate of incorporation authorizes 300,000,000 shares of common stock, \$0.0001 par value per share, and 5,000,000 shares of preferred stock, \$0.0001 par value per share. As of December 31, 2014, there were outstanding:

- 33,257,978 shares of our common stock; and
- 5,770,307 shares of our common stock issuable upon exercise of outstanding stock options.

As of December 31, 2014, there were approximately 90 holders of record of our common stock. This number does not include beneficial owners whose shares are held by nominees in street name.

### Common Stock

#### ***Voting Rights***

Each holder of our common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors. Our stockholders do not have cumulative voting rights in the election of directors. Accordingly, holders of a majority of the voting shares are able to elect all of the directors.

#### ***Dividends***

Subject to preferences that may be applicable to any then outstanding preferred stock, holders of our common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of legally available funds.

#### ***Liquidation***

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities and the satisfaction of any liquidation preference granted to the holders of any then outstanding shares of preferred stock.

#### ***Rights and Preferences***

Holders of our common stock have no preemptive, conversion, subscription or other rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of our common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of our preferred stock that we may designate in the future.

#### ***Fully Paid and Nonassessable.***

All of our outstanding shares of common stock are, and the shares of common stock to be issued in this offering will be, fully paid and nonassessable.

### **Preferred Stock**

Our board of directors has the authority, without further action by our stockholders, to issue up to 5,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting, or the designation of, such series, any or all of which may be greater than the rights of common stock. The issuance of our preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon our liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in control of our company or other corporate action. No shares of preferred stock are outstanding, and we have no present plan to issue any shares of preferred stock.

### **Registration Rights**

Under our third amended and restated investor rights agreement, the holders of approximately 21.3 million shares of common stock, or their transferees, have the right to require us to register their shares under the Securities Act so that those shares may be publicly resold, or to include their shares in any registration statement we file, in each case as described below.

#### ***Demand Registration Rights***

Based on the number of shares outstanding as of December 31, 2014, the holders of approximately 21.3 million shares of our common stock, or their transferees, are entitled to certain demand registration rights. Beginning on May 5, 2015, the 180th day following the effectiveness of the registration statement filed in connection with our initial public offering in November 2014, the holders of at least 50% of these shares can, on not more than four occasions, request that we register all or a portion of their shares. Such request for registration must cover a number of shares with an anticipated aggregate offering price, net of underwriting discounts and commissions, of at least \$5.0 million. Additionally, we will not be required to effect a demand registration during the period beginning 60 days prior to the filing and 180 days following the effectiveness of a company-initiated registration statement relating to a public offering of our securities, provided that we have complied with certain notice requirements to the holders of these shares.

#### ***Form S-3 Registration Rights***

Based on the number of shares outstanding as of December 31, 2014, the holders of approximately 21.3 million shares of our common stock, or their transferees, are entitled to certain Form S-3 registration rights. Beginning on May 5, 2015, the 180th day following the effectiveness of the registration statement filed in connection with our initial public offering in November 2014, the holders of these shares can make a written request that we register their shares on Form S-3 if we are eligible to file a registration statement on Form S-3 and if the aggregate price to the public of the shares offered is at least \$1.0 million. These stockholders may make an unlimited number of requests for registration on Form S-3, but in no event shall we be required to file more than two registrations on Form S-3 in any 12-month period. However, we will not be required to effect a registration on Form S-3 during the period beginning 60 days prior to the filing and 180 days following the effectiveness of a company-initiated registration statement relating to a public offering of our securities, provided that we have complied with certain notice requirements to the holders of these shares.

#### ***Piggyback Registration Rights***

Based on the number of shares outstanding as of December 31, 2014, in the event that we determine to register any of our securities under the Securities Act (subject to certain exceptions), either for our own account or for the account of other security holders, the holders of approximately 21.3 million shares of our common

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stock, or their transferees, are entitled to certain “piggyback” registration rights allowing the holders to include their shares in such registration, subject to certain marketing and other limitations. As a result, whenever we propose to file a registration statement under the Securities Act, other than with respect to a registration related to employee benefit plans, the offer and sale of debt securities, or corporate reorganizations or certain other transactions, the holders of these shares are entitled to notice of the registration and have the right, subject to limitations that the underwriters may impose on the number of shares included in the registration, to include their shares in the registration. In an underwritten offering, the managing underwriter, if any, has the right, subject to specified conditions, to limit the number of shares such holders may include.

### ***Expenses of Registration***

We will pay the registration expenses of the holders of the shares registered pursuant to the demand, piggyback and Form S-3 registration rights described above.

### ***Expiration of Registration Rights***

The demand, piggyback and Form S-3 registration rights described above will expire, with respect to any particular stockholder, upon the earlier of five years after the consummation of our initial public offering in November 2014 or when that stockholder can sell all of its shares under Rule 144 of the Securities Act during any 90 day period.

### **Anti-Takeover Effects of Provisions of our Amended and Restated Certificate of Incorporation, our Amended and Restated Bylaws and Delaware Law**

Some provisions of Delaware law and our amended and restated certificate of incorporation and our amended and restated bylaws could make the following transactions more difficult: acquisition of us by means of a tender offer; acquisition of us by means of a proxy contest or otherwise; or removal of our incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in our best interests, including transactions that might result in a premium over the market price for our shares.

These provisions, summarized below, are expected to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

### ***Delaware Anti-Takeover Statute***

We are subject to Section 203 of the Delaware General Corporation Law, which prohibits persons deemed “interested stockholders” from engaging in a “business combination” with a publicly-held Delaware corporation for three years following the date these persons become interested stockholders unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, an “interested stockholder” is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation’s voting stock. Generally, a “business combination” includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by the board of directors, such as discouraging takeover attempts that might result in a premium over the market price of our common stock.

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### ***Undesignated Preferred Stock***

The ability to authorize undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change control of us. These and other provisions may have the effect of deterring hostile takeovers or delaying changes in control or management of our company.

### ***Special Stockholder Meetings***

Our amended and restated bylaws provide that a special meeting of stockholders may be called only by our corporate secretary pursuant to a resolution adopted by a majority of our board of directors.

### ***Requirements for Advance Notification of Stockholder Nominations and Proposals***

Our amended and restated bylaws establish advance notice procedures with respect to stockholder proposals and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of directors.

### ***Elimination of Stockholder Action by Written Consent***

Our amended and restated certificate of incorporation eliminates the right of stockholders to act by written consent without a meeting.

### ***Classified Board; Election and Removal of Directors;***

Our board of directors is divided into three classes. The directors in each class will serve for a three-year term, one class being elected each year by our stockholders, with staggered three-year terms. Only one class of directors will be elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms. Because our stockholders do not have cumulative voting rights, our stockholders holding a majority of the shares of common stock outstanding will be able to elect all of our directors. In addition, a vote of not less than 66 2/3% of all outstanding shares of our capital stock is required for removal of a director only for cause (and a director may only be removed for cause). This system of electing and removing directors may tend to discourage a third party from making a tender offer or otherwise attempting to obtain control of us, because it generally makes it more difficult for stockholders to replace a majority of the directors.

### ***Choice of Forum***

Our amended and restated certificate of incorporation provides that unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law; or any action asserting a claim against us that is governed by the internal affairs doctrine.

### ***Amendment of Charter Provisions***

The amendment of any of the above provisions, except for the provision making it possible for our board of directors to issue “blank check” preferred stock, would require approval by holders of at least 66 2/3% of the voting power of our then outstanding voting stock.

The provisions of the Delaware General Corporation Law, our amended and restated certificate of incorporation and our amended and restated bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our

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common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in our management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

### **Limitations of Liability and Indemnification Matters**

Our amended and restated certificate of incorporation contains provisions that limit the liability of our directors for monetary damages to the fullest extent permitted by Delaware law. Consequently, our directors will not be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duties as directors, except liability for:

- any breach of the director's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the Delaware General Corporation Law; or
- any transaction from which the director derived an improper personal benefit.

Our amended and restated certificate of incorporation and our amended and restated bylaws provide that we are required to indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law. Our amended and restated bylaws also provide that we may advance expenses incurred by a director or officer in advance of the final disposition of any action or proceeding, and permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in that capacity regardless of whether we would otherwise be permitted to indemnify him or her under Delaware law. We have entered and expect to continue to enter into agreements to indemnify our directors, executive officers and other employees as determined by our board of directors. With specified exceptions, these agreements provide for indemnification for related expenses including, among other things, attorneys' fees, judgments, fines and settlement amounts incurred by any of these individuals in any action or proceeding. We believe that these bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers. We also maintain directors' and officers' liability insurance.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against our directors and officers for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and our stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damage.

### **NASDAQ Listing**

Our common stock is listed on The NASDAQ Global Market under the symbol "CHRS."

### **Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is Wells Fargo Shareowner Services. The transfer agent and registrar's address is Wells Fargo Shareowner Services, Attn: Manager of Account Administration, 1110 Centre Pointe Curve, Suite 101, Mendota Heights, MN 55120-4101.

## SHARES ELIGIBLE FOR FUTURE SALE

Future sales of our common stock, including shares issued upon the exercise of outstanding options, in the public market after this offering, or the perception that those sales may occur, could cause the prevailing market price for our common stock to fall or impair our ability to raise equity capital in the future. As described below, only a limited number of shares of our common stock will be available for sale in the public market for a period of several months after consummation of this offering due to contractual and legal restrictions on resale described below. Future sales of our common stock in the public market either before (to the extent permitted) or after restrictions lapse, or the perception that those sales may occur, could adversely affect the prevailing market price of our common stock at such time and our ability to raise equity capital at a time and price we deem appropriate.

### Sale of Restricted Shares

Based on the number of shares of our common stock outstanding as of December 31, 2014, and the sale by us of \_\_\_\_\_ shares based on the assumed offering price of \$ \_\_\_\_\_, the last reported sale price of our common stock on The NASDAQ Global Market on \_\_\_\_\_, 2015, upon the closing of this offering and assuming no exercise of the underwriters' option to purchase additional shares of common stock, as well as no exercise of any of our other outstanding options, we will have outstanding an aggregate of approximately \_\_\_\_\_ shares of common stock. Of these shares, all of the shares of common stock sold in our initial public offering (other than any shares purchased by our then-existing investors, including the limited partners of such investors and one of our executive officers) and to be sold in this offering, including both the shares sold by us, and any shares sold upon exercise of the underwriters' option to purchase additional shares, will be freely tradable in the public market without restriction or further registration under the Securities Act, unless the shares are held by any of our "affiliates" as such term is defined in Rule 144 of the Securities Act. All remaining shares of common stock held by existing stockholders immediately prior to the consummation of this offering will be "restricted securities" as such term is defined in Rule 144. These restricted securities were issued and sold by us, or will be issued and sold by us, in private transactions and are eligible for public sale only if registered under the Securities Act or if they qualify for an exemption from registration under the Securities Act, including the exemptions provided by Rule 144 or Rule 701, which rules are summarized below.

### Lock-Up Agreements

In connection with our initial public offering, we, our directors, our executive officers and holders of substantially all of our other then-outstanding shares of common stock or securities convertible into or exchangeable for shares of our common stock agreed, subject to certain exceptions, with the underwriters not to dispose of or hedge any shares of our common stock or securities convertible into or exchangeable for shares of common stock during the period from the date of the lock-up agreement continuing through May 5, 2015, except with the prior written consent of J.P. Morgan Securities LLC and Credit Suisse Securities (USA) LLC.

In connection with this offering, we, and our directors and executive officers and certain stockholders that are affiliated with our directors, collectively holding approximately 33% of our outstanding common stock, have agreed, subject to certain exceptions, with the underwriters not to dispose of or hedge any shares of our common stock or securities convertible into or exchangeable for shares of common stock during the period from the date of the lock-up agreement continuing through the date 60 days after the date of this prospectus for our officers, directors and certain stockholders affiliated with our directors and 90 days after the date of this prospectus for us, except with the prior written consent of J.P. Morgan Securities LLC and Credit Suisse Securities (USA) LLC.

### Rule 144

In general, under Rule 144, as currently in effect, a person (or persons whose shares are required to be aggregated) who is not deemed to have been one of our "affiliates" for purposes of Rule 144 at any time during the three months preceding a sale, and who has beneficially owned restricted securities within the meaning of Rule 144 for at least six months, including the holding period of any prior owner other than one of our "affiliates," is entitled to sell those shares in the public market (subject to the lock-up agreement referred to above, if applicable) without complying with the manner of sale, volume limitations or notice provisions of



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Rule 144, but subject to compliance with the public information requirements of Rule 144. If such a person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than “affiliates,” then such person is entitled to sell such shares in the public market without complying with any of the requirements of Rule 144 (subject to the lock-up agreement referred to above, if applicable). In general, under Rule 144, as currently in effect, once we have been subject to the public company reporting requirements of the Exchange Act for at least 90 days, our “affiliates,” as defined in Rule 144, who have beneficially owned the shares proposed to be sold for at least six months are entitled to sell in the public market, upon expiration of any applicable lock-up agreements and within any three-month period, a number of those shares of our common stock that does not exceed the greater of:

- 1% of the number of common shares then outstanding, which will equal approximately \_\_\_\_\_ shares of common stock immediately after this offering (calculated as of December 31, 2014 on the basis of the assumptions described above); or
- the average weekly trading volume of our common stock on The NASDAQ Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale. Such sales under Rule 144 by our “affiliates” or persons selling shares on behalf of our “affiliates” are also subject to certain manner of sale provisions, notice requirements and to the availability of current public information about us. Notwithstanding the availability of Rule 144, the holders of substantially all of our restricted securities have entered into lock-up agreements as referenced above and their restricted securities will become eligible for sale (subject to the above limitations under Rule 144) upon the expiration of the restrictions set forth in those agreements.

### **Rule 701**

In general, under Rule 701 as currently in effect, any of our employees, directors, officers, consultants or advisors who acquired common stock from us in connection with a written compensatory stock or option plan or other written agreement in compliance with Rule 701 under the Securities Act before the effective date of a registration statement under the Securities Act is entitled to rely on Rule 701 to resell such shares in reliance on Rule 144. An affiliate of the issuer can resell shares in reliance on Rule 144 without having to comply with the holding period requirements of Rule 144, and a non-affiliate of the issuer can resell shares in reliance on Rule 144 without having to comply with the holding period requirements of Rule 144 and without regard to the volume of such sales or the availability of public information about the issuer.

The SEC has indicated that Rule 701 will apply to typical stock options granted by an issuer before it becomes subject to the reporting requirements of the Exchange Act, along with the shares acquired upon exercise of such options, including exercises after an issuer becomes subject to the reporting requirements of the Exchange Act. In 2014, we filed a registration statement on Form S-1 under the Securities Act to register shares in connection with our initial public offering and a registration statement on Form S-8 under the Securities Act to register all of the shares of our common stock subject to outstanding options and other awards issuable pursuant to our 2010 Stock Incentive Plan and 2014 Equity Incentive Award Plan.

### **Registration Rights**

Based on the number of shares outstanding as of December 31, 2014, the holders of approximately 21.3 million shares of our common stock, or their transferees, are subject to any lock-up agreements they have entered into, entitled to certain rights with respect to the registration of the offer and sale of those shares under the Securities Act. For a description of these registration rights, please see the section titled “Description of Capital Stock — Registration Rights.” If the offer and sale of these shares are registered, they will be freely tradable without restriction under the Securities Act.

### **Stock Plans**

We have filed with the SEC a registration statement on Form S-8 under the Securities Act covering the shares of common stock that we may initially issue upon exercise of outstanding options reserved for issuance

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under our 2010 Stock Incentive Plan, as amended, and our 2014 Equity Incentive Award Plan, as well as any shares we may reserve for issuance pursuant to our Employee Stock Purchase Plan. Such registration statement was filed and became effective in November 2014. Accordingly, shares registered under such registration statement are available for sale in the open market, subject to Rule 144 volume limitations and the lock-up agreements described above, if applicable.

## MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS

The following discussion is a summary of the material U.S. federal income tax consequences to Non-U.S. Holders (as defined below) of the purchase, ownership and disposition of our common stock issued pursuant to this offering, but does not purport to be a complete analysis of all potential tax effects. The effects of other U.S. federal tax laws, such as estate and gift tax laws, and any applicable state, local or non-U.S. tax laws are not discussed. This discussion is based on the U.S. Internal Revenue Code of 1986, as amended, or the Code, Treasury Regulations promulgated thereunder, judicial decisions, and published rulings and administrative pronouncements of the U.S. Internal Revenue Service, or the IRS, in each case in effect as of the date hereof. These authorities may change or be subject to differing interpretations. Any such change or differing interpretation may be applied retroactively in a manner that could adversely affect a Non-U.S. Holder. We have not sought and will not seek any rulings from the IRS regarding the matters discussed below. There can be no assurance the IRS or a court will not take a contrary position to that discussed below regarding the tax consequences of the purchase, ownership and disposition of our common stock.

This discussion is limited to Non-U.S. Holders that hold our common stock as a “capital asset” within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all U.S. federal income tax consequences relevant to a Non-U.S. Holder’s particular circumstances, including the impact of the Medicare contribution tax on net investment income. In addition, it does not address consequences relevant to Non-U.S. Holders subject to special rules, including, without limitation:

- U.S. expatriates and former citizens or long-term residents of the United States;
- persons subject to the alternative minimum tax;
- persons holding our common stock as part of a hedge, straddle or other risk reduction strategy or as part of a conversion transaction or other integrated investment;
- banks, insurance companies, and other financial institutions;
- brokers, dealers or traders in securities;
- “controlled foreign corporations,” “passive foreign investment companies,” and corporations that accumulate earnings to avoid U.S. federal income tax;
- partnerships or other entities or arrangements treated as partnerships for U.S. federal income tax purposes (and investors therein);
- tax-exempt organizations or governmental organizations;
- persons deemed to sell our common stock under the constructive sale provisions of the Code; and
- tax-qualified retirement plans.

If an entity treated as a partnership for U.S. federal income tax purposes holds our common stock, the tax treatment of a partner in the partnership will depend on the status of the partner, the activities of the partnership and certain determinations made at the partner level. Accordingly, partnerships holding our common stock and the partners in such partnerships should consult their tax advisors regarding the U.S. federal income tax consequences to them.

**INVESTORS SHOULD CONSULT THEIR TAX ADVISORS WITH RESPECT TO THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS AS WELL AS ANY TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK ARISING UNDER THE U.S. FEDERAL ESTATE OR GIFT TAX LAWS OR UNDER THE LAWS OF ANY STATE, LOCAL OR NON-U.S. TAXING JURISDICTION OR UNDER ANY APPLICABLE INCOME TAX TREATY.**

### **Definition of a Non-U.S. Holder**

For purposes of this discussion, a “Non-U.S. Holder” is any beneficial owner of our common stock that is neither a “U.S. person” nor an entity treated as a partnership for U.S. federal income tax purposes. A U.S. person is any person that, for U.S. federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation created or organized under the laws of the United States, any state thereof or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust that (1) is subject to the primary supervision of a U.S. court and all substantial decisions of which are controlled by one or more “United States persons” (within the meaning of Section 7701(a)(30) of the Code), or (2) has a valid election in effect to be treated as a United States person for U.S. federal income tax purposes.

### **Distributions**

As described in the section entitled “Dividend Policy,” we do not anticipate paying any cash dividends in the foreseeable future. However, if we do make distributions of cash or property on our common stock, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and first be applied against and reduce a Non-U.S. Holder’s adjusted tax basis in its common stock, but not below zero. Any excess will be treated as capital gain and will be treated as described below under “— Sale or Other Taxable Disposition.”

Subject to the discussion below on effectively connected income, dividends paid to a Non-U.S. Holder will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends (or such lower rate specified by an applicable income tax treaty, provided the Non-U.S. Holder furnishes a valid IRS Form W-8BEN or W-8BEN-E (or other applicable documentation) certifying qualification for the lower treaty rate). A Non-U.S. Holder that does not timely furnish the required documentation, but that qualifies for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. Holders should consult their tax advisors regarding their entitlement to benefits under any applicable income tax treaty.

If dividends paid to a Non-U.S. Holder are effectively connected with the Non-U.S. Holder’s conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such dividends are attributable), the Non-U.S. Holder will be exempt from the U.S. federal withholding tax described above. To claim the exemption, the Non-U.S. Holder must furnish to the applicable withholding agent a valid IRS Form W-8ECI, certifying that the dividends are effectively connected with the Non-U.S. Holder’s conduct of a trade or business within the United States.

Any such effectively connected dividends will be subject to U.S. federal income tax on a net income basis at the regular graduated rates. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected dividends, as adjusted for certain items. Non-U.S. Holders should consult their tax advisors regarding any applicable tax treaties that may provide for different rules.

## **Sale or Other Taxable Disposition**

A Non-U.S. Holder will not be subject to U.S. federal income tax on any gain realized upon the sale or other taxable disposition of our common stock unless:

- the gain is effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such gain is attributable);
- the Non-U.S. Holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition and certain other requirements are met; or
- our common stock constitutes a U.S. real property interest, or a USRPI, by reason of our status as a U.S. real property holding corporation, or a USRPHC, for U.S. federal income tax purposes.

Gain described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis at the regular graduated rates. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected gain, as adjusted for certain items.

Gain described in the second bullet point above will be subject to U.S. federal income tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty), which may be offset by certain U.S.-source capital losses of the Non-U.S. Holder (even though the individual is not considered a resident of the United States), provided the Non-U.S. Holder has timely filed U.S. federal income tax returns with respect to such losses.

With respect to the third bullet point above, we believe we currently are not, and do not anticipate becoming, a USRPHC. Because the determination of whether we are a USRPHC depends, however, on the fair market value of our USRPIs relative to the fair market value of our non-U.S. real property interests and our other business assets, there can be no assurance we currently are not a USRPHC or will not become one in the future. Even if we are or were to become a USRPHC, gain arising from the sale or other taxable disposition by a Non-U.S. Holder of our common stock will not be subject to U.S. federal income tax if our common stock is "regularly traded," as defined by applicable Treasury Regulations, on an established securities market, and such Non-U.S. Holder owned, actually and constructively, 5% or less of our common stock throughout the shorter of the five-year period ending on the date of the sale or other taxable disposition or the Non-U.S. Holder's holding period.

Non-U.S. Holders should consult their tax advisors regarding any applicable tax treaties that may provide for different rules.

## **Information Reporting and Backup Withholding**

Payments of dividends on our common stock will not be subject to backup withholding, provided the applicable withholding agent does not have actual knowledge or reason to know the holder is a United States person and the holder either certifies its non-U.S. status, such as by furnishing a valid IRS Form W-8BEN, W-8BEN-E or W-8ECI, or otherwise establishes an exemption. However, information returns are required to be filed with the IRS in connection with any dividends on our common stock paid to the Non-U.S. Holder, regardless of whether any tax was actually withheld. In addition, proceeds of the sale or other taxable disposition of our common stock within the United States or conducted through certain U.S.-related brokers generally will not be subject to backup withholding or information reporting, if the applicable withholding agent receives the certification described above and does not have actual knowledge or reason to know that such holder is a United States person, or the holder otherwise establishes an exemption. Proceeds of a disposition of our common stock conducted through a non-U.S. office of a non-U.S. broker that does not have certain enumerated relationships with the United States generally will not be subject to backup withholding or information reporting.

Copies of information returns that are filed with the IRS may also be made available under the provisions of an applicable treaty or agreement to the tax authorities of the country in which the Non-U.S. Holder resides or is established.

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Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a Non-U.S. Holder's U.S. federal income tax liability, provided the required information is timely furnished to the IRS.

### **Additional Withholding Tax on Payments Made to Foreign Accounts**

Withholding taxes may be imposed under Sections 1471 to 1474 of the Code, which Sections are commonly referred to as the Foreign Account Tax Compliance Act, or FATCA, on certain types of payments made to non-U.S. financial institutions and certain other non-U.S. entities. Specifically, a 30% withholding tax will be imposed on dividends on, or gross proceeds from the sale or other disposition of, our common stock paid to a "foreign financial institution" or a "non-financial foreign entity" (each as defined in the Code), unless (1) the foreign financial institution undertakes certain diligence and reporting obligations, (2) the non-financial foreign entity either certifies it does not have any "substantial United States owners" (as defined in the Code) or furnishes identifying information regarding each substantial United States owner, or (3) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. If the payee is a foreign financial institution and is subject to the diligence and reporting requirements in (1) above, it must enter into an agreement with the U.S. Department of the Treasury requiring, among other things, that it undertake to identify accounts held by certain "specified United States persons" or "United States-owned foreign entities" (each as defined in the Code), annually report certain information about such accounts, and withhold 30% on certain payments to non-compliant foreign financial institutions and certain other account holders. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing FATCA may be subject to different rules.

Under the applicable Treasury Regulations, withholding under FATCA generally applies to payments of dividends on our common stock made on or after July 1, 2014, and will apply to payments of gross proceeds from the sale or other disposition of such stock on or after January 1, 2017.

Prospective investors should consult their tax advisors regarding the potential application of withholding under FATCA to their investment in our common stock.

## UNDERWRITING

We are offering the shares of common stock described in this prospectus through a number of underwriters. J.P. Morgan Securities LLC and Credit Suisse Securities (USA) LLC are acting as joint book-running managers of the offering and as representatives of the underwriters. We have entered into an underwriting agreement with the underwriters. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to the underwriters, and each underwriter has severally agreed to purchase, at the public offering price less the underwriting discounts and commissions set forth on the cover page of this prospectus, the number of shares of common stock listed next to its name in the following table:

<u>Name</u>	<u>Number of Shares</u>
J.P. Morgan Securities LLC	
Credit Suisse Securities (USA) LLC	
Cowen and Company, LLC	
Total	

The underwriters are committed to purchase all the common shares offered by us if they purchase any shares. The underwriting agreement also provides that if an underwriter defaults, the purchase commitments of non-defaulting underwriters may also be increased or the offering may be terminated.

The underwriters propose to offer the common shares directly to the public at the public offering price set forth on the cover page of this prospectus and to certain dealers at that price less a concession not in excess of \$ per share. After the public offering of the shares, the offering price and other selling terms may be changed by the underwriters. Sales of shares made outside of the United States may be made by affiliates of the underwriters.

The underwriters have an option to buy up to additional shares of common stock from us to cover sales of shares by the underwriters which exceed the number of shares specified in the table above. The underwriters have 30 days from the date of this prospectus to exercise this option. If any shares are purchased with this option, the underwriters will purchase shares in approximately the same proportion as shown in the table above. If any additional shares of common stock are purchased, the underwriters will offer the additional shares on the same terms as those on which the shares are being offered.

The underwriting fee is equal to the public offering price per share of common stock less the amount paid by the underwriters to us per share of common stock. The underwriting fee is \$ per share. The following table shows the per share and total underwriting discounts and commissions to be paid to the underwriters assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

	<u>Without option exercise</u>	<u>With full option exercise</u>
Per Share	\$	\$
Total	\$	\$

We estimate that the total expenses of this offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding the underwriting discounts and commissions, will be approximately \$ million. We have agreed to reimburse the underwriters for expenses of \$ relating to the clearance of this offering with the Financial Industry Regulatory Authority.

A prospectus in electronic format may be made available on the web sites maintained by one or more underwriters or selling group members, if any, participating in the offering. The underwriters may agree to allocate a number of shares to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters and selling group members that may make Internet distributions on the same basis as other allocations.

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We have agreed that we will not (i) offer, pledge, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase or otherwise dispose of, directly or indirectly, or file with the Securities and Exchange Commission a registration statement under the Securities Act of 1933, as amended, or the Securities Act, relating to, any shares of our common stock or securities convertible into or exchangeable or exercisable for any shares of our common stock, or publicly disclose the intention to make any offer, sale, pledge, disposition or filing, or (ii) enter into any swap or other arrangement that transfers all or a portion of the economic consequences associated with the ownership of any shares of common stock or any such other securities (regardless of whether any of these transactions are to be settled by the delivery of shares of common stock or such other securities, in cash or otherwise), in each case without the prior written consent of J.P. Morgan Securities LLC and Credit Suisse Securities (USA) LLC for a period of 90 days after the date of this prospectus, other than (a) the shares of our common stock to be sold hereunder, (b) any shares of our common stock issued upon the exercise of options granted under our existing plans, (c) any options and other awards granted under our existing plans, (d) the filing of any Form S-8 relating to shares of our common stock granted pursuant to or reserved for issuance under our existing plans, (e) the issuance of shares of our common stock in connection with the acquisition by us or any of our subsidiaries of the securities, business, properties or other assets of another person or entity or pursuant to any employee benefit plan assumed by the us or any of our subsidiaries in connection with such acquisition or (f) the issuance of shares of our common stock in connection with joint ventures, commercial relationships or other strategic transactions; *provided that*, in the case of clauses (e) and (f), the aggregate number of shares of our outstanding common stock or other securities (including securities convertible into or exchangeable or exercisable for outstanding common stock or other securities) issued in all such acquisitions and transactions, on an as-converted, as-exchanged and as-exercised basis, does not exceed 5% of our common stock outstanding following this offering.

Our directors and our executive officers and certain stockholders that are affiliated with our directors have entered into lock-up agreements with the underwriters prior to the commencement of this offering pursuant to which each of these persons or entities, with limited exceptions, for a period of 60 days after the date of this prospectus, may not, without the prior written consent of J.P. Morgan Securities LLC and Credit Suisse Securities (USA) LLC, (1) offer, pledge, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase or otherwise transfer or dispose of, directly or indirectly, any shares of our common stock or any securities convertible into or exercisable or exchangeable for our common stock (including, without limitation, common stock or such other securities which may be deemed to be beneficially owned by such directors, executive officers, managers and members in accordance with the rules and regulations of the Securities and Exchange Commission, or SEC, and securities which may be issued upon exercise of a stock option or warrant) or (2) enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of the common stock or such other securities, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of common stock or such other securities, in cash or otherwise, or (3) make any demand for or exercise any right with respect to the registration of any shares of our common stock or any security convertible into or exercisable or exchangeable for our common stock. These agreements will not restrict:

- our directors and our executive officers and certain stockholders that are affiliated with our directors from entering into 10b5-1 trading plans, provided that (1) such plan does not provide for any transfers of our common stock during the restricted period and (2) no filing under the Exchange Act or other public announcement shall be required or shall be made voluntarily during the restricted period; or
- our directors and our executive officers and certain stockholders that are affiliated with our directors from transferring or distributing shares acquired in this offering or in the open market after this offering, provided that no filing under the Exchange Act or other public announcement shall be required or shall be made voluntarily during the restricted period.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act of 1933.



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Our common stock is listed on The NASDAQ Global Market under the symbol “CHRS”.

In connection with this offering, the underwriters may engage in stabilizing transactions, which involves making bids for, purchasing and selling shares of common stock in the open market for the purpose of preventing or retarding a decline in the market price of the common stock while this offering is in progress. These stabilizing transactions may include making short sales of the common stock, which involves the sale by the underwriters of a greater number of shares of common stock than they are required to purchase in this offering, and purchasing shares of common stock on the open market to cover positions created by short sales. Short sales may be “covered” shorts, which are short positions in an amount not greater than the underwriters’ option referred to above, or may be “naked” shorts, which are short positions in excess of that amount. The underwriters may close out any covered short position either by exercising their option, in whole or in part, or by purchasing shares in the open market. In making this determination, the underwriters will consider, among other things, the price of shares available for purchase in the open market compared to the price at which the underwriters may purchase shares through the option. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market that could adversely affect investors who purchase in this offering. To the extent that the underwriters create a naked short position, they will purchase shares in the open market to cover the position.

The underwriters have advised us that, pursuant to Regulation M of the Securities Act of 1933, they may also engage in other activities that stabilize, maintain or otherwise affect the price of the common stock, including the imposition of penalty bids. This means that if the representatives of the underwriters purchase common stock in the open market in stabilizing transactions or to cover short sales, the representatives can require the underwriters that sold those shares as part of this offering to repay the underwriting discount received by them.

These activities may have the effect of raising or maintaining the market price of the common stock or preventing or retarding a decline in the market price of the common stock, and, as a result, the price of the common stock may be higher than the price that otherwise might exist in the open market. If the underwriters commence these activities, they may discontinue them at any time. The underwriters may carry out these transactions on The NASDAQ Global Market, in the over-the-counter market or otherwise.

Certain of the underwriters and their affiliates have engaged in and may provide to us and our affiliates from time to time in the future certain commercial banking, financial advisory, investment banking and other services for us and such affiliates in the ordinary course of their business, for which they may receive customary fees and commissions. In addition, from time to time, certain of the underwriters and their affiliates may effect transactions for their own account or the account of customers and hold on behalf of themselves or their customers, long or short positions in our debt or equity securities or loans, and may do so in the future.

## **Selling Restrictions**

### ***General***

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

### **United Kingdom**

This document is only being distributed to and is only directed at (i) persons who are outside the United Kingdom or (ii) to investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, the Order, or (iii) high net worth entities and other persons to whom it may lawfully be communicated, falling with Article 49(2)(a) to (d) of the Order, or all such persons together, relevant persons. The securities are only available to, and any invitation, offer or agreement to subscribe, purchase or otherwise acquire such securities will be engaged in only with, relevant persons. Any person who is not a relevant person should not act or rely on this document or any of its contents.

### **European Economic Area**

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive, each, a Relevant Member State, from and including the date on which the European Union Prospectus Directive, or the E.U. Prospectus Directive, was implemented in that Relevant Member State, or the Relevant Implementation Date, an offer of securities described in this prospectus may not be made to the public in that Relevant Member State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Relevant Member State or, where appropriate, approved in another Relevant Member State and notified to the competent authority in that Relevant Member State, all in accordance with the E.U. Prospectus Directive, except that, with effect from and including the Relevant Implementation Date, an offer of securities described in this prospectus may be made to the public in that Relevant Member State at any time:

- to any legal entity which is a qualified investor as defined under the E.U. Prospectus Directive;
- to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150 natural or legal persons (other than qualified investors as defined in the E.U. Prospectus Directive); or
- in any other circumstances falling within Article 3(2) of the E.U. Prospectus Directive, provided that no such offer of securities described in this prospectus shall result in a requirement for the publication by us of a prospectus pursuant to Article 3 of the E.U. Prospectus Directive.

For the purposes of this provision, the expression an “offer of securities to the public” in relation to any securities in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the securities to be offered so as to enable an investor to decide to purchase or subscribe for the securities, as the same may be varied in that Member State by any measure implementing the E.U. Prospectus Directive in that Member State. The expression “E.U. Prospectus Directive” means Directive 2003/71/EC (and any amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State) and includes any relevant implementing measure in each Relevant Member State, and the expression “2010 PD Amending Directive” means Directive 2010/73/EU.

### **Switzerland**

The shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or the SIX, or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this prospectus nor any other offering or marketing material relating to the shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this prospectus nor any other offering or marketing material relating to the offering, the Company, or the shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of shares will not be supervised by, the Swiss Financial Market

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Supervisory Authority FINMA, and the offer of shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or the CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of shares.

### ***Hong Kong***

The shares have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (a) to “professional investors” as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance; or (b) in other circumstances which do not result in the document being a “prospectus” as defined in the Companies Ordinance (Cap. 32) of Hong Kong or which do not constitute an offer to the public within the meaning of that Ordinance. No advertisement, invitation or document relating to the shares has been or may be issued or has been or may be in the possession of any person for the purposes of issue, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to “professional investors” as defined in the Securities and Futures Ordinance and any rules made thereunder.

### ***Singapore***

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale or invitation for subscription or purchase, of shares may not be circulated or distributed, nor may the shares be offered or sold or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore, or SFA, (ii) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275, of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is: (a) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or (b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor, securities (as defined in Section 239(1) of the SFA) of that corporation or the beneficiaries’ rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares pursuant to an offer made under Section 275 of the SFA except: (1) to an institutional investor or to a relevant person defined in Section 275(2) of the SFA, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA; (2) where no consideration is or will be given for the transfer; (3) where the transfer is by operation of law; (4) as specified in Section 276(7) of the SFA; or (5) as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore.

### ***Japan***

The shares have not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948, as amended) and, accordingly, will not be offered or sold, directly or indirectly, in Japan, or for the benefit of any Japanese Person or to others for re-offering or resale, directly or indirectly, in Japan or to any Japanese Person, except in compliance with all applicable laws, regulations and ministerial guidelines promulgated by relevant Japanese governmental or regulatory authorities in effect at the relevant time. For the purposes of this paragraph, “Japanese Person” shall mean any person resident in Japan, including any corporation or other entity organized under the laws of Japan.

## LEGAL MATTERS

The validity of the issuance of our common stock offered in this prospectus will be passed upon for us by Latham & Watkins LLP, Menlo Park, California. Davis Polk & Wardwell LLP, Menlo Park, California is acting as counsel for the underwriters in connection with this offering. Latham & Watkins LLP and certain attorneys and investment funds affiliated with the firm collectively own an aggregate of 5,242 shares of common stock.

## EXPERTS

Ernst & Young LLP, independent registered public accounting firm, has audited our consolidated financial statements at December 31, 2013 and 2014, and for each of the three years in the period ended December 31, 2014, as set forth in their report. We have included our financial statements in the prospectus and elsewhere in the registration statement in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

## WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits and schedules filed therewith. Whenever a reference is made in this prospectus to any of our contracts, agreements or other documents, the reference may not be complete and you should refer to the exhibits that are a part of the registration statement or the exhibits to the reports or other documents incorporated by reference in this prospectus for a copy of such contract, agreement or other document. Statements contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the registration statement. For further information with respect to Coherus BioSciences, Inc. and the common stock offered hereby, reference is made to the registration statement and the exhibits and schedules filed therewith. A copy of the registration statement and the exhibits and schedules filed therewith may be inspected without charge at the public reference room maintained by the SEC, located at 100 F Street N.E., Room 1580, Washington, D.C. 20549, and copies of all or any part of the registration statement may be obtained from such offices upon the payment of the fees prescribed by the SEC. Please call the SEC at 1-800-SEC-0330 for further information about the public reference room. The SEC also maintains a website that contains reports, proxy and information statements and other information regarding registrants that file electronically with the SEC. The address is [www.sec.gov](http://www.sec.gov).

We are subject to the information and periodic reporting requirements of the Exchange Act and, in accordance therewith, file periodic reports, proxy statements and other information with the SEC. Such periodic reports, proxy statements and other information are available for inspection and copying at the public reference room and website of the SEC referred to above. We maintain a website at [www.coherus.com](http://www.coherus.com). You may access our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act with the SEC free of charge at our website as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. The reference to our website address does not constitute incorporation by reference of the information contained on our website, and you should not consider the contents of our website in making an investment decision with respect to our common stock.

## **INCORPORATION OF CERTAIN INFORMATION BY REFERENCE**

The following documents filed by us with the SEC are incorporated by reference into this prospectus. You should carefully read and consider all of these documents before making an investment decision:

- Our Annual Report on Form 10-K for the year ended December 31, 2014 filed with the SEC on March 23, 2015;
- Our Current Report on Form 8-K filed on March 11, 2015; and
- The description of our common stock contained in our registration statement on Form 8-A filed with the SEC on November 3, 2014, including any amendments or reports filed for the purpose of updating such description.

Nothing in this prospectus shall be deemed to incorporate information deemed furnished but not filed with the SEC. Any statement contained in a document that is incorporated by reference will be modified or superseded for all purposes to the extent that a statement contained in this prospectus modifies or is contrary to that previous statement. Any statement so modified or superseded will not be deemed a part of this prospectus except as so modified or superseded.

We will provide to each person, including any beneficial owner, to whom a prospectus is delivered, a copy of any or all of the reports or documents that have been incorporated by reference into this prospectus but not delivered with this prospectus. We will provide these reports upon written or oral request at no cost to the requester. Please direct your request, either in writing or by telephone, to the General Counsel, 201 Redwood Shores Parkway, Suite 200, Redwood City, California 94065, telephone number (650) 649-3530. In addition, copies of the documents incorporated herein by reference may be accessed at our website at [www.coherus.com](http://www.coherus.com). The reference to our website address does not constitute incorporation by reference of the information contained on our website, and you should not consider the contents of our website in making an investment decision with respect to our common stock.

**\$100,000,000**



**Common Stock**

**Prospectus**

**J.P. Morgan**

**Credit Suisse**

**Cowen and Company**

, 2015

**PART II**  
**Information Not Required in Prospectus**

**Item 13. Other Expenses of Issuance and Distribution.**

The following table sets forth the costs and expenses, other than the underwriting discounts and commissions, payable by the registrant in connection with the sale of Common Stock being registered. All amounts are estimates except for the Securities and Exchange Commission, or SEC, registration fee, and the FINRA filing fee.

<u>Item</u>	<u>Amount to be paid</u>
SEC registration fee	\$ 13,363
FINRA filing fee	\$ 17,750
The NASDAQ Global Market supplemental listing fee	*
Printing and engraving expenses	*
Legal fees and expenses	*
Accounting fees and expenses	*
Blue Sky, qualification fees and expenses	*
Transfer agent fees and expenses	*
Miscellaneous expenses	*
Total	<u>\$ *</u>

\* To be filed by amendment.

**Item 14. Indemnification of Directors and Officers.**

As permitted by Section 102 of the Delaware General Corporation Law, we have adopted provisions in our amended and restated certificate of incorporation and bylaws that limit or eliminate the personal liability of our directors for a breach of their fiduciary duty of care as a director. The duty of care generally requires that, when acting on behalf of the corporation, directors exercise an informed business judgment based on all material information reasonably available to them. Consequently, a director will not be personally liable to us or our stockholders for monetary damages for breach of fiduciary duty as a director, except for liability for:

- any breach of the director's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- any act related to unlawful stock repurchases, redemptions or other distributions or payment of dividends; or
- any transaction from which the director derived an improper personal benefit.

These limitations of liability do not affect the availability of equitable remedies such as injunctive relief or rescission. Our amended and restated certificate of incorporation also authorizes us to indemnify our officers, directors and other agents to the fullest extent permitted under Delaware law.

As permitted by Section 145 of the Delaware General Corporation Law, our amended and restated bylaws provide that:

- we may indemnify our directors, officers, and employees to the fullest extent permitted by the Delaware General Corporation Law, subject to limited exceptions;
- we may advance expenses to our directors, officers and employees in connection with a legal proceeding to the fullest extent permitted by the Delaware General Corporation Law, subject to limited exceptions; and
- the rights provided in our amended and restated bylaws are not exclusive.

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Our amended and restated certificate of incorporation, filed as Exhibit 3.1 hereto, and our amended and restated bylaws, filed as Exhibit 3.2 hereto, provide for the indemnification provisions described above and elsewhere herein. We have entered into separate indemnification agreements with our directors and officers which may be broader than the specific indemnification provisions contained in the Delaware General Corporation Law. These indemnification agreements generally require us, among other things, to indemnify our officers and directors against liabilities that may arise by reason of their status or service as directors or officers, other than liabilities arising from willful misconduct. These indemnification agreements also generally require us to advance any expenses incurred by the directors or officers as a result of any proceeding against them as to which they could be indemnified. In addition, we have purchased a policy of directors' and officers' liability insurance that insures our directors and officers against the cost of defense, settlement or payment of a judgment in some circumstances. These indemnification provisions and the indemnification agreements may be sufficiently broad to permit indemnification of our officers and directors for liabilities, including reimbursement of expenses incurred, arising under the Securities Act of 1933, as amended, or the Securities Act.

The form of Underwriting Agreement, to be filed as Exhibit 1.1 hereto, provides for indemnification by the underwriters of us and our officers who sign this Registration Statement and directors for specified liabilities, including matters arising under the Securities Act.

### **Item 15. Recent Sales of Unregistered Securities.**

The following list sets forth information as to all securities we have sold since January 1, 2012, which were not registered under the Securities Act.

1. In January 2012, we issued an aggregate of 5,251,792 shares of our Series B convertible preferred stock at a price per share of \$6.9750 for a combination of cash and conversion of \$10.6 million in convertible debt, for an aggregate gross consideration of \$36.6 million, to 18 accredited investors. An aggregate of 501,799 shares were issued as consideration for past and future services provided to the Company by one investor, for an aggregate value of \$3.5 million, which was determined (i) exceeded the par value of such shares and (ii) was no less than the aggregate purchase price for such shares.
2. In April 2012, we issued an aggregate of 57,347 shares of our Series B convertible preferred stock at a price per share of \$0.0167, for an aggregate gross consideration of \$956, pursuant to the exercise of outstanding stock purchase warrants to two accredited investors.
3. In December 2012, we issued an aggregate of 2,872,442 shares of our Series B convertible preferred stock at a price per share of \$6.9750 for an aggregate gross consideration of \$20.0 million, to seven accredited investors. An aggregate of 1,725,472 shares were issued as consideration for past and future services provided to the Company by five investors, for an aggregate value of \$12.0 million, which was determined (i) exceeded the par value of such shares and (ii) was no less than the aggregate purchase price for such shares.
4. From July 2013 through September 2013, in a series of closings, we issued an aggregate of \$9,950,000 in principal amount of secured convertible promissory notes and stock purchase warrants to purchase an aggregate of 4,279,620 shares of Series B convertible preferred stock at an exercise price of \$0.0167 per share to 19 accredited investors. The warrants may be exercised at any time prior to their termination dates, which are seven years from the date of issuance.
5. In February 2014, we issued an aggregate of 252,013 shares of our Series B convertible preferred stock at a price per share of \$6.9749 for an aggregate gross consideration of \$1.8 million, to two accredited investors. An aggregate of 8,172 shares were issued as consideration for past and future services provided to the Company by one investor, for an aggregate value of \$57,000, which was determined (i) exceeded the par value of such shares and (ii) was no less than the aggregate purchase price for such shares.
6. In February 2014, we issued an aggregate of 86,021 shares of our Series B convertible preferred stock in consideration for services rendered to four service providers.



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7. In February 2014, we issued an aggregate of 630,618 shares of our Series B convertible preferred stock to certain stockholders of InteKrin Therapeutics Inc., or InteKrin, in connection with our acquisition of InteKrin. In addition, in March 2015, we released 143,355 shares of our common stock from escrow for issuance to certain former stockholders of InteKrin and issued 358,384 shares of our common stock to certain former stockholders of InteKrin in satisfaction of an earn-out payable under the acquisition agreement with InteKrin.
8. In April and May 2014, we issued an aggregate of 4,451,662 shares of our Series B convertible preferred stock at a price per share of \$0.0167, for an aggregate gross consideration of \$74,209, pursuant to the exercise of outstanding stock purchase warrants to 19 accredited investors.
9. In May 2014, we issued an aggregate of 6,556,978 shares of our Series C convertible preferred stock at a price per share of \$10.0020 for a combination of cash and conversion of \$10.6 million in convertible debt, for an aggregate gross consideration of \$65.6 million, to 35 accredited investors. An aggregate of 9,997 shares were issued as consideration for past and future services provided to the Company by three investors, for an aggregate value of \$100,000.00, which was determined (i) exceeded the par value of such shares and (ii) was no less than the aggregate purchase price for such shares.
10. Prior to filing our registration statement on Form S-8 in November 2014, we granted stock options and stock awards to employees, directors and consultants under our 2010 Equity Incentive Plan, as amended, covering an aggregate of 5,358,088 shares of common stock, at a weighted-average exercise price of \$2.7225 per share. Of these, options covering an aggregate of 599,889 shares were canceled without being exercised.
11. Prior to filing our registration statement on Form S-8 in November 2014, we sold an aggregate of 52,224 shares of common stock to employees, directors and consultants for cash consideration in the aggregate amount of \$26,070 upon the exercise of stock options and stock awards.

We claimed exemption from registration under the Securities Act for the sales and issuances of securities in the transactions described in paragraphs (1)- (10) above under Section 4(a)(2) of the Securities Act in that such sales and issuances did not involve a public offering or under Rule 701 promulgated under the Securities Act, in that they were offered and sold either pursuant to written compensatory plans or pursuant to a written contract relating to compensation, as provided by Rule 701.

### **Item 16. Exhibits and Financial Statement Schedules.**

- (a) **Exhibits.** See the Exhibit Index attached to this registration statement, which is incorporated by reference herein.
- (b) **Financial Statement Schedules.** Schedules not listed above have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements incorporated by reference or notes thereto.

### **Item 17. Undertakings.**

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer, or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question of whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

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The undersigned Registrant hereby undertakes that:

1. For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this Registration Statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this Registration Statement as of the time it was declared effective.
2. For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

The undersigned Registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreement certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant has duly caused this Registration Statement on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized, in Redwood City, California, on March 23, 2015.

**COHERUS BIOSCIENCES, INC.**

By: /s/ Dennis M. Lanfear  
Dennis M. Lanfear  
President and Chief Executive Officer

**POWER OF ATTORNEY**

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Dennis M. Lanfear and Jean-Frédéric Viret, and each of them acting individually, as his true and lawful attorneys-in-fact and agents, each with full power of substitution, for him in any and all capacities, to sign any and all amendments to this Registration Statement, including post-effective amendments or any abbreviated registration statement and any amendments thereto filed pursuant to Rule 462(b) increasing the number of securities for which registration is sought, and to file the same, with all exhibits thereto and other documents in connection therewith, with the SEC, granting unto said attorneys-in-fact and agents, with full power of each to act alone, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully for all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or his or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Dennis M. Lanfear</u> Dennis M. Lanfear	Chairman, President and Chief Executive Officer (Principal Executive Officer)	March 23, 2015
<u>/s/ Jean-Frédéric Viret, Ph.D.</u> Jean-Frédéric Viret, Ph.D.	Chief Financial Officer (Principal Financial and Accounting Officer)	March 23, 2015
<u>/s/ James I. Healy, M.D., Ph.D.</u> James I. Healy, M.D., Ph.D.	Director	March 23, 2015
<u>/s/ V. Bryan Lawlis, Ph.D.</u> V. Bryan Lawlis, Ph.D.	Director	March 23, 2015
<u>/s/ Christos Richards</u> Christos Richards	Director	March 23, 2015
<u>/s/ Ali J. Satvat</u> Ali J. Satvat	Director	March 23, 2015

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<u>Signature</u>	<u>Title</u>	<u>Date</u>
<hr/> <p>/s/ August J. Troendle, M.D. August J. Troendle, M.D.</p>	Director	March 23, 2015
<hr/> <p>/s/ Mats Wahlström Mats Wahlström</p>	Director	March 23, 2015
<hr/> <p>/s/ Mary T. Szela Mary T. Szela</p>	Director	March 23, 2015

**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Incorporated by Reference</b>			<b>Filed Herewith</b>
		<b>Form</b>	<b>Date</b>	<b>Number</b>	
1.1*	Form of Underwriting Agreement.				
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	Form of Common Stock Certificate.	S-1/A	10/24/2014	4.2	
4.3	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	
5.1*	Opinion of Latham & Watkins LLP.				
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)	

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<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Incorporated by Reference</u>			<u>Filed Herewith</u>
		<u>Form</u>	<u>Date</u>	<u>Number</u>	
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)	
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)	

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<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Incorporated by Reference</u>			<u>Filed Herewith</u>
		<u>Form</u>	<u>Date</u>	<u>Number</u>	
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)	
23.1	Consent of independent registered public accounting firm.				X
23.2*	Consent of Latham & Watkins LLP (included in Exhibit 5.1).				
24.1	Power of Attorney (included on signature page hereto).				X

\* To be filed by amendment.

† 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.

**Consent of Independent Registered Public Accounting Firm**

We consent to the reference to our firm under the caption "Experts" and to the use of our report dated March 23, 2015, in the Registration Statement (Form S-1 No. 333-00000) and related Prospectus of Coherus BioSciences, Inc. for the registration of shares of its common stock.

/s/ Ernst & Young LLP

Redwood City, California

March 23, 2015