Confidential Draft Amendment Submission No. 2 submitted to the Securities and Exchange Commission on September 15, 2014. This draft registration statement has not been filed publicly with the Securities and Exchange Commission and all information contained herein remains confidential.

**Registration No. 333-**

### UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

### **AMENDMENT NO. 2 TO**

### FORM S-1

**REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933** 

### **COHERUS BIOSCIENCES, INC.**

(Exact name of Registrant as specified in its charter)

Delaware

(Primary Standard Industrial

Classification Code Number) 201 Redwood Shores Parkway, Suite 200

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

Smaller reporting company  $\Box$ 

(State or other jurisdiction of incorporation or organization)

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)

Copies to:

Alan C. Mendelson, Esq. Latham & Watkins LLP 140 Scott Drive Menlo Park, CA 94025 Telephone: (650) 328-4600 Facsimile: (650) 463-2600

Accelerated filer  $\Box$ 

Alan F. Denenberg, Esq. Davis Polk & Wardwell LLP 1600 El Camino Real Menlo Park, CA 94025 Telephone: (650) 752-2000 Facsimile: (650) 752-2111

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.  $\Box$ 

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.  $\Box$ 

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.  $\Box$ 

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.  $\Box$ 

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  $\Box$ 

Non-accelerated filer  $\boxtimes$ (Do not check if a smaller reporting company)

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Proposed maximum aggregate offering price <sup>(1)</sup>	Amount of registration fee
Common Stock, \$0.0001 par value per share	\$	\$

Estimated solely for the purpose of calculating the amount of the registration fee in accordance with Rule 457(o) under the Securities Act of 1933, as amended. Includes shares that the underwriters have (1)the option to purchase.

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.

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The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any jurisdiction where such offer or sale is not permitted

Prospectus

Subject to completion, dated

, 2014

**Credit Suisse** 



### **Common Stock**

This is an initial public offering of common stock by Coherus BioSciences, Inc. We are selling shares of common stock. The initial public offering price is expected to be between \$ and \$ per share.

Prior to this offering, there has been no public market for our common stock. We intend to apply for listing of our common stock on The NASDAQ Global Market under the symbol "CHRS."

We are an "emerging growth company" under applicable Securities and Exchange Commission rules and will be subject to reduced public company reporting requirements.

	Per share	Total
Initial public offering price	\$	\$
Underwriting discounts and commissions <sup>(1)</sup>	\$	\$
Proceeds to Coherus, before expenses	\$	\$

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

We have granted the underwriters an option for a period of 30 days to purchase up to additional shares of common stock.

Investing in our common stock involves a high degree of risk. See "Risk Factors" beginning on page 12.

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

The underwriters expect to deliver the shares of common stock to investors on , 2014.

### J.P. Morgan

### **Cowen and Company**

, 2014

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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 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 is accurate only as of the date on the front of this prospectus, regardless of the time of delivery of this prospectus or any sale of shares of our common stock.

Until , 2014 (the 25<sup>th</sup> day after the date of this prospectus), all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

Coherus BioSciences<sup>®</sup> and our logo are some of our trademarks used in this prospectus. This prospectus also includes 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 <sup>®</sup> and <sup>TM</sup> 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.

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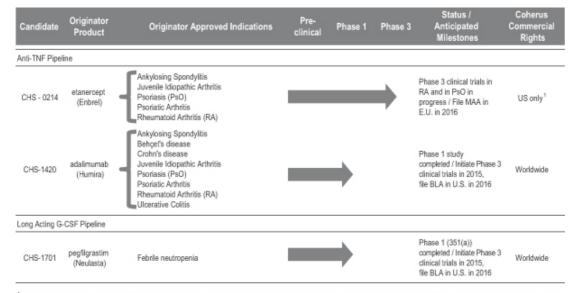
#### PROSPECTUS SUMMARY

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.

#### Overview

We are a late-stage clinical biologics platform company focused on the global biosimilar market. Biosimilars are an emerging class of protein-based therapeutics with high similarity to approved originator products on the basis of various physicochemical and structural properties, as well as in terms of safety, purity and potency. Our goal is to become a global leader in the biosimilar market by leveraging our team's collective expertise in key areas such as process science, analytical characterization, protein production and clinical-regulatory development. Since our founding in 2010, we have advanced 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:



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

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 that we expect will begin Phase 3 clinical trials in the first half of 2015. 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, 24 "blockbuster" biologics, each with annual sales in excess of \$1 billion, will lose 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.
- *Formulation technologies.* The stabilization of proteins in solution is an essential part of obtaining a commercially viable therapeutic. We believe that our investment in proprietary formulation technology will allow us to innovate around certain patent protected formulations, thereby enabling earlier market entry than otherwise would be possible.
- 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, 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.

### 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.

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• *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, and are currently planning to initiate two Phase 3 clinical trials in the first half of 2015. The primary objective of these studies will be to evaluate the efficacy of CHS-1701 in reducing the duration of severe neutropenia in the first cycle of chemotherapy. If results are positive, we intend to file a BLA for CHS-1701 in the United States in 2016. Under the 351(a) (novel biologic) pathway, demonstration of bioequivalence of CHS-1701 to Neulasta is not required. However, to preserve the option to change from the 351(a) (novel biologic) pathway to the 351(k) (biosimilar) pathway, we are making preparations that we believe would enable us to conduct a new pivotal Phase 1 PK / PD study in healthy volunteers, but have not yet made a decision to proceed with this additional study.

### **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 before we can expect to become profitable from sales of our products. 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 this offering, (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 will present only two years of audited financial statements and only two years of related management's discussion and analysis of financial condition and results of operations;
- we will avail 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 are irrevocably electing to "opt out" of the extended transition periods available under the JOBS Act for complying with new or revised accounting standards.

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2014 and excludes the following:

	THE OFFERING
Issuer	Coherus BioSciences, Inc.
Common stock we are offering	shares
Common stock to be outstanding after the offering	shares
Underwriters' option to purchase additional shares	shares
Use of proceeds	We estimate that the net proceeds from this offering will be approximately \$million, or approximately \$million if the underwriters exercise their option to purchase additional shares in full, at an assumed initial public offering price of \$per share, the midpoint of the range set forth on the cover page of this prospectus, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use substantially all of the net proceeds from this offering as follows: approximately \$million to fund clinical development of CHS-0214 (our etanercept (Enbrel) biosimilar candidate), approximately \$ million to fund clinical development of CHS-1420 (our adalimumab (Humira) biosimilar candidate), approximately \$million to fund clinical development of CHS-1701 (our pegfilgrastim (Neulasta) biosimilar candidate), approximately \$million to pursue our development pipeline, and to use the balance for working capital and general corporate purposes. See "Use of Proceeds" on page 59 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.
Proposed symbol on NASDAQ	"CHRS"
The number of shares of common stock to be out	tstanding after this offering is based on 42,934,776 shares of common stock outstanding as of June 30,

- 922,309 shares of common stock issuable upon exercise of warrants to purchase common stock with an exercise price of \$1.00 per share as of June 30, 2014, which warrants will automatically be net exercised immediately prior to this offering if not previously exercised;
  - 9,251,560 shares of common stock issuable upon the exercise of outstanding stock options as of June 30, 2014 having a weighted-average exercise price of \$0.97 per share;
  - 311,708 shares of common stock issuable upon the exercise of outstanding warrants as of June 30, 2014 having a weighted-average exercise price of \$0.26 per share, which warrants prior to the completion of this offering are exercisable to purchase convertible preferred stock, and which will automatically be net exercised immediately prior to this offering if not previously exercised;
  - 991,414 shares of common stock reserved for issuance pursuant to future awards under our 2010 Equity Incentive Plan, as amended, as of June 30, 2014, which will become available for issuance under our 2014 Equity Incentive Award Plan after consummation of this offering;

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- 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, which will become effective immediately prior to the consummation of this offering; and
- shares of common stock reserved for issuance pursuant to future awards under our 2014 Employee Stock Purchase Plan, which will become effective upon the effectiveness of the registration statement to which this prospectus relates.

Unless otherwise indicated, the number of shares of our common stock described above reflects and assumes the following, which we refer to collectively in this prospectus as the "Transactions":

- the conversion of all outstanding shares of our preferred stock into an aggregate of 35,225,839 shares of common stock immediately prior to the consummation of this offering;
- the filing of our amended and restated certificate of incorporation and adoption of our amended and restated bylaws immediately prior to the consummation of this offering; and
- no exercise by the underwriters' of their option to purchase additional shares of common stock.

We refer to our Series A, Series B and Series C convertible preferred stock collectively as "convertible preferred stock" for audited financial reporting purposes and in the financial tables included in this prospectus, as more fully explained in Note 9 to our audited consolidated financial statements. In other parts of this prospectus, we refer to our Series A, Series B and Series C convertible preferred stock collectively as "preferred stock."

### SUMMARY CONSOLIDATED FINANCIAL DATA

The following tables summarize our consolidated financial data as of, and for the periods ended on, the dates indicated. We have derived the consolidated statements of operations data for the years ended December 31, 2012 and 2013 from our audited consolidated financial statements included elsewhere in this prospectus. The consolidated statement of operations data for the six months ended June 30, 2013 and 2014 and the consolidated balance sheet data as of June 30, 2014 are derived from our unaudited interim condensed consolidated financial statements included elsewhere in this prospectus. We have prepared the unaudited financial statements on the same basis as the audited financial statements and have included, in our opinion, all adjustments, consisting only of normal recurring adjustments that we consider necessary for a fair presentation of the financial information set forth in those statements. Our historical results are not necessarily indicative of the results that may be expected in the future. The following summary consolidated financial data should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations," "Selected Consolidated Financial Data" and our consolidated financial statements and related notes included elsewhere in this prospectus.

	Year Ended December 31,		Six Months Ended June 30,	
	2012	2013	2013	2014
	(unaudited) (in thousands, except share and per share data)			
Consolidated Statement of Operations Data:		( · · · · · · · · · · · · · · · · · · ·	· · · · · · · · · · · · · · · · · · ·	
Revenue:				
Collaboration and license revenue — related party <sup>(1)</sup>	\$ 1,899	\$ 2,025	\$ 1,013	\$ 1,013
Collaboration and license revenue		726		7,548
Total revenue	1,899	2,751	1,013	8,561
Operating expenses:				
Research and development <sup>(2)</sup>	34,886	31,279	17,123	32,861
General and administrative <sup>(2)</sup>	5,531	7,465	2,613	7,399
Total operating expenses	40,417	38,744	19,736	40,260
Loss from operations	(38,518)	(35,993)	(18,723)	(31,699)
Interest expense	(1,514)	(5,293)		(3,899)
Other income (expense), net	7,014	(12,349)	1,152	(14,642)
Net loss	(33,018)	(53,635)	(17,571)	(50,240)
Net loss attributable to noncontrolling interest	—	—	—	113
Net loss attributable to Coherus	\$ (33,018)	\$ (53,635)	\$ (17,571)	\$ (50,127)
Net loss per share attributable to Coherus, basic and diluted <sup>(3)</sup>	\$ (9.51)	\$ (9.66)	\$ (3.55)	\$ (7.19)
Weighted-average number of shares used in computing net loss per share attributable to Coherus, basic and diluted <sup>(3)</sup>	3,471,731	5,554,477	4,947,171	6,971,482
Pro forma net loss per share attributable to Coherus, basic and diluted (unaudited) <sup>(3)</sup>		\$ (1.68)		\$ (1.18)
Weighted-average number of shares used in computing pro forma net loss per share attributable to Coherus, basic and diluted (unaudited) <sup>(3)</sup>		24,488,112		30,145,504
$(1)$ Demonstrate from Definition Compared Limits is described as $100/10^{-1}$				

(1) Represents revenue from Daiichi Sankyo Company, Limited, a holder of more than 10% of our common stock on an as-converted basis.

(2) Includes stock-based compensation expense as follows:					
		Ended	Six Mont	hs Ended	
	Decem	December 31,		June 30,	
	2012	2013	2013	2014	
		(unaudited)		dited)	
		(in thousands)			
Research and development	\$ 268	\$ 682	\$ 299	\$ 2,202	
General and administrative	175	1,363	437	2,299	
Total stock-based compensation expense	\$ 443	\$ 2,045	\$ 736	\$ 4,501	

(3) See Note 12 to our audited consolidated financial statements and Note 11 to our interim condensed consolidated financial statements for an explanation of the method used to calculate basic and diluted net loss per share attributable to Coherus, the unaudited pro forma basic and diluted net loss per share attributable to Coherus and the weighted-average shares outstanding used to calculate the per share amounts.

		June 30, 2014		
	Actual Pro Forma <sup>(1)</sup> (unaudited)		Pro Forma As Adjusted <sup>(2)</sup>	
		(in thousands)		
Consolidated Balance Sheet Data:				
Cash and cash equivalents	\$ 108,869	\$ 109,873	\$	
Working capital	70,145	72,738		
Total assets	122,183	123,187		
Convertible preferred stock warrant liability	1,589	—		
Convertible preferred stock	161,224	—		
Accumulated deficit	(149,719)	(149,719)		
Total stockholders' (deficit) equity	(146,648)	17,169		

The unaudited pro forma column in the balance sheet data above gives effect to: (i) the Transactions immediately prior to the completion of this offering, (ii) the related reclassification of convertible preferred stock warrant liability to additional paid-in capital, (iii) the issuance of 922,309 shares of common stock upon the cash exercise of all warrants to purchase common stock outstanding as of June 30, 2014, at \$1.00 per share (which warrants will automatically be net exercised immediately prior to this offering if not previously exercised) and (iv) the issuance of 311,708 shares of common stock upon the cash exercise of all warrants to purchase convertible preferred stock as of June 30, 2014, at a weighted-average exercise price of \$0.26 per share (which warrants will automatically be net exercised) and the subsequent conversion of such shares of convertible preferred stock into common stock immediately prior to the consummation of this offering. The unaudited pro forma as adjusted column in the balance sheet data above gives further effect to the sale of per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the underwriting discounts and commissions and the estimated offering expenses pavable by us (1)

(2) offering expenses payable by us.

### **RISK FACTORS**

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this prospectus and any related free writing prospectus, including our consolidated financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

#### **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 \$33.0 million and \$53.6 million for the years ended December 31, 2012 and 2013, respectively, and \$50.2 million for the six months ended June 30, 2014. As of June 30, 2014, we had an accumulated deficit of \$149.7 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 CHS-0214 (our etanercept (Enbrel) biosimilar candidate). We are in the earlier stages of clinical development for 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 yet 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;

- 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, 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 file or that may be filed 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;
- 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; and
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how.

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 fr

# 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 June 30, 2014, our cash and cash equivalents were \$108.9 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;
- 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 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 in Phase 1 clinical development. 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.

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 biologics license application, or BLA, a biosimilar product application under the 351(k) pathway of the Public Health Service Act, or PHSA, a biosimilar marketing authorization under Article 6 of Regulation (EC) No. 726/2004 and/or Article 10(4) of Directive 2001/83/EC in the EEA or other submission or to obtain regulatory approval in the United States, the EEA or elsewhere;
- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical studies;
- the population studied in the clinical program may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from analytical and bioanalytical studies, nonclinical studies or clinical studies;
- we may be unable to demonstrate to the FDA or comparable foreign regulatory authorities that a product candidate's risk-benefit ratio for its proposed indication is acceptable;

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- 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. To preserve the option of pursuing a 351(k) (biosimilar) approval path for CHS-1701, we are making necessary preparations that we believe would enable us to conduct a new pivotal Phase 1 PK / PD study in healthy volunteers, but have not yet made a decision to proceed with this additional study.

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 to manufacture our products are unable to produce our products within an acceptable range of variability.

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

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

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical study process. The results of preclinical studies and early clinical studies of our product candidates may not be predictive of the results of later-stage clinical studies. Product candidates that have shown promising results in early-stage clinical studies may still suffer significant setbacks in subsequent registration clinical studies. 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.

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

- inability to generate sufficient preclinical, toxicology or other in vivo or in vitro data to support the initiation of human clinical studies;
- delays in reaching a consensus with regulatory agencies on study design;
- delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical study sites, the terms of
  which can be subject to extensive negotiation and may vary significantly among different CROs and clinical study sites;
- delays in obtaining required Institutional Review Board, or IRB, approval at each clinical study site;
- imposition of a clinical hold by regulatory agencies, after review of an investigational new drug, or IND, application or amendment or equivalent
  application or amendment, or an inspection of our clinical study operations or study sites or as a result of adverse events reported during a clinical
  trial;
- delays in recruiting suitable patients to participate in our clinical studies sponsored by us or our partners;
- difficulty collaborating with patient groups and investigators;
- failure by our CROs, other third parties or us to adhere to clinical study requirements;
- failure to perform in accordance with the FDA's good clinical practices requirements or applicable regulatory guidelines in other countries;
- · delays in having patients complete participation in a study or return for post-treatment follow-up, or patients dropping out of a study;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- the cost of clinical studies of our product candidates being greater than we anticipate;
- clinical studies of our product candidates producing negative or inconclusive results, which may result in us deciding or regulators requiring us to conduct additional clinical studies or abandon product development programs; and
- delays in manufacturing, testing, releasing, validating or importing/exporting and/or distributing sufficient stable quantities of our product candidates and originator products for use in clinical studies or the inability to do any of the foregoing.

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

For example, we intend to alter the manufacturing 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;
- 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 PHSA. Subsequent to the enactment of the BPCIA, the FDA issued draft guidance regarding the demonstration of biosimilarity as well as the submission and review of biosimilar applications. To our knowledge, there has been only one biosimilar product application accepted for review by the FDA under the 351(k) pathway to date. 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. However, President Obama's proposed budget for fiscal year 2014 included a legislative proposal to cut this 12-year period of exclusivity down to seven years. It also proposed to prohibit additional periods of exclusivity due to minor changes in product formulations, a practice often referred to as "evergreening." However, Congress may fail to take these or other measures to reduce periods of exclusivity.

The BPCIA is complex and only beginning to be interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning is 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.

Generally speaking, 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 innovator 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, who 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.

### 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 biosimilars candidates for these originator products are not, our business would suffer.

The FDA or other relevant regulatory authorities may determine that a proposed biosimilar product is "interchangeable" with a reference product, meaning that the biosimilar product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product, if the application includes sufficient information to show that the product is biosimilar to the reference product and that it can be expected to produce the same clinical result as the reference product in any given patient. If the biosimilar product may be administered more than once to a patient, the applicant must demonstrate that the risk in terms of safety or diminished efficacy of alternating or switching between the biosimilar product candidate and the reference product is not greater than the risk of using the reference product without such alternation or switch. To make a final determination of biosimilarity or interchangeability, regulatory authorities may require additional confirmatory information beyond what we plan to initially submit in our applications for approval, such as more indepth 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 as a biosimilar product or 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(1)(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(1)(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 has not been sued under 42 U.S.C. § 262(1)(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 first market our products in Europe and Japan followed by 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

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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 reactions 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 study or failure to complete such a study could result in the withdrawal of marketing approval.

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

- 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, and CHS-1420, our adalimumab (Humira) biosimilar, we have opted to proceed under the 351(a) (novel biologic) regulatory pathway for CHS-170, our pegfilgrastim (Neulasta) biosimilar for a variety of clinical, regulatory and business reasons. To preserve our option to pursue the 351(k) (biosimilar) approval pathway for CHS-1701, we are planning an additional Phase 1 study to demonstrate PK / PD bioequivalence, but have not yet made a decision to proceed with that study. 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 June 30, 2014, we had 46 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 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 produced 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 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 manufactures 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;
- 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;
- 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; 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

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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.

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.

The biologic substance used in CHS-0214 is currently manufactured for us by a single contract manufacturer (Rentschler Biotechnologie, GmbH). The final (filled and finished) biosimilar product for CHS-0214 is currently manufactured by Catalent, Inc. Cook Pharmica, LLC, or Cook, manufactured the biologic substance in CHS-0214 and CHS-1420 for our Phase 1 trials. We have also entered into commitments with a single contract manufacturer, Cook, for commercial manufacture of the biologic substance used in CHS-1420, but we have not yet engaged a contract manufacturer for Phase 3 clinical supply of CHS-1420. The biologic substance used in our Phase 1 trial of CHS-1701 was manufactured by a single contract manufacturer, Cytovance Biologics. We have engaged a single contract manufacturer, KBI Biopharma, Inc., to manufacture and supply the biological substance in CHS-1701 for our potential Phase 3 trial of CHS-1701. However, we have not yet engaged a contract manufacturer to supply us the final (filled and finished) biosimilar product for CHS-1701 for our potential Phase 3 trial. We currently engage Medpace, Inc. to provide clinical trial services, Lancaster Laboratories for product testing and Legacy BioDesign LLC for development of product formulation. We do not currently have any other suppliers or vendors for the above-mentioned requirements for our product candidates and, although we believe that there are alternate sources that could satisfy these requirements, we cannot assure you that identifying and establishing relationships with such would not result in significant 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 upon 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 have never produced a commercially approved pharmaceutical product and therefore have not obtained the requisite regulatory authority approvals to do so. The facilities and quality systems of some or all of our collaboration partners and third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates or any of our orbor tendidates or our 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. In addition, 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 t

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 to delay regulatory approval and to seek to restrict competition from manufacturers of biosimilars. These efforts may include or have included:

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

In 2012, Abbott Laboratories filed a Citizen Petition with the FDA asking the agency to refrain from accepting biosimilar applications under the BPCIA arguing that to approve such applications, without compensation to the originator, would constitute an unconstitutional taking of an originator company's valuable trade secrets under the fifth amendment of the United States constitution. The FDA has not yet acted on this petition and its outcome is uncertain. If the FDA grants Abbott Laboratories' petition, we may be precluded from applying for approval of CHS-0214, CHS-1420 and CHS-1701 under 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, 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, Samsung 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 trial. 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 and Amgen are examples of companies engaged in development of biosimilar product candidates for adalimumab (Humira). We understand Boehringer Ingelheim's program is in Phase 1 and that Amgen's program is in 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 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. 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;
- 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, believing the difference in nomenclature to be indicative of an important difference in quality of function from the reference product or the competing biosimilar product candidate. If this were to occur, our business could be negatively affected.

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

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

There is significant uncertainty related to third-party coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologics will be covered and reimbursed. The Medicare program covers certain individuals aged 65 or older or those who are disabled or suffering from end-stage renal disease. The Medicaid program, which varies from state to state, covers certain individuals and families who have limited financial means. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our biosimilar product candidates, if approved. In addition, in the United States, no uniform policy of coverage and reimbursement for biologics exists among third-party payors. Therefore, coverage and reimbursement for biologics can differ significantly from payor to payor. As a result, the process for obtaining favorable coverage determinations often is time-consuming and costly and may require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

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 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 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, 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.

A further example of a submarine patent is Fiers, *et al.*, U.S. patent 7,588,755 owned by Biogen Idec Inc., or Biogen, directed to Biogen's multiple sclerosis, or MS, drug, Avonex, which issued September 15, 2009 and expires in September 2026. This patent was not published prior to its issuance, and the public therefore had no notice that it was pending in the USPTO. Although we have no present plans to commercialize a biosimilar version of Avonex, we understand that the issuance of this patent disrupted the commercial plans of certain competitors of Biogen that market MS drugs in the United States, and those competitors have initiated litigation to challenge the '755 patent.

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

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

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

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

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

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

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

Although we have no issued patents, when and if we do obtain issued patents, we may discover that competitors are infringing those patents. Expensive and time-consuming litigation may be required to abate such

infringement. Although we are not currently involved in any litigation to enforce patents, if we or one of our collaboration partners, such as 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. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties or enter into development partnerships that would help us bring our product candidates to market.

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

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

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

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

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

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

The patent positions of biopharmaceutical companies generally are highly uncertain and involve complex legal and factual questions for which legal principles remain unresolved. As a result, the patent applications that we own or license may fail to result in issued patents with claims that cover our product candidates in the United States or in other foreign countries for many reasons. There is no assurance that all potentially relevant prior art relating to our patents and patent applications. 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 us 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 the ability to prevent others from using the technologies claimed in such issued patents. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced.

While our business is based primarily on the timing of our biosimilar product launches to occur after the expiration of relevant patents, we have filed a number of patents covering our own proprietary formulations and processes for our product candidates when we have believed securing such patents may afford a competitive advantage. For example, the companies that originated Enbrel and Humira (Amgen and AbbVie, respectively) own patents directed to formulations for these products. 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 for of etanercept (Enbrel) and adalimumab (Humira) and has filed patent applications directed to formulations for of etanercept (Enbrel) and 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 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.

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# 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 chose not to file patent applications in certain jurisdictions in which we may obtain commercial rights, thereby precluding the possibility of later obtaining patent protection in these countries. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States or importing products made using our inventions into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export infringing products to territories where we have patent protection, but the ability to enforce our patents is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Governments of 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 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 financial investors. However we cannot be certain that such agreements have been entered into with all relevant parties. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems, but it is possible that these security measures could be breached. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. Our confidential information and trade secrets thus may become known by our competitors in ways we cannot prove or remedy.

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

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

Although we are not currently aware of any claims challenging the inventorship of our patent applications or ownership of our intellectual property, we may in the future be subject to claims that former employees, collaborators or other third parties have an interest in our patent applications or patents we may be granted or other intellectual property as an inventor or co-inventor. For example, we may have inventorship or ownership disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of or right to use valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

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

We are a party to certain non-exclusive intellectual property license agreements with Genentech (pertaining to the production of monoclonal antibodies directed to tumor necrosis factor alpha, or TNF) 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;
- 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, 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 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 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.

Although we are not aware that the patent disclosure and dispute resolution mechanisms of the BPCIA patent exchange process have yet been employed by any biosimilar companies, nor legally tested in any court cases, we are aware that some biosimilar companies, namely Sandoz and Celltrion, Inc., or Celltrion, are 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's patents directed to Enbrel, but instead determined that Sandoz must use the patent exchange mechanism established in the BPCIA.

While the ability to file declaratory judgment actions outside the framework of the BPCIA 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 uphold the District Court's decision in the Sandoz v. Amgen case. This would require biosimilar applicants to test (or defend against) originator patents <u>only</u> in the BPCIA process, <u>after</u> 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 the BPCIA framework, such as 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.

Whether courts will view the BPCIA process as the *sole* avenue for a biosimilar entity and the originator to identify and potentially litigate such patents 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.

# 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 this offering. 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 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.

We have identified a material weakness with regard to our valuation of complex securities in our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, that creates a reasonable possibility that a material misstatement of a company's annual or interim financial statements will not be prevented or detected on a timely basis. Given this material weakness with regard to the valuation of warrants, embedded derivatives and contingent consideration and the underlying securities, management concluded that we did not maintain effective internal control over financial reporting as of March 31, 2014.

Although we are taking steps that we believe will address the underlying causes of the material weakness described above, primarily through hiring additional accounting and financial staff with appropriate public company experience and technical accounting knowledge to augment our current staff, if we fail to effectively remediate this material weakness or other material weaknesses or deficiencies in our control environment that we identify in the future, 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, to induce or in return for the purchase, recommendation, order or furnishing of an item
  or service reimbursable, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting or causing to be presented claims for payment from Medicare, Medicaid or other third-party payors that are false or fraudulent and which may apply to entities that provide coding and billing advice to customers;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;
- the federal physician "sunshine" requirements under the PPACA, which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services information related to payments and other transfers of value made by such

manufacturers to physicians and teaching hospitals and ownership and investment interests held by physicians and their immediate family members and applicable group purchasing organizations; and

state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers, state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

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

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

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

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

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

regulatory and compliance risks that relate to maintaining accurate information and control over sales and activities that may fall within the purview
of the U.S. Foreign Corrupt Practices Act its books and records provisions or its anti-bribery provisions.

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

Due to Russia's recent military intervention in Ukraine, the United States and the E.U. have imposed sanctions on certain individuals and one financial institution in Russia and have proposed the use of broader economic sanctions. In response, Russia has imposed entry bans on certain U.S. lawmakers and officials. Our wholly owned subsidiary, InteKrin Therapeutics, Inc., or InteKrin, which we acquired in February 2014 is majority owner of a Russian pharmaceutical development entity, ZAO InteKrin, which holds \$1.5 million of cash in Russian banks as of June 30, 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 MS. While not a biosimilar, this PPAR gamma inhibitor compound may be complementary to biosimilar products for treatment of multiple sclerosis 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 clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposing of these materials and specified waste products. Although we believe that the safety procedures utilized by us and our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. We do not currently carry biological or hazardous waste insurance coverage.

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

Our corporate headquarters and laboratory are located in the San Francisco Bay Area and in Southern California (Camarillo), respectively, and one of our collaboration partners, Daiichi Sankyo, is located in Japan. These locations have in the past experienced severe earthquakes and other natural disasters. We do not carry earthquake insurance. Earthquakes or other natural disasters could severely disrupt our operations or those of our collaboration partners and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage or other event occurred that prevented us from using

all or a significant portion of our headquarters, that damaged critical infrastructure (such as the manufacturing facilities of our third-party contract manufacturers) or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business.

### Risks Related to this Offering and Ownership of Our Common Stock

#### The market price of our common stock may be highly volatile, and you may not be able to resell your shares at or above the initial public offering price.

Prior to this offering, there has not been a public market for our common stock. An active trading market for our common stock may not develop following this offering. You may not be able to sell your shares quickly or at the market price if trading in our common stock is not active. The initial public offering price for the shares will be determined by negotiations between us and the representative of the underwriters and may not be indicative of prices that will prevail in the trading market.

The market price of our common stock is likely to be volatile. Our stock price could be subject to wide fluctuations in response to a variety of factors, including but not limited to the following:

- adverse results or delays in preclinical or clinical studies;
- any inability to obtain additional funding;
- any delay in filing an IND, NDA, BLA or other regulatory submission for any of our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory agency's review of that IND, NDA, BLA or other regulatory submission;
- the perception of limited market sizes or pricing for our product candidates;
- failure to successfully develop and commercialize our product candidates;
- post-marketing safety issues relating to our product candidates or biosimilars generally;
- failure to maintain our existing strategic collaborations or enter into new collaborations;
- failure by us or our licensors and strategic collaboration partners to prosecute, maintain or enforce our intellectual property rights;
- changes in laws or regulations applicable to our products;
- any inability to obtain adequate product supply for our product candidates or the inability to do so at acceptable prices;
- adverse regulatory decisions;
- introduction of new products, services or technologies by our competitors;
- failure to meet or exceed financial projections we may provide to the public;
- failure to meet or exceed the financial projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us, our strategic collaboration partners or our competitors;

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- 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;
- significant 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 June 30, 2014, our executive officers, directors, five percent stockholders and their affiliates beneficially owned approximately 83% of our voting stock and, upon closing of this offering, that same group will beneficially own approximately % of our outstanding voting stock (assuming no exercise of the underwriters' option to purchase additional shares and no exercise of outstanding options and warrants). Therefore, even after this offering, these stockholders will 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.

### 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 pro forma 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 initial public offering price of \$ per share, the midpoint of the price range set forth on the cover of this prospectus, and our pro forma net tangible book value as of June 30, 2014. 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 June 30, 2014, we had outstanding options and warrants to purchase 10,485,577 shares of our common stock; the exercise of any of these options or warrants 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, on an as-converted basis, outstanding as of June 30, 2014, upon the closing of this offering we will have outstanding a total of shares of common stock, assuming no exercise of the underwriters' option to purchase additional shares. Of these shares, as of the date of this prospectus, approximately shares of our common stock, 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, assuming that current stockholders do not purchase shares in this offering.

The lock-up agreements pertaining to this offering will expire 180 days from the date of this prospectus. After the lock-up agreements expire, based upon the number of shares of common stock, on an as-converted basis, outstanding as of March 31, 2014, up to an additional shares of common stock will be eligible for sale in the public market, of which approximately shares are held by directors, executive officers and other affiliates and will be subject to the manner of sale, volume limitations and public reporting requirements of Rule 144 under the Securities Act of 1933, as amended, or the Securities Act. 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 June 30, 2014, approximately shares of common stock that are either subject to outstanding options, reserved for future issuance under our equity incentive plans or subject to outstanding warrants 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 shares of our common stock, or including the shares underlying outstanding warrants, will be entitled to rights with respect to the registration of their shares under the Securities Act, subject to the 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.

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

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

Pursuant to our 2014 Equity Incentive Award Plan, or the 2014 Plan, which will become effective immediately prior to the completion of this offering, our management is authorized to grant stock options and other equity-based awards to our employees, directors and consultants. An aggregate of shares will be available for issuance under the 2014 Plan. The number of shares available for future grant under the 2014 Plan will automatically increase on January 1 of each year by up to the least of shares and % of all shares of our capital stock outstanding as of December 31 of the prior calendar year, subject to the ability of our compensation committee to take action to reduce the size of the increase in any given year. Currently, we plan to register the increased number of shares available for issuance under the 2014 Plan each year. Pursuant to our 2014 Employee Stock Purchase Plan, or 2014 ESPP, which will become effective immediately prior to the completion of this offering, eligible employees will be able to acquire shares of our common stock at a discount to the prevailing market price, and an aggregate of shares will be available for issuance under the 2014 ESPP. The number of shares available for issuance under the 2014 ESPP will automatically increase on January 1 of each year by up to the least of shares and % of all shares of our capital stock outstanding as of December 31 of the prior calendar year, subject to the ability of our compensation committee to take action to reduce the size of the increase in any given year. 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.

#### We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds 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 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 from this offering in investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders.

### 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 this offering and/or subsequent 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, which will become effective upon the closing of this offering, include provisions that:

- authorize "blank check" preferred stock, which could be issued by our board of directors without stockholder approval and may contain voting, liquidation, dividend and other rights superior to our common stock;
- create a classified board of directors whose members serve staggered three-year terms;
- specify that special meetings of our stockholders can be called only by our corporate secretary pursuant to a resolution adopted by a majority of our board of directors;
- prohibit stockholder action by written consent;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors other than nominations made by or at the direction of the board of directors or a committee of the board of directors;
- provide that our directors may be removed only for cause or without cause by the holders of 66 2/3% of the voting power of all then outstanding shares of voting stock;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;

- specify that no stockholder is permitted to cumulate votes at any election of directors;
- expressly authorize our board of directors to modify, alter or repeal our amended and restated bylaws; and
- require holders of 66 2/3% of the voting power of all then outstanding shares of voting stock to amend specified provisions of our amended and
  restated certificate of incorporation except for the provision making it possible for our board of directors to issue "blank check" preferred stock, and
  amended and restated bylaws.

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

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders owning in excess of 15% of our outstanding voting stock to merge or combine with us.

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

### SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

#### MARKET, INDUSTRY AND OTHER DATA

This prospectus contains 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 shares of common stock in this offering will be approximately \$ million at an assumed per share, the midpoint of the range set forth on the cover page of this prospectus, after deducting the underwriting discounts initial public offering price of \$ and commissions and estimated offering expenses payable by us. If the underwriters exercise in full their option to purchase additional shares of common stock, we estimate that 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 initial public offering price of \$ per share (the midpoint of the price range set forth on the cover page of this prospectus) would increase (decrease) the net proceeds to us from this offering, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, by approximately \$ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same. We may also increase or decrease the number of shares we are offering. An increase (decrease) of 1,000,000 in the number of shares we are offering would increase (decrease) the net proceeds to us from this offering, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, by approximately \$ million, assuming the assumed initial public offering price stays the same. We do not expect that a change in the offering price or the number of shares by these amounts would have a material effect on our intended uses of the net proceeds from this offering, although it may impact the amount of time prior to which we may need to seek additional capital.

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

- approximately million to fund clinical development for CHS-0214 (our etanercept (Enbrel) biosimilar candidate);
- approximately million to fund clinical development for CHS-1420 (our adalimumab (Humira) biosimilar candidate);
- approximately \$ million to fund clinical development for CHS-1701 (our pegfilgrastim (Neulasta) biosimilar candidate);
- approximately \$ million to pursue our development pipeline; and
- the remainder for working capital and other general 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 estimate that such funds will be sufficient to enable us to complete our ongoing clinical studies 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.

### 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 June 30, 2014:

- on an actual basis;
- on a pro forma basis to give effect to:
  - the conversion of all outstanding shares of our preferred stock into an aggregate of 35,225,839 shares of common stock immediately prior to the consummation of this offering;
  - the issuance of 922,309 shares of common stock upon the cash exercise of all warrants to purchase common stock outstanding as of June 30, 2014, at \$1.00 per share (which warrants will automatically be net exercised immediately prior to this offering if not previously exercised);
  - the issuance of 311,708 shares of common stock upon the cash exercise of all warrants to purchase convertible preferred stock as of June 30, 2014, at a weighted-average exercise price of \$0.26 per share, and the subsequent conversion of such shares of convertible preferred stock into common stock immediately prior to the consummation of this offering (which warrants will automatically be net exercised immediately prior to this offering if not previously exercised);
  - the reclassification of our convertible preferred stock warrant liability to additional paid-in capital; and
  - the filing of our amended and restated certificate of incorporation and adoption of our amended and restated bylaws immediately prior to the consummation of this offering.
- on a pro forma as adjusted basis to give further effect to our issuance and sale of shares of our common stock in this offering at an assumed initial public offering price of \$ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

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# **Index to Financial Statements**

You should read this table together with "Selected Consolidated Financial Data," our consolidated financial statements and the related notes appearing elsewhere in this prospectus and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in this prospectus.

	June 30, 2014			
	Actual	Pro Forma	Pro Forma As Adjusted	
		(in thousands, except share per share data) (unaudited)	hare data)	
Cash and cash equivalents	\$ 108,869	\$ 109,873	\$	
Convertible preferred stock warrant liability	\$ 1,589	\$ —	\$	
Series A convertible preferred stock \$0.0001 par value:				
Shares authorized: 1,727,448 actual, no shares pro forma and pro forma as adjusted; shares				
issued and outstanding: 1,620,888 actual; no shares issued and outstanding, pro forma and				
pro forma as adjusted	1,191	—		
Series B convertible preferred stock \$0.0001 par value:				
Shares authorized: 23,479,591 actual, no shares pro forma and pro forma as adjusted; shares				
issued and outstanding: 22,674,443 actual; no shares pro forma and pro forma as adjusted	94,630	—		
Series C convertible preferred stock \$0.0001 par value:				
Shares authorized: 11,000,000 actual, no shares pro forma and pro forma as adjusted; shares				
issued and outstanding: 10,930,508 actual; no shares pro forma and pro forma as adjusted	65,403	_		
Stockholders' (deficit) equity:				
Preferred stock, par value \$0.0001:				
Shares authorized: no shares, actual, pro forma and pro forma as adjusted; shares				
issued and outstanding: no shares actual, pro forma and pro forma as adjusted		—		
Common stock, \$0.0001 par value:				
Shares authorized: 57,000,000 actual, pro forma and pro forma as adjusted; shares				
issued and outstanding: 7,708,937 actual, 44,168,793 pro forma, pro forma as				
adjusted	1	4		
Additional paid-in capital	3,151	166,965		
Accumulated other comprehensive income	32	32		
Accumulated deficit	(149,719)	(149,719)		
Total Coherus stockholders' (deficit) equity	(146,535)	17,282		
Noncontrolling interest	(113)	(113)		
Total stockholders' (deficit) equity	(146,648)	17,169	·	
Total capitalization	\$ 16,165	\$ 17,169	\$	

In the table above, the number of shares of common stock outstanding as of June 30, 2014, on an actual basis, does not include:

- 922,309 shares of common stock issuable upon exercise of warrants to purchase common stock with an exercise price of \$1.00 per share as of June 30, 2014, which warrants will automatically be net exercised immediately prior to this offering if not previously exercised;
- 9,251,560 shares of common stock issuable upon the exercise of outstanding stock options as of June 30, 2014 having a weighted-average exercise price of \$0.97 per share;
- 311,708 shares of common stock issuable upon the exercise of outstanding warrants as of June 30, 2014 having a weighted-average exercise price of \$0.26 per share, which warrants prior to the



completion of this offering are exercisable to purchase convertible preferred stock, and which will automatically be net exercised immediately prior to this offering if not previously exercised;

- 991,414 shares of common stock reserved for issuance pursuant to future awards under our 2010 Equity Incentive Plan, as amended, as of June 30, 2014, which will become available for issuance under our 2014 Equity Incentive Award Plan after consummation of this offering;
- 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, which will become effective
  immediately prior to the consummation of this offering; and
- shares of common stock reserved for issuance pursuant to future awards under our 2014 Employee Stock Purchase Plan, which will become effective upon the effectiveness of the registration statement to which this prospectus relates.

#### DILUTION

If you invest in our common stock, your interest will be diluted to the extent of the difference between the initial public offering price per share of our common stock in this offering and the net tangible book value per share of our common stock after this offering. As of June 30, 2014, we had a historical net tangible book value of \$(150.2) million, or \$(19.49) per share of common stock. Our net tangible book value represents total tangible assets less total liabilities, all divided by the number of shares of common stock outstanding as of June 30, 2014. Our pro forma net tangible book value at June 30, 2014, before giving effect to this offering, was \$13.6 million, or \$0.31 per share of our common stock, based on the total number of shares of our common stock outstanding as of June 30, 2014, after giving effect to the Transactions.

After giving effect to the sale of shares of common stock in this offering at an assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, and after deducting the underwriting discounts and commissions and estimated offering expenses, our pro forma as adjusted net tangible book value at June 30, 2014 would have been approximately \$ million, or \$ per share. This represents an immediate increase in pro forma as adjusted net tangible book value of \$ per share to existing stockholders and an immediate dilution of \$ per share to new investors. The following table illustrates this per share dilution:

Assumed initial public offering price per share		\$
Historical net tangible book value per share as of June 30, 2014	\$(19.49)	
Pro forma increase in net tangible book value per share	19.80	
Pro forma net tangible book value per share as of June 30, 2014	0.31	
Increase in pro forma net tangible book value per share attributable to new investors		
Pro forma as adjusted net tangible book value per share after this offering		
Dilution per share to new investors participating in this offering		\$

A \$1.00 increase (decrease) in the assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) our pro forma as adjusted net tangible book value as of June 30, 2014 after this offering by approximately million, or approximately \$ per share, and would decrease (increase) dilution to investors in this offering by approximately \$ per share, assuming \$ that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of shares we are offering. An increase (decrease) of 1,000,000 in the number of shares we are offering would increase (decrease) our pro forma as adjusted net tangible book value as of June 30, 2014 after this offering by approximately \$ million, or approximately \$ per share, and would decrease (increase) dilution to investors in this offering by approximately per share, assuming the assumed initial public offering price per share remains the same, after deducting the underwriting discounts and commissions and \$ estimated offering expenses payable by us. The pro forma as adjusted information is illustrative only, and we will adjust this information based on the actual initial public offering price and other terms of this offering determined at pricing.

If the underwriters fully exercise their option to purchase additional shares of common stock, pro forma as adjusted net tangible book value after this offering would increase to approximately \$ per share, and there would be an immediate dilution of approximately \$ per share to new investors.

To the extent that outstanding options or warrants with an exercise price per share that is less than the pro forma as adjusted net tangible book value per share, before giving effect to the issuance and sale of shares in this offering, are exercised, new investors will experience further dilution.

In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

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# **Index to Financial Statements**

The following table shows, as of June 30, 2014, on a pro forma as adjusted basis, after giving effect to the Transactions, the number of shares of common stock purchased from us, the total consideration paid to us and the average price paid per share by existing stockholders and by new investors purchasing common stock in this offering at an assumed initial public offering price of \$ per share, before deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

	Shares Purchased		Total Consideration		Average Price
	Number	Percent	Amount	Percent	Per Share
Existing stockholders			\$	%	\$
Investors participating in this offering					\$
Total		100%	\$	100%	

The number of shares of common stock to be outstanding after this offering is based on the number of shares outstanding as of June 30, 2014 and excludes the following:

- 922,309 shares of common stock issuable upon exercise of warrants to purchase common stock with an exercise price of \$1.00 per share as of June 30, 2014, which warrants will automatically be net exercised immediately prior to this offering if not previously exercised;
- 9,251,560 shares of common stock issuable upon the exercise of outstanding stock options as of June 30, 2014 having a weighted-average exercise price of \$0.97 per share;
- 311,708 shares of common stock issuable upon the exercise of outstanding warrants as of June 30, 2014 having a weighted-average exercise price of \$0.26 per share, which warrants prior to the completion of this offering are exercisable to purchase convertible preferred stock, and which will automatically be net exercised immediately prior to this offering if not previously exercised;
- 991,414 shares of common stock reserved for issuance pursuant to future awards under our 2010 Equity Incentive Plan, as amended, as of June 30, 2014, which will become available for issuance under our 2014 Equity Incentive Award Plan after consummation of this offering;
- 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, which will become effective immediately prior to the consummation of this offering; and
- shares of common stock reserved for issuance pursuant to future awards under our 2014 Employee Stock Purchase Plan, which will become effective upon the effectiveness of the registration statement to which this prospectus relates

### SELECTED CONSOLIDATED FINANCIAL DATA

You should read the following selected consolidated financial data together with the section of this prospectus entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the related notes included in this prospectus. The consolidated statement of operations data for the years ended December 31, 2012 and 2013 and the consolidated balance sheet data as of December 31, 2012 and 2013 are derived from our audited consolidated financial statements included elsewhere in this prospectus. The consolidated statement of operations data for the consolidated balance sheet data as of June 30, 2014 are derived from our unaudited interim condensed consolidated financial statements included elsewhere in this prospectus. We have included, in our opinion, all adjustments, consisting only of normal recurring adjustments that we consider necessary for a fair presentation of the financial information set forth in those statements. Our historical results are not necessarily indicative of the results to be expected for the full year or any other period.

	Year Ended December 31,		Six Months Ended June 30,	
	2012	2013	2013	2014
		(unaud) (in thousands, except share and per share data)		
Consolidated Statement of Operations Data:		(in mousulus, except sh	are and per share data)	
Revenue:				
Collaboration and license revenue — related party <sup>(1)</sup>	\$ 1,899	\$ 2,025	\$ 1,013	\$ 1,013
Collaboration and license revenue		726		7,548
Total revenue	1,899	2,751	1,013	8,561
Operating expenses:				
Research and development <sup>(2)</sup>	34,886	31,279	17,123	32,861
General and administrative <sup>(2)</sup>	5,531	7,465	2,613	7,399
Total operating expenses	40,417	38,744	19,736	40,260
Loss from operations	(38,518)	(35,993)	(18,723)	(31,699)
Interest expense	(1,514)	(5,293)	—	(3,899)
Other income (expense), net	7,014	(12,349)	1,152	(14,642)
Net loss	(33,018)	(53,635)	(17,571)	(50,240)
Net loss attributable to noncontrolling interest				113
Net loss attributable to Coherus	\$ (33,018)	\$ (53,635)	\$ (17,571)	\$ (50,127)
Net loss per share attributable to Coherus, basic and diluted <sup>(3)</sup>	\$ (9.51)	\$ (9.66)	\$ (3.55)	\$ (7.19)
Weighted-average number of shares used in computing net loss per share attributable to Coherus, basic and diluted <sup>(3)</sup>	3,471,731	5,554,477	4,947,171	6,971,482
Pro forma net loss per share attributable to Coherus, basic and diluted (unaudited) <sup>(3)</sup>		\$ (1.68)		\$ (1.18)
Weighted-average number of shares used in computing pro forma net loss per share attributable to Coherus, basic and diluted (unaudited) <sup>(3)</sup>		24,488,112		30,145,504

(1) Represents revenue from Daiichi Sankyo Company, Limited, a holder of more than 10% of our common stock on an as-converted basis.

<sup>(2)</sup> Includes stock-based compensation expense as follows:

		Ended ıber 31,		Six Mon Jun	ths End e 30,	ded
	2012	2013	2	013		2014
				(unau	idited)	
		(in	thousai	ıds)		
Research and development	\$268	\$ 682	\$	299	\$	2,202
General and administrative	175	1,363		437		2,299
Total stock-based compensation expense	\$443	\$2,045	\$	736	\$	4,501

(3) See Note 12 to our audited consolidated financial statements and Note 11 to our interim condensed consolidated financial statements for an explanation of the method used to calculate basic and diluted net loss per share attributable to Coherus and the weighted-average shares outstanding used to calculate the per share attributable to Coherus and the weighted-average shares outstanding used to calculate the per share attributable to Coherus and the weighted-average shares outstanding used to calculate the per share attributable to Coherus and the weighted-average shares outstanding used to calculate the per share attributable to Coherus att

	Decem	December 31,	
	2012	2013	2014
		(in thousands)	(unaudited)
Consolidated Balance Sheet Data:			
Cash and cash equivalents	\$ 14,548	\$ 39,554	\$ 108,869
Working capital (deficit)	13,546	(8,024)	70,145
Total assets	26,533	47,447	122,183
Convertible notes	—	1,111	
Convertible notes — related parties	—	3,092	
Convertible preferred stock warrant liability	1,738	24,251	1,589
Convertible preferred stock	54,695	54,695	161,224
Accumulated deficit	(45,957)	(99,592)	(149,719)
Total stockholders' deficit	(45,503)	(97,077)	(146,648)

# MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with the section of this prospectus entitled "Selected Consolidated Financial Data" and our consolidated financial statements and related notes included elsewhere in this prospectus. This discussion and other parts of this prospectus contain forward-looking statements that involve risk and uncertainties, such as statements of our plans, objectives, expectations and intentions. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section of this prospectus entitled "Risk Factors."

## Overview

We are a late-stage clinical biologics platform company focused on the global biosimilar market. Biosimilars are an emerging class of protein-based therapeutics with high similarity to approved originator products on the basis of various physicochemical and structural properties, as well as in terms of safety, purity and potency. Our goal is to become a global leader in the biosimilar market by leveraging our team's collective expertise in key areas such as process science, analytical characterization, protein production and clinical-regulatory development. Since our founding in 2010, we have advanced 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.

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

- CHS-0214 (our etanercept (Enbrel) biosimilar candidate). CHS-0214 is a product candidate that we have partnered with Baxter International, Inc., Baxter Healthcare Corporation and Baxter Healthcare SA, or together, Baxter, and Daiichi Sankyo Company, Limited, or Daiichi Sankyo, to develop and commercialize in key markets outside of the United States. Please see "Business — Collaboration and License Agreements" for additional information. We are currently enrolling two Phase 3 clinical trials in rheumatoid arthritis and psoriasis. We expect results of these trials, if positive, combined with data from our Phase 1 studies, will support the expected filing of a marketing application in Europe in 2016. We have retained the development and commercial rights in the United States. However, at this time, we do not expect patent expiration in the United States until 2029.
- *CHS-1420 (our adalimumab (Humira) biosimilar candidate).* We completed a Phase 1 study for CHS-1420 in August 2014. We plan to initiate a Phase 3 clinical trial or trials in psoriasis or rheumatoid arthritis during the first half of 2015 to support the expected filing of a marketing application in the United States in 2016 and the European Union, or E.U., in 2017.
- **CHS-1701 (our pegfilgrastim (Neulasta) biosimilar candidate).** We conducted a Phase 1 study for CHS-1701 between November 2012 and March 2013. We intend to begin a Phase 3 clinical trial in breast cancer patients exhibiting chemotherapy-induced neutropenia, i.e., increased susceptibility to infections, in the first half of 2015 to support the expected filing of a license application in the United States in 2016.

Our revenue to date has been generated primarily from collaboration and license payments pursuant to our license agreements with Daiichi Sankyo and Baxter. We have not generated any commercial product revenue. We have incurred significant losses in the past and expect to incur significant and increasing losses in the foreseeable future as we advance our product candidates into later stages of development and, if approved, commercialization. Our net losses were \$33.0 million and \$53.6 million for the years ended December 31, 2012 and 2013 and \$17.6 million and \$50.2 million for the six months ended June 30, 2013 and 2014. As of June 30, 2014, we had an accumulated deficit of \$149.7 million.

On February 12, 2014, we completed the acquisition of InteKrin Therapeutics, Inc., or InteKrin, a privately held, clinical-stage biopharmaceutical company focused on the development and commercialization of novel therapies for the treatment of immune diseases such as multiple sclerosis. Pursuant to a licensing agreement with Amgen, we are obligated to use commercially reasonable efforts to develop InteKrin's product candidate.

We accounted for the acquisition as the purchase of a business. Total consideration for the acquisition of InteKrin was \$5.0 million and consisted of: (a) the issuance of 1,194,686 shares of Series B convertible preferred stock with a fair value of \$2.7 million, (b) the assumption of InteKrin's convertible promissory note payable to investors of InteKrin, which was concurrently paid off by issuing 406,483 shares of our Series B convertible preferred stock with an estimated fair value of \$1.0 million, (c) a cash payment of \$1,485 and (d) contingent consideration with a fair value of \$1.3 million at the acquisition date. For additional information on the InteKrin merger, please see "Certain Relationships and Related Party Transactions — Sales and Purchases of Securities."

### **Financial Operations Overview**

### Revenue

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

# **Research and Development Expenses**

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

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

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

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

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

	Phase of Development	Year Ended December 31,			ths Ended e 30,
	as of June 30, 2014	2012	2013	2013	2014
			(in tho	usands)	
External costs incurred by product candidate:					
CHS-0214 <sup>(5)</sup>	Pre-phase 3 <sup>(1)</sup>	\$14,949	\$10,011	\$ 4,248	\$15,439
CHS-1420	Phase 1 <sup>(2)</sup>	1,798	6,603	3,661	7,226
CHS-1701	Pre-phase 3 <sup>(3)</sup>	6,536	4,902	3,933	1,633
Other research and development expenses <sup>(4)</sup>		7,034	2,058	1,731	962
Internal costs		4,569	7,705	3,550	7,601
Total research and development expenses <sup>(5)</sup>		\$34,886	\$31,279	\$17,123	\$32,861

- (1) (2) CHS-0214 entered Phase 3 clinical trials in June and July 2014
- CHS-1420 completed Phase 1 studies during the second half of 2014. (3) CHS-1701 is expected to begin Phase 3 clinical trials in the first half of 2015.
- (4) Amount consists of costs for other pipeline candidates
- Our research and development expenses have been reduced by reimbursements of certain research and development expenses pursuant to the cost-sharing provision of our licensing agreement with Daiichi (5)Sankyo. Reimbursement of research and development expenses under the Baxter licensing agreement was recognized as revenue pursuant to the revenue recognition accounting policy applicable to that

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

#### General and Administrative Expenses

General and administrative expenses consist primarily of personnel costs, allocated facilities costs and other expenses for outside professional services, including legal, human resources, audit and accounting services. Personnel costs consist of salaries, benefits and stock-based compensation. We expect to incur increased expenses as a result of operating as a public company, including expenses related to compliance with the rules and regulations of the Securities and Exchange Commission, or SEC, or The NASDAQ Global Market, or NASDAQ, additional insurance expenses, investor relations activities and other administration and professional services.

### Interest Expense

Interest expense consists primarily of interest incurred on our outstanding indebtedness and non-cash interest related to the amortization of debt discount associated with our various debt agreements and for the year ended December 31, 2012, includes interest expense resulting from a beneficial conversion feature related to our 2011 convertible notes. We expect that our interest expense will decrease as our outstanding convertible notes and related accrued interest were converted into shares of our Series C convertible preferred stock in May 2014.

### Other Income (Expense), Net

Other income (expense), net consists of gains and losses resulting from the remeasurement of the fair value of our convertible preferred stock warrant liability, derivative liability associated with our convertible notes, and our contingent consideration. Additionally, for the year ended December 31, 2012 and for six months ended June 30, 2014, other income (expense), net includes the gain on the extinguishment of our 2011 convertible notes and the gain on the extinguishment of our 2013 convertible notes, respectively. We will continue to record adjustments to the estimated fair value of the convertible preferred stock warrants until these warrants are

exercised or expire. Upon completion of our initial public offering, our outstanding warrants will automatically net exercise and the convertible preferred stock warrant liability will be reclassified to additional paid-in capital, and we will no longer record adjustments to reflect the remeasurement of the fair values. Similarly, we will continue to record adjustments to the estimated fair value of our contingent consideration until the contingency settles or expires. We recorded adjustments to the estimated fair value of the embedded derivative liability associated with convertible notes until May 2014 when the notes were converted into shares of our Series C convertible preferred stock.

## **Critical Accounting Policies**

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

### **Revenue Recognition**

We generate revenue from collaboration and license agreements for the development and commercialization of our product candidates. Collaboration and license agreements may include non-refundable upfront payments, partial or complete reimbursement of research and development costs, contingent payments based on the occurrence of specified events under our collaboration arrangements, license fees and royalties on sales of product candidates if they are successfully approved and commercialized. Our performance obligations under the collaborations may include the transfer of intellectual property rights in the form of licenses, obligations to provide research and development services and related materials and participation on certain development and/or commercialization committees with the collaboration partners. We make judgments that affect the periods over which we recognize revenue.

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

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

For revenue agreements with multiple-elements, we identify the deliverables included within the agreement and evaluate which deliverables represent separate units of accounting based on the achievement of certain criteria including whether the deliverable has stand-alone value to the collaborator. Upfront payments received in connection with licenses of our technology rights are deferred if facts and circumstances dictate that the license

does not have stand-alone value and are recognized as license revenue over the estimated period of performance that is generally consistent with the terms of the research and development obligations contained in the specific collaboration and license agreement. We periodically review our estimated periods of performance based on the progress under each arrangement and account for the impact of any changes in estimated periods of performance on a prospective basis.

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

#### Accrued Research and Development Expenses

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

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

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

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

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

To date, we have not experienced significant changes in our estimates of accrued research and development expenses after a reporting period. However, due to the nature of estimates, we cannot assure you that we will not make changes to our estimates in the future as we become aware of additional information about the status or conduct of our clinical trials and other research activities.

### Estimated Fair Value of Convertible Preferred Stock Warrants

Freestanding warrants for the purchase of convertible preferred stock that is either subject to a put right or contingently redeemable are classified as liabilities on the consolidated balance sheet at their estimated fair value. At the end of each reporting period, changes in the estimated fair value during the period are recorded as other income (expense), net in the statement of operations and comprehensive loss. We will continue to adjust the liability for changes in fair value until the earlier of the exercise or expiration of the warrants, at which time the liability would be reclassified to additional paid-in capital.

We estimate the fair values of the convertible preferred stock warrants by allocating the Company's equity value, using an option-pricing model. Our equity value was allocated among preferred stock, common stock, warrants and stock options expected to be outstanding at the liquidity events based on the rights and preferences of each class.

#### **Derivative Liabilities**

We had derivative instruments related to redemption features embedded within the outstanding convertible notes. The embedded derivatives were accounted for as a liability and were remeasured to fair value as of each balance sheet date, with the related remeasurement adjustment recognized as other income (expense), net in the statement of operations and comprehensive loss. The fair value of the derivative liability was determined based on an income approach that identified the cash flows using a "with-and-without" valuation methodology. The inputs used to determine estimated fair value of the derivative instruments include the probabilities of the underlying events triggering the embedded derivative and their timing.

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

#### Stock-Based Compensation

#### Common Stock Options

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

We account for stock-based compensation arrangements with non-employees using a fair value approach. The fair value of these options is measured using the Black-Scholes option pricing model reflecting the same

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assumptions as applied to employee options in each of the reported periods, other than the expected life, which is assumed to be the remaining contractual life of the option. The fair value of the unvested options under these arrangements is subject to remeasurement over the vesting terms as earned.

We recorded non-cash stock-based compensation expense related to options granted to employees and nonemployees of \$101,000 and \$764,000 for the years ended December 31, 2012 and 2013, respectively, and \$382,000 and \$1.6 million for the six months ended June 30, 2013 and 2014, respectively.

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

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

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

Historically, for all periods prior to this initial public offering, the fair values of the shares of common stock underlying our share-based awards were estimated on each grant date by our board of directors. In order to determine the fair value of our common stock underlying option grants, our board of directors considered, among other things, contemporaneous valuations of our common stock prepared by an unrelated third-party valuation firm in accordance with the guidance provided by the American Institute of Certified Public Accountants Practice Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. Given the absence of a public trading market for our common stock, our board of directors exercised reasonable judgment and considered a number of objective and subjective factors to determine the best estimate of the fair value of our common stock, including our stage of development; progress of our research and development efforts; the rights, preferences and privileges of our preferred stock relative to those of our common stock; equity market conditions affecting comparable public companies; and the lack of marketability of our common stock.

In determining a fair value for our common stock, we estimated the enterprise value of our business using the prior sale of stock method of the market approach. The prior sale of stock method of the market approach estimates the enterprise value of a company based on transactions involving equity securities of the enterprise with unrelated investors or among unrelated investors themselves. In using this method, factors about whether those transactions involve any stated or unstated rights or privileges, the sophistication of the purchasers, relationship with us and size of the purchase are also considered. All of the contemporaneous valuations of our common stock used the "back solve" method of the option-pricing method, or OPM, which derives the implied equity value for one type of equity security from a contemporaneous transaction involving another equity security. The contemporaneous transactions occurred in close proximity and involved third-party investors. Given the arm's-length nature of the recent financings and the close proximity of the Series B and C convertible preferred stock financings to the respective valuation dates, we believe the per share issuance price of the Series

B and C convertible preferred stock provided indications of our equity value, as well as the fair value of common stock, as of each of the valuation dates. The estimated enterprise value is then allocated to the common stock using the OPM, the Probability Weighted Expected Return Method, or PWERM, or the hybrid method. The hybrid method applied the PWERM utilizing the probability of two exit scenarios, going public or being acquired and a liquidation scenario.

For valuations after the completion of this offering, our board of directors will determine the fair value of each share of underlying common stock based on the closing price of our common stock on the date of grant.

The intrinsic value of all outstanding options as of June 30, 2014 was \$ million based on the estimated fair value of our common stock of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus.

#### Founders' Shares

In October 2010 and January 2011, we issued 6,885,000 shares and 1,615,000 shares of common stock, respectively, at \$0.005 per share to our founders under the founder stock agreements. These founders' shares are subject to a repurchase option in our favor that lapses over time subject to continued service. As such, we recorded stock-based compensation based on the fair value of the common stock on the date of issuance. One of the holders of the founders' shares is a consultant, therefore the fair value of the consultant's founder shares is measured using the Black-Scholes option-pricing model reflecting the same assumptions as applied to employee options in each of the reported years, other than the expected life, which is assumed to be the remaining contractual life of the vesting period. We recorded non-cash stock-based compensation expense related to the founders' shares of \$342,000 and \$1.3 million for the years ended December 31, 2012 and 2013, and \$354,000 and \$238,000 for the six months ended June 30, 2013 and 2014.

### Common Stock Warrants

In March 2014, we issued warrants to purchase 922,309 shares of common stock with an exercise price of \$1.00 per share to two employees and a member of our board of directors in his capacity as a consultant to us for past services. We valued the warrants at \$2.7 million using the Black-Scholes option-pricing model. Due to the immediate exercisability of the warrants upon issuance, we immediately recognized \$1.3 million and \$1.4 million in research and development expense and general and administrative expense, respectively, in the condensed consolidated statement of operations. None of the warrants were exercised as of June 30, 2014.

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# **Results of Operations**

		r Ended Six Months Ende ember 31, June 30,		
	2012	2013	2013	2014
		(in the	(unau usands)	dited)
Revenue:		(in tho	usanus)	
Collaboration and license revenue — related party <sup>(1)</sup>	\$ 1,899	\$ 2,025	\$ 1,013	\$ 1,013
Collaboration and license revenue	—	726	_	7,548
Total revenue	1,899	2,751	1,013	8,561
Operating expenses:				
Research and development	34,886	31,279	17,123	32,861
General and administrative	5,531	7,465	2,613	7,399
Total operating expenses	40,417	38,744	19,736	40,260
Loss from operations	(38,518)	(35,993)	(18,723)	(31,699)
Interest expense	(1,514)	(5,293)	_	(3,899)
Other income (expense), net	7,014	(12,349)	1,152	(14,642)
Net loss	(33,018)	(53,635)	(17,571)	(50,240)
Net loss attributable to noncontrolling interest				113
Net loss attributable to Coherus	\$(33,018)	\$(53,635)	\$(17,571)	\$(50,127)

(1) Represents revenue from Daiichi Sankyo Company, Limited, a holder of more than 10% of our common stock on an as-converted basis.

# Comparison of Six Months Ended June 30, 2013 and 2014

Collaboration and License Revenue

		ths Ended ie 30,	Increase/
	2013	2014	(Decrease)
		(in thousands)	
Daiichi Sankyo — related party	\$ 1,013	\$ 1,013	\$ —
Baxter		7,548	7,548
Total collaboration and license revenue	\$ 1,013	\$ 8,561	\$ 7,548

The increase in collaboration and license revenue was primarily due to \$7.5 million of revenue recognized in connection with the amortization of deferred revenue from our license agreement with Baxter, which we entered into in August 2013.

### Research and Development Expenses

The increase in research and development expenses of \$15.7 million to \$32.9 million during the six months ended June 30, 2014 compared to the same period in 2013 was primarily due to an increase of \$11.2 million in costs incurred to advance CHS-0214 to a Phase 3 clinical trial, which is already net of an increase of \$1.8 million in cost reimbursements from Daiichi Sankyo that was recognized as a reduction of research and development expense, an increase of \$3.6 million to advance CHS-1420 to a Phase 1 study and an increase of \$3.5 million in personnel and consulting related expenses. The increase in personnel related expenses was due to the increase in stock-based compensation expense related to common stock warrants granted to certain employees and a consultant in March 2014 and an increase in headcount by ten employees. The increase was partly offset by a decrease of \$2.3 million for CHS-1701 as we completed a Phase 1 study in March 2013.

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# General and Administrative Expenses

The increase in general and administrative expenses of \$4.8 million to \$7.4 million during the six months ended June 30, 2014 compared to the same period in 2013 was primarily due to a \$3.3 million increase in personnel and consulting related expenses associated with an increase in stock-based compensation related to the common stock warrants granted to certain employees and a consultant in March 2014 and from an increase in headcount by eight employees. Additionally, there was an increase of \$1.3 million in legal and accounting services to support the increasing infrastructure as we expand our operations and prepare to become a public company.

### Interest Expense

Interest expense was \$3.9 million during the six months ended June 30, 2014 compared to none for the six months ended June 30, 2013. The increase in interest expense was due to \$3.6 million of non-cash amortization of the debt discount and \$0.3 million of interest expense related to our convertible notes entered into during the third quarter of 2013.

### Other Income (Expense), Net

The change in other income (expense), net from \$1.2 million of income in the six months ended June 30, 2013 to expense of \$14.6 million in the six months ended June 30, 2014 was due to the increase in the fair value of our convertible preferred stock warrants of \$15.8 million and the increase in the estimated fair value of our contingent consideration obligations of \$1.7 million. These charges were partly offset by the gain on the extinguishment of our 2013 Notes of \$2.0 million.

# Comparison of Years Ended December 31, 2012 and 2013

Collaboration and License Revenue

	Decen	Year Ended December 31,		rease/
	2012	2013	(De	crease)
		(in thousands)		
Daiichi Sankyo — related party	\$1,899	\$2,025	\$	126
Baxter		726		726
Total collaboration and license revenue	\$1,899	\$2,751	\$	852

The increase in collaboration and license revenue was primarily due to the \$0.7 million of revenue recognized in connection with the amortization of deferred revenue under our license agreement with Baxter, which we entered into in August 2013.

### Research and Development Expenses

The decrease in research and development expenses of \$3.6 million to \$31.3 million in 2013 compared to 2012 was due to the following:

- net decrease of \$1.6 million for our CHS-1701 product candidate, primarily due to the decrease of \$3.0 million in manufacturing, process development, pre-clinical studies and consulting costs due to costs incurred in 2012 in preparation for Phase 1 study. These decreases were partly offset by an increase of \$1.5 million in Phase 1 study which took place in late 2012 and carried over to 2013;
- net decrease of \$4.9 million for our CHS-0214 product candidate, primarily due to the decrease of \$7.1 million in manufacturing, process development, pre-clinical studies and consulting costs due to costs incurred in 2012 in preparation for Phase 1 study which included the increase of \$1.2 million in cost reimbursements from Daiichi Sankyo that was recognized as a reduction of research and development expense. These decreases were partly offset by an increase of \$2.0 million in Phase 1 study which took place in 2013.

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decrease of \$5.2 million in manufacturing, process development, pre-clinical studies and consulting costs for two of our pre-clinical candidates that
were not further advanced due to partnering and market considerations in late 2012 and early 2013.

These decreases were partly offset by:

- increase of \$4.8 million for our CHS-1420 product candidate, primarily due to manufacturing and pre-clinical study costs to advance to Phase 1 study;
- increase of \$0.5 million in facility and other costs to support our increasing infrastructure; and
- increase of \$2.5 million in personnel related expenses, including salaries and other employee related costs, resulting from additional headcount. The
  research and development headcount at the beginning of 2012 was two, increased to 19 at the end of 2012 and further increased to 22 at the end of
  the 2013.

#### General and Administrative Expenses

The increase in general and administrative expenses of \$1.9 million to \$7.5 million in 2013 compared to 2012 was primarily due to an increase in personnel and consulting related expenses resulting from additional headcount. The general and administrative headcount at the beginning of 2012 was three, increased to 11 at the end of 2012 and further increased to 14 by the end of 2013.

#### Interest Expense

Interest expense increased \$3.8 million to \$5.3 million in 2013 compared to \$1.5 million in 2012. The interest expense of \$1.5 million in 2012 is related to the accrued interest and amortization of debt discount, of which \$1.0 million related to the beneficial conversion feature, \$0.4 million related to debt discount amortization and \$0.1 million related to interest on the outstanding debt. The interest expense of \$5.3 million in 2013 is composed of \$4.4 million of debt discount amortization, \$0.3 million of interest on the outstanding debt, and \$0.5 million related to an extended payment arrangement with one of our vendors.

### Other Income (Expense), Net

Other income (expense), net, was \$7.0 million in 2012 compared to (\$12.3 million) in 2013. Other income in 2012 is primarily due to the gain on extinguishment of our 2011 convertible notes in 2012 of \$6.4 million and the change in fair value of our convertible preferred stock warrant liability of \$0.6 million. Other expense in 2013 is primarily due to the issuance of additional preferred stock warrants in 2013 resulting in an expense of \$3.6 million and an increase in the fair value of our convertible preferred stock warrants of \$8.9 million.

#### Liquidity and Capital Resources

Due to our significant research and development expenditures, we have generated significant operating losses since our inception. We have funded our operations primarily through the issuance of debt, sales of our convertible preferred stock and payments received under our collaboration and license agreements. As of June 30, 2014, we had cash and cash equivalents of \$108.9 million.

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

In July 2014, we received additional funds of \$15.0 million from Baxter and expect to receive \$10.0 million in September 2014. Of the amount received, \$2.5 million is subject to the potential refund to Baxter in the event that we commercialize the etanercept (Enbrel) biosimilar molecule in the United States.

# Summary Statement of Cash Flows

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

		Year Ended December 31,		Six Months Ended June 30,	
	2012	2013	2013	2014	
			(unauc	lited)	
		(in thou	isands)		
Net cash provided by (used in) operating activities	\$(18,251)	\$15,423	\$(11,089)	\$14,528	
Net cash provided by (used in) investing activities	(1,823)	(373)	(172)	781	
Net cash provided by financing activities	26,938	9,956	_	53,974	
Effect of exchange rate changes in cash and cash equivalents	—	—		32	
Net increase (decrease) in cash and cash equivalents	\$ 6,864	\$25,006	\$(11,261)	\$69,315	

# Cash provided by (used in) operating activities

Cash provided by operating activities was \$14.5 million for the six months ended June 30, 2014 reflecting a net loss of \$50.2 million, which was partially offset by non-cash charges of \$14.7 million for the remeasurement of our convertible preferred stock warrant liability, \$1.7 million for remeasurement of our contingent consideration obligations, \$3.9 million of non-cash interest expense, \$4.5 million for stock-based compensation and \$0.2 million for depreciation and amortization, partially offset by the gain on the extinguishment of our 2013 convertible notes of \$2.0 million. Cash provided by operating activities reflected an increase in net operating assets of \$41.7 million primarily due to an increase in deferred revenue of \$19.4 million and an increase in contingent liability to collaborator of \$17.7 million both related to the additional payments received from Baxter under our license agreement. In addition, accounts payable and accounts payable-related parties increased by \$4.2 million as a result of the increase in clinical activities and timing of vendor payments.

Cash used in operating activities was \$11.1 million for the six months ended June 30, 2013 reflecting a net loss of \$17.6 million, which was partially offset by non-cash charges of \$7.4 million in preferred stock issued in exchange for services received, \$0.7 million for stock-based compensation and \$0.2 million for depreciation and amortization, partly offset by a non-cash gain of \$1.2 million for the remeasurement of the convertible preferred stock warrant liability. Cash used in operating activities also reflected a decrease in net operating assets of \$0.7 million due to a decrease in accounts payable and accounts payable-related parties of \$1.9 million as a result of the timing of vendor payments and a decrease of \$1.0 million due to the recognition of deferred revenue related to the Daiichi Sankyo license agreement partially offset by decrease of prepaid assets of \$1.4 million in clinical, material and manufacturing as a result of increase research and development activity and an increase of advance payments under our license agreement with a related party of \$0.6 million as a result of the timing of payments.

Cash provided by operating activities was \$15.4 million for the year ended December 31, 2013 reflecting a net loss of \$53.6 million, which was partially offset by non-cash charges of \$7.6 million in preferred stock issued in exchange for services received, \$7.8 million for the fair value of warrants and embedded derivatives issued in excess of debt proceeds, \$5.3 million of non-cash interest expense, \$2.0 million for stock-based compensation, \$0.4 million for depreciation and amortization and a non-cash gain of \$4.6 million for the remeasurement of our convertible preferred stock warrant liability and embedded derivatives. Cash provided by operating activities also reflected an increase in net operating assets of \$41.4 million primarily due to an increase in deferred revenue of \$34.7 million, an increase in contingent liability to collaborator of \$7.5 million both related to the payments received from Baxter and an increase in accrued and other liabilities of \$2.8 million related to an increase in the accrual for clinical development activities. These increases were partially offset by an increase in prepaid and other current assets of \$3.2 million related to an increase in prepaid clinical, material and manufacturing costs.

Cash used in operating activities was \$18.3 million for the year ended December 31, 2012 reflecting a net loss of \$33.0 million, which was partially offset by non-cash charges of \$8.0 million in preferred stock issued in exchange for services received, \$1.5 million of non-cash interest expense, \$0.4 million for stock-based compensation and \$0.2 million for depreciation and amortization, partially offset by the gain on the extinguishment of our 2011 convertible notes of \$6.4 million and a non-cash gain of \$0.6 million for the

remeasurement of our convertible preferred stock warrant liability. Cash used in operating activities also reflected an increase in net operating assets of \$11.6 million primarily due to an increase in deferred revenue of \$8.1 million related to payments received from Daiichi Sankyo, an increase in accounts payable and accounts payable-related parties of \$3.4 million as a result of the timing in vendor payments and \$2.2 million in accrued and other liabilities related to increase in the accrual for clinical materials and manufacturing. These changes were partially offset by the increase in prepaid and other current assets of \$2.0 million related to an increase in prepaid in clinical, materials and manufacturing costs.

### Cash provided by (used in) investing activities

Cash provided by investing activities of \$0.8 million for the six months ended June 30, 2014 was related to net cash acquired from the acquisition of InteKrin in February 2014 of \$2.3 million, partially offset by cash used for purchases of capital equipment of \$1.6 million.

Cash used in investing activities of \$0.2 million for the six months ended June 30, 2013 was related to capital equipment purchases.

Cash used in investing activities of \$1.8 million and \$0.4 million for the years ended December 31, 2012 and 2013 was related to capital equipment purchases.

## Cash provided by financing activities

Cash provided by financing activities of \$54.0 million for the six months ended June 30, 2014 was primarily related to the net proceeds from the issuance of our Series C convertible preferred stock of \$54.7 million, offset by our payment of costs related to our planned initial public offering of \$0.8 million.

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

Cash provided by financing activities of \$26.9 million for the year ended December 31, 2012 was related to net proceeds from issuance of our Series B convertible preferred stock.

### **Funding Requirements**

We believe that our existing capital resources, together with funding we expect to receive under our license agreements with Daiichi Sankyo and Baxter, will be sufficient to meet our projected operating requirements for the next 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Further, our operating plan may change, and we may need additional funds to meet operational needs and capital requirements for product development and commercialization sooner than planned. We currently have no credit facility or committed sources of capital although we may receive milestone and other contingent payments under our current license and collaboration agreements. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates and the extent to which we may enter into additional agreements with third parties to participate in their development and commercialization, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical trials. Our future funding requirements will depend on many factors, including the following:

- the scope, rate of progress, results and cost of our clinical trials, preclinical testing and other related activities;
- the cost of manufacturing clinical supplies and establishing commercial supplies of our product candidates and any products that we may develop;
- the costs of acquiring originator comparator materials and manufacturing pre-clinical study and clinical trial supplies and other materials from CMOs
  and related costs associated with release and stability testing;
- the receipt of any collaboration payments;

- the number and characteristics of product candidates that we pursue;
- the cost, timing and outcomes of regulatory approvals;
- the terms and timing of any other collaborative, licensing and other arrangements that we may establish;
- the timing, receipt and amount of sales, profit sharing or royalties, if any, from our potential products;
- the cost of preparing, filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and
- the extent to which we acquire or invest in businesses, products or technologies.

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

## **Off-Balance Sheet Arrangements**

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

### **Contractual Obligations**

Our future contractual obligations as of December 31, 2013 were as follows:

		Payments Due by Perio	d	
	Less than			More than
Total	1 year	1 to 3 years	3 to 5 years	5 Years
		(in thousands)		
\$ 4,082	\$ 4,082	\$ —	\$ —	\$ —
1,555	516	993	46	—
9,950	9,950			
431	431	—		
\$16,018	\$14,979	\$ 993	\$ 46	\$ —
	\$ 4,082 1,555 9,950 431	Less than           Total         Less than           1 year         1           \$ 4,082         \$ 4,082           1,555         516           9,950         9,950           431         431	Less than         1 to 3 years           Total         1 year         1 to 3 years           (in thousands)         (in thousands)           \$ 4,082         \$           1,555         516         993           9,950         9,950            431         431	Total         1 year         1 to 3 years         3 to 5 years           (in thousands)         (in thousands)         (in thousands)         (in thousands)           \$ 4,082         \$ 4,082         \$         \$           1,555         516         993         46           9,950              431         431

(1) Consists of repayment obligations related to principal outstanding under our convertible notes as of December 31, 2013. The convertible notes bear interest of 8% per annum and are due and payable on July 15, 2014. The convertible notes also contain a provision under which all outstanding principal and accrued interest would automatically convert upon the issuance of preferred stock.

We enter into contracts in the normal course of business with contract research organizations, or CROs, for preclinical studies and clinical trials and contract manufacturing organizations, or CMOs, for the manufacture of clinical trial materials. As of December 31, 2013, we had commitments of \$4.1 million with CMOs for the manufacture of clinical trial due within a year. We also have an agreement with a CRO vendor which provides for a minimum fee commitment of \$35.0 million for clinical trial services. As of December 31, 2013, \$5.7 million of the services related to these agreements have been performed. To date, we have entered into

commitments with this CRO vendor providing for future payments of approximately \$51.0 million. As of June 30, 2014, we have expensed approximately \$14.5 million of this amount for our clinical development program. These agreements provide for notice of termination by either party and are therefore cancelable contracts.

### **JOBS Act Accounting Election**

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have irrevocably elected to opt out of the extended transition period for complying with new or revised accounting standards pursuant to Section 107(b) of the JOBS Act.

#### **Recent Accounting Pronouncements**

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2014-09, *Revenue from Contracts with Customers*, or ASU 2014-09, which converges the FASB and the International Accounting Standards Board standards on revenue recognition. Areas of revenue recognition that will be affected include, but are not limited to, transfer of control, variable consideration, allocation of transfer pricing, licenses, time value of money, contract costs and disclosures. This guidance is effective for the fiscal years and interim reporting periods beginning after December 15, 2016, at which time we may adopt the new standard under the full retrospective method or the modified retrospective method. Early adoption is not permitted. We are currently evaluating the impact that the adoption of ASU 2014-09 will have on its consolidated financial statements and related disclosures.

In June 2014, the FASB issued ASU 2014-10, *Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation.* ASU 2014-10 simplifies the accounting guidance by removing all incremental financial reporting requirements for development stage entities. The amendments related to the elimination of the inception-to-date information and other disclosure requirement of Topic 915 should be applied retrospectively and are effective for annual reporting periods beginning after December 15, 2014 and interim periods therein. We early adopted ASU 2014-10 effective as of January 1, 2012. Adoption of this standard had no impact on our financial position, results of operations or cash flows; however, the presentation of the financial statements has been changed to eliminate the disclosures that are no longer required.

#### Quantitative and Qualitative Disclosures about Market Risk

As of June 30, 2014, we had cash and cash equivalents of \$108.9 million. A portion of our cash equivalents, which are in money market funds, may be subject to interest rate risk and could fall in value if market interest rates increase. However, because our cash equivalents are primarily short-term in duration, we believe that our exposure to interest rate risk is not significant and a 1% movement in market interest rates would not have a significant impact on the total value of our portfolio.

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

We acquired InteKrin in February 2014, which has a subsidiary based in Russia and thus subjects us to foreign currency rates fluctuation against the Russian Ruble. As of June 30, 2014, we had \$0.5 million of cash that is located in Russia and denominated in Rubles (15.5 million Rubles as of June 30, 2014).

# BUSINESS

# Overview

We are a late-stage clinical biologics platform company focused on the global biosimilar market. Biosimilars are an emerging class of protein-based therapeutics with high similarity to approved originator products on the basis of various physicochemical and structural properties, as well as in terms of safety, purity and potency. Our goal is to become a global leader in the biosimilar market by leveraging our team's collective expertise in key areas such as process science, analytical characterization, protein production and clinical-regulatory development. Since our founding in 2010, we have advanced 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.

Our clinical-stage pipeline consists of two anti-inflammatory agents targeting tumor necrosis factor, or TNF, and a long-acting form of granulocyte colonystimulating factor, or G-CSF. TNF is a substance in the body that is involved in the inflammatory response. G-CSF is a beneficial substance in the body that stimulates production of granulocytes (a type of white blood cell) in order to promote the body's ability to fight infections. Our most clinically advanced anti-TNF product candidate, CHS-0214, is an etanercept (Enbrel) biosimilar candidate that we have partnered with Baxter International, Inc., Baxter Healthcare Corporation and Baxter Healthcare SA, or together, Baxter, and Daiichi Sankyo Company, Limited, or Daiichi Sankyo, in key markets outside of the United States. We are currently enrolling two Phase 3 clinical trials with CHS-0214 in rheumatoid arthritis and psoriasis which, if positive, should support the planned filing of a marketing application in Europe in 2016. Our second anti-TNF product candidate, CHS-1420, is an adalimumab (Humira) biosimilar candidate, and completed Phase 1 studies in August 2014. We plan to initiate a Phase 3 clinical trial or trials in psoriasis or rheumatoid arthritis 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 a pegfilgrastim (Neulasta) biosimilar that we expect will begin Phase 3 clinical trials in febrile neutropenia (a condition characterized by fever and infections) in the first half of 2015.

According to Evaluate Pharma, total annual revenues from the anti-tumor necrosis factor alpha, or anti-TNF-a, and pegfilgrastim-based originator products will exceed approximately \$21 billion in the sales territories targeted by our current clinical-stage pipeline. We have retained full commercial rights to all of our product candidates in the United States and plan to seek strategic partnerships in territories outside of the United States to support the global development and commercialization of our product candidates. We intend to pursue a brand strategy for our biosimilar products that projects high similarity to the originator and positive differentiation to competing biosimilars, at a competitive price.

The global market opportunity for biosimilars is emerging as a result of several factors. First, through 2020, 24 "blockbuster" biologics, each with worldwide annual sales in excess of \$1 billion, will lose patent exclusivity in at least one major pharmaceutical market. In aggregate, these products achieved more than \$89 billion in worldwide sales in 2013. Second, regulatory agencies around the world have responded to these upcoming patent expirations by defining new biosimilar approval pathways. We believe these regulatory initiatives will help streamline the approval process across various international regulatory agencies and encourage growth of the overall biosimilar market. Third, implementation of more stringent cost containment practices on the part of governments and insurers has increased demand for high-quality biosimilars, which we believe will result in substantial market growth over time. We believe the growing number of global biopharmaceutical companies establishing biosimilars capabilities provides further validation for the size and importance of this opportunity.

While the potential market opportunity is significant, biosimilar product development poses a number of scientific, regulatory and technical challenges that distinguish it from traditional, small-molecule generic product development. We believe our world class team of biologic therapeutic developers and renowned scientists gives us the critical capabilities to successfully address the complexities underlying these challenges. Our team includes industry veterans with decades of experience in pioneering biologics companies, such as Amgen and Genentech, where they were responsible for leading, and in some cases establishing, these organizations' core

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capabilities in process development, protein manufacturing and analytical research and development. Senior members of our internal team have contributed to the filing of over 100 Investigational New Drug applications, or INDs, and over 40 marketing applications, including those for Enbrel, the originator product for our lead biosimilar product candidate. We have also assembled a distinguished Scientific Advisory Board of leading scientists who are acknowledged experts in their respective fields.

Our business model places our internal team at the center of a coordinated development effort in which our senior team of experts focuses on the highlyspecialized, 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. We believe these elements of our business model have helped us maintain a relatively modest cost structure while providing important fundamental advantages over larger companies. In addition, our dynamic organization allows us to respond to the rapidly evolving biosimilar landscape.

# **Our Strategy**

Our goal is to become a leading global biosimilar company. The 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. Our team possesses a deep understanding of the technical advancements that enable the development of biosimilars. We believe we are able to effectively select product candidates using a stringent process that factors in technical feasibility, size of originator products opportunity and market receptivity to biosimilars, as well as other criteria. With this comprehensive approach, we believe we are able to move quickly and in a capital efficient manner to advance product candidates into clinical trials with strong potential to be partnered and commercialized.
- Advance our lead programs through clinical development to secure approvals in major markets. We have developed a clinical-stage pipeline consisting of three product candidates. We recently initiated our first Phase 3 clinical trials, advancing CHS-0214 in rheumatoid arthritis and psoriasis, to support the planned filing of a marketing application in Europe in 2016. We expect to initiate Phase 3 clinical trials of CHS-1420 in psoriasis or rheumatoid arthritis in the first half of 2015, to support the planned filing of a marketing application in the United States in 2016 and the E.U. in 2017. We intend to initiate two Phase 3 clinical trials of CHS-1701 in breast cancer patients undergoing chemotherapy in the first half of 2015. We attempt to harmonize our clinical trials across multiple regulatory geographies, including United States, Europe and Japan, such that one set of clinical trials may be sufficient to meet the regulatory requirements for approval in all territories.
- *Continue to advance our early-stage product pipeline.* We will apply our team's expertise and our platform to identify and pursue multiple additional biosimilar product opportunities. In addition to our clinical-stage product portfolio, we have identified three potential product candidates that meet our stringent selection criteria, which have entered early development. Our goal is to advance at least one of these product candidates into clinical trials in 2016. We continue to evaluate other potential product development candidates to further expand our pipeline.
- Maximize the value of our portfolio and pipeline by retaining commercial rights to our products in the United States and by selectively partnering with leading pharmaceutical companies to commercialize our products in other geographies. We currently intend to retain U.S. rights to the assets we develop, while licensing ex-U.S. rights in exchange for upfront, cost sharing, milestone and royalty payments. For example, we have partnered CHS-0214 with Baxter and Daiichi Sankyo in key

markets outside of the United States and we intend to seek a partner for CHS-1420 for non-U.S. territories in 2015. Such arrangements are intended to support the Phase 3 clinical trials required for regulatory approval of our product candidates and provide us with financial resources and commercial access to ex-U.S. markets.

Attract and retain exceptionally capable team members who share our vision of bringing high quality, lower cost biologic therapeutics to patients. We value the experience that has been gained by our veteran team members over the course of decades in the biotechnology industry as essential for execution at all stages of biosimilar product development. Our level of technical expertise is also rare, difficult for others to replicate and a basis for screening those who would join our team. We intend to maintain the capabilities that will enable us to realize our vision of expanding patient access to high quality, lower cost biologic therapeutics globally.

#### **Background on Biosimilars**

#### Significant Market Opportunity

According to the IMS Institute for Healthcare Informatics, the 2012 global biologics market represented over \$160 billion in sales, with virtually the entire market composed of branded originator products. The next six years will see a surge in patent expirations for many commercially successful branded biologic products that will provide an unprecedented opportunity for cost containment through the introduction of biosimilars. For 24 major branded biologic products facing loss of patent exclusivity in at least one major market from 2015 through 2020, aggregate global sales in 2013 exceeded \$89 billion. We believe this wave of patent expirations will create one of the most significant opportunities for the biotechnology industry in the coming years. The following originator products (all of which are "blockbuster" biologics) are expected to lose patent exclusivity in at least one major market from 2015 through 2020:

Actemra	Forteo	Neulasta	Rebif
Advate	Herceptin	Norditropin SimpleXx	Remicade
Avastin	Humira	NovoMix 30	Rituxin
Botox	Lantus	Orencia	Synagis
Enbrel	Levemir	Pediarix	Tysabri
Erbitux	Lucentis	Pegasys	Xolair

Escalating healthcare costs and healthcare reform have been major drivers for the advancement of the biosimilar market. Governments and insurers are in search of mechanisms to contain costs and expand patient access without sacrificing quality of care. An increasing and disproportionate amount of healthcare spending by governments and private payors is on biologic therapeutics. According to data from Express Scripts, approximately \$4 out of every \$10 spent on prescription drugs in 2014 in the United States is projected to be spent on specialty medications, mostly complex biologics, that are only used by 2% of the population. Compounding the issue is the fact that biologic therapeutic costs are escalating at an increasingly unsustainable rate. Express Scripts also reported that the unit-cost increase for specialty biologic therapeutics in 2012 was as high as about 27%, depending on payor segment. Consequently, we believe there is tremendous cost pressure to bring high-quality, lower-priced biologic therapeutics to market. We further believe our products target payor segments having among the highest rates of spending and anticipated spending growth (see chart below).

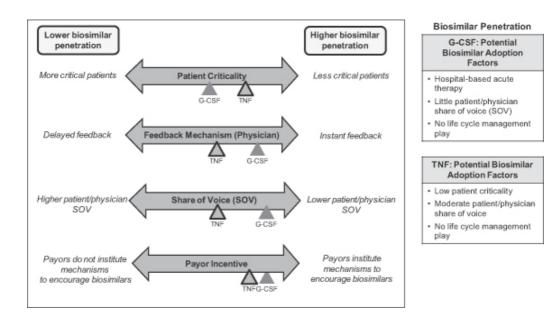
# **Top Drug Spending Classes**

Class	Per Member	2013 Trend			Projected Trend		
Class	Per Year Spend	Utilization	Unit Cost	Total	2014	2015	2016
Diabetes	\$84	2.4%	11.6%	14.0%	11%	12%	11%
Inflammatory	\$63	6.8%	15.0%	21.8%	23%	22%	21%
High Cholesterol	\$52	-2.1%	-12.3%	-14.4%	-12%	-12%	-14%
Multiple Sclerosis	\$46	1.0%	14.7%	15.7%	13%	12%	12%
High BP/ Heart Disease	\$40	0.4%	-9.1%	-8.7%	-12%	-11%	-11%
Cancer	\$36	10.5%	13.6%	24.1%	24%	25%	24%
Ulcers	\$36	0.9%	-4.1%	-3.2%	-15%	-7%	-6%
Asthma	\$35	1.0%	-15.1%	-14.1%	-5%	-0%	1%
Attention Disorders	\$33	5.3%	-1.3%	4.0%	7%	5%	5%
Depression	\$32	1.5%	-10.5%	-9.1%	-15%	-12%	-12%

Source: Express Scripts (2013 Drug Trend Report)

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

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# The Challenge of Biosimilar Product Development

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

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

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

Accordingly, inherent variation is a fundamental consideration with respect to establishing biosimilarity to an originator product to support regulatory approval requirements. Since the product quality characteristics of originator molecules exist as a range of values rather than as an absolute, regulators have issued guidelines that

require demonstration of biological similarity and functional equivalence. In contrast, small molecules are homogeneous and therefore relatively simple to replicate, obtain regulatory approval for and commercialize as generics. This simplicity of small molecules allows multiple market entrants and rapid price erosion upon loss of exclusivity. Thus, we believe the ultimate result of protein heterogeneity and complexity is a biosimilar market where only organizations with great technical skill can compete successfully and will do so in a market of relatively few participants and relatively stable prices.

# **Our Approach**

# **Our Platform**

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

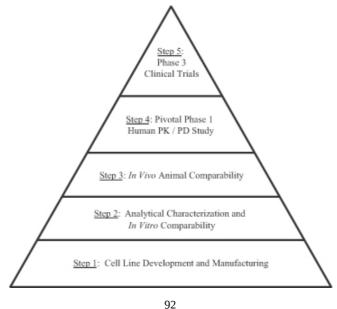
- *Advanced proprietary analytics.* Regulators require extensive and sophisticated analytics to demonstrate comparability with the originator molecule. Analytical techniques, such as mass spectrometry, which enable the measurement of the structure and elemental composition of individual molecules, are an essential tool in this process, and we have invested a substantial part of our capital budget in this area.
- Molecular tuning to achieve biosimilarity. After a protein is produced in a cell, a number of modifications to the protein can occur. These modifications can vary greatly depending on the type of cell that was selected to produce the protein and the process conditions used to generate the protein in the cell, as well as metabolic mechanisms and other considerations. One such modification, glycosylation, results when the cell that produces the protein adds sugar molecules, called glycans, to the backbone of the protein. For a highly glycosylated molecule such as etanercept (Enbrel), accurately reproducing the glycosylation pattern of the originator protein is particularly critical as glycoform distribution profiles substantially impact pharmacokinetics and biologic activity. With CHS-0214, we were able to complete the molecular tuning in an extremely short period of time by conducting a number of critical steps in a parallel fashion, making adjustments to cell growth conditions and process conditions while conducting in vivo and in vitro testing simultaneously. The same parallel process has been applied to our other biosimilar product candidates. While the range of acceptability for pharmacokinetic equivalence is 80% to 125% with the target being at 100%, for CHS-0214, we achieved a geometric ratio of 98% indicating pharmacokinetic equivalence in the Phase 1 study and earned a milestone payment under our partnership agreement with Baxter. As used herein, the term "geometric ratio" denotes the comparison of a measured pharmacokinetic value observed for a first drug, to the same measured value observed for a different drug, where the geometric mean of each drug's measured values is used as the basis for the comparison. The geometric mean is a type of mathematical average, which indicates the central tendency or typical value of a set of numbers. The use of a geometric mean "normalizes" the ranges being averaged, so that no range dominates the weighting, and a given percentage change in any numerical range has the same effect on the geometric mean. The geometric means ratio, or GMR, which is the ratio of a first geometric mean to a second geometric mean for a measured pharmacokinetic parameter, such as maximum concentration, or Cmax, is commonly used to determine bioequivalence between drugs, such that a GMR value of 1 (or 100%) signifies that the two compared pharmacokinetic values are the same.
- **Process science.** Originators are required by regulators to manufacture under the same decades-old protocols in existence when their biologic therapeutics were first approved unless they invest in costly process change protocols and file appropriate amendments. In contrast, we are not constrained to replicate outdated processes and are free to design and develop systems that integrate state-of-the-art growth media, chromatography resins, filters and techniques to produce our products. We have demonstrated that our cutting-edge protein production processes are highly scalable, extremely robust and easily automated, resulting in consistent product quality, biosimilarity and yield.
- *Formulation technologies.* The stabilization of proteins 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. Originator companies have pursued a strategy of establishing intellectual property around

specific formulations, potentially extending patent coverage on the products. We believe that our investment in proprietary formulation technology will allow us to innovate around certain patent protected formulations, thereby enabling earlier market entry than otherwise would be possible. For example, the originator formulations for Humira and Enbrel are subject to unexpired patents that specify use of various formulation ingredients for stabilizing the therapeutic protein. We have developed proprietary formulations for our Enbrel and Humira biosimilar products which do not require these ingredients.

- *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 regulatory rationale and the nuanced approach required to successfully navigate global requirements. To date, meetings with regulators have been held as follows:
  - *CHS-0214*: We met with regulators in the United States and Japan in 2013 and in the E.U. in 2014. The subject of these meetings was our overall development plan and the amount of evidence needed to support marketing approval in each of these regions.
  - *CHS-1420:* We met with E.U. regulators on September 10, 2014 to discuss our development plan and the amount of evidence needed to support our application to obtain approval for all of the indications in the originator label. We are planning to hold meetings with U.S. regulators by the first quarter of 2015.
  - *CHS-1701:* We met with U.S. regulators in 2012 and 2014 to discuss our overall development plan. Based on feedback from these meetings, we are planning further meetings with U.S. and E.U. regulators by the first quarter of 2015.

## Five Key Steps to Biosimilar Drug Development

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



# Step 1: Cell Line Development and Manufacturing

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

## Step 2: Analytical Characterization and In Vitro Comparability

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

#### Step 3: In Vivo Animal Comparability

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

# Step 4: Pivotal Phase 1 Human Pharmacokinetic and Pharmacodynamic Study

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

- C<sub>max</sub>: maximum measured serum concentration;
- AUC<sub>0gt</sub>: area under the concentration-time curve from the first time point measured (0) to the last time point measured (t); and
- AUC<sub>0ginf</sub>: area under the concentration-time curve from the first time point measured (0) extrapolated to infinity.

The area under the curve, or the AUC, is a measure of how much of a drug is in a patient's system over a given time period. In order to calculate the AUC, the concentration of the drug in blood serum or plasma is plotted over time starting at the time the drug is administered and ending when the last time point is collected ( $AUC_{0gt}$ ) or when the serum or plasma concentration would be below the level of detection or zero ( $AUC_{0ginf}$ ), and then the area under this curve is calculated. To be deemed bioequivalent, regulators require that, for each parameter, the ratio of the originator product and the biosimilar candidate fall within 80% and 125%, with the identical match being at 100%.

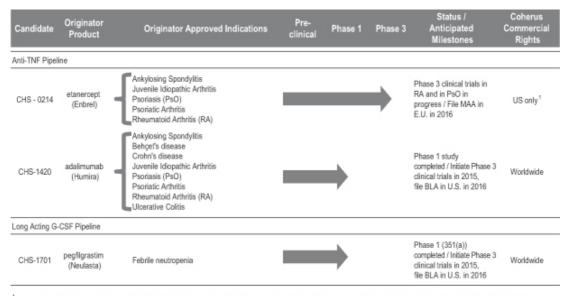
# Step 5: Phase 3 Confirmatory Safety and Efficacy Clinical Trials

The final step to support approval is a single Phase 3 confirmatory safety and efficacy study in a therapeutic indication for which the originator product has been approved. The objective of this study is to demonstrate

biosimilarity between the two molecules with respect to safety and efficacy. Subject to discussions with regulators and agreement on trial endpoints, we strive to demonstrate that our biosimilar products are as effective and safe as the originators. Trial endpoints include considerations such as the number of subjects, statistical significance, confidence intervals and accumulated safety database size.

# **Development Portfolio**

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



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

### Anti-TNF Pipeline Opportunity

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

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

*Large market opportunity.* Global sales of Enbrel and Humira are projected to exceed \$24 billion in 2017, representing over 60% of combined estimated global sales in the anti-TNF monoclonal antibody and TNF inhibitor markets in 2017. Approximately \$19 billion of this estimated market is in territories



in which we or our partners currently intend to commercialize our anti-TNF products. In addition, among the top ten selling drugs in its pharmacological class, Humira is also approved for the largest number of inflammatory indications worldwide.

- *Receptivity to biosimilars.* Because anti-TNF agents are typically used to treat diseases where there is low risk of imminent mortality, we believe
  physicians and payors will be inclined to support adoption of biosimilar anti-TNF agents that allow for rapid confirmation of safety and efficacy for
  the individual patient. We believe that physicians recognize the payor will be a key influencer in driving the adoption of biosimilar anti-TNF agents.
- *Technical barriers to entry.* There are numerous challenges in the development of biosimilars to these reference products related to quality characteristics such as glycosylation that we believe our specialized expertise in protein chemistry and process science will allow us to overcome.
- *Timing of patent expiration.* The expiration of certain originator patents pertaining to etanercept (Enbrel) and adalimumab (Humira) in major markets offers us a near-term opportunity to introduce biosimilar competitors in these markets. Specifically, we believe we would not be precluded by the originator's patents from introducing an etanercept (Enbrel) biosimilar candidate in Europe after August 2015 or in Japan after September 2015. In the case of adalimumab (Humira), we do not believe originator patents would preclude us from introducing a biosimilar in the United States after December 2016, in Europe after October 2018 and in Japan after August 2018 (for rheumatoid arthritis) or May 2020 (for psoriasis).

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

## Product Overview

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

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

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

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

- rheumatoid arthritis; and
- juvenile idiopathic arthritis.

In 2017, sales of Enbrel are projected to exceed \$9 billion worldwide and \$2.8 billion in Europe. Because patents in the United States, assuming validity and enforceability, provide market exclusivity for the etanercept (Enbrel) originator molecule until 2029, we focused our CHS-0214 regulatory program on Europe and Japan, but harmonized as needed for potential FDA approval. We have licensed CHS-0214 to Daiichi Sankyo in Japan and to Baxter in territories outside of Japan, the United States and certain Caribbean and Latin American countries. We have licensed CHS-0214 to Orox for certain Caribbean and Latin American countries. According to Evaluate Pharma, in 2017 sales of Enbrel in Europe, Japan and other territories outside the United States are projected to be approximately \$4.4 billion, as shown below.

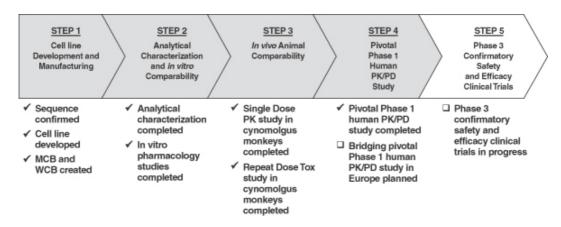


### Current Development Status and Data

The diagram below summarizes the current development status of CHS-0214. We have successfully advanced CHS-0214 through steps 1 through 4. Our pivotal Phase 1 human PK / PD study was conducted in the United States. We are currently evaluating CHS-0214 in two randomized Phase 3 clinical trials. One of these Phase 3 clinical trials will use subjects with rheumatoid arthritis in the following countries: United States, Argentina, Belarus, France, Germany, Hungary, Israel, Japan, Poland, Russia, South Africa and the United Kingdom. The other of these Phase 3 clinical trials will use subjects with psoriasis in the following countries: United States, Canada, Australia, Chile, Germany, Israel, Poland, Russia, South Africa and the United Kingdom. We have filed an IND application or equivalent request for approval in all of these countries where we are performing studies. We expect the European marketing application for CHS-0214 to be filed with the EMA 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 the indications included in the label for Enbrel.



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# Step 1: Cell Line Development and Manufacturing

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

# Step 2: Analytical Characterization and In Vitro Comparability

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

### Step 3: In Vivo Animal Comparability

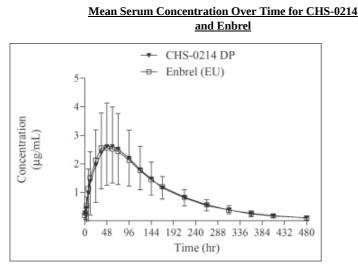
We compared CHS-0214 to Enbrel in a single-dose PK study and a 28-day study in evaluating toxicity and PK in cynomolgus monkeys and no appreciable differences were identified.



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Step 4: Pivotal Phase 1 Human Pharmacokinetic and Pharmacodynamic Study

We announced the Phase 1 PK similarity trial results for CHS-0214 in October 2013. This study was a single



dose cross-over study conducted in 60 healthy adult human volunteers to evaluate the PK and safety of CHS-0214 compared to Enbrel. CHS-0214 met the primary endpoint of clinical PK similarity to Enbrel with the study demonstrating a 98% correlation between CHS-0214 and Enbrel.

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

Due to the change in the manufacturing location from the United States to the E.U., we are planning an additional PK similarity trial comparing CHS-0214 to a lot of Enbrel manufactured in Europe. The design of this trial is a single-dose, cross-over study similar to the one described above. We plan to begin the new study in the second half of 2014.

### Step 5: Phase 3 Confirmatory Safety and Efficacy Clinical Trials

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

The Phase 3 clinical trial in rheumatoid arthritis is a double blind, multi-center, parallel group study in which approximately 486 patients with DMARD (disease-modifying antirheumatic drug)-refractory active rheumatoid arthritis will be put on a stable dose of methotrexate. Subjects will be randomized 1:1 to CHS-0214 50 mg or Enbrel 50 mg, administered subcutaneously weekly over a period of 24 weeks. The primary efficacy endpoint will be ACR 20 (20% improvement according to American College of Rheumatology Criteria) scores at 24 weeks, the same primary endpoint that was used in the Enbrel registration trial for rheumatoid arthritis. Following the initial 24-week double-blind period, all patients will be moved to CHS-0214 treatment for a period of 6 months.

The Phase 3 clinical trial in psoriasis is a double-blind, parallel group, multi-center study in 424 patients with active psoriasis. Patients will be randomized 1:1 to CHS-0214 or Enbrel, 50 mg administered subcutaneously twice weekly for the first 12 weeks, switching to once weekly and continuing in the same treatment arms for an additional 40 weeks, which includes four weeks of follow-up. The primary efficacy endpoint will be the mean Psoriasis Area and Severity Index, or PASI, or percentage of subjects achieving a 75% improvement in the PASI from baseline (PASI-75), scores at 12 weeks.

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

Product Overview

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

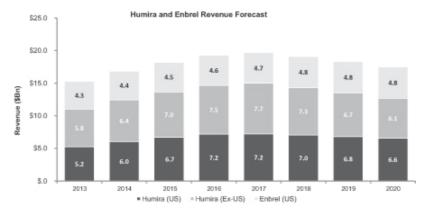
Humira has been approved by the EMA and the FDA for the treatment of the following indications only when conventional therapies are not sufficiently effective:

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

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

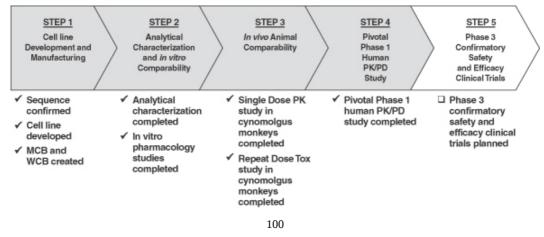
- rheumatoid arthritis;
- psoriatic arthritis;
- psoriasis; and
- Behçet's disease.

Worldwide sales of Humira are projected to total approximately \$15 billion in 2017, with about \$7.2 billion in the United States and \$5.2 billion in Europe, the two primary regions in which we plan to focus our commercialization efforts. CHS-1420 will target a large global anti-TNF market, including but not limited to the worldwide market for the originator product, Humira. According to Evaluate Pharma, in 2017, sales of Humira worldwide and of Enbrel in the United States are projected at approximately \$19.6 billion, as shown below.



## Current Development Status and Data

The diagram below summarizes the current development status of CHS-1420. We have successfully advanced CHS-1420 through steps 1 through 4, and we have completed a Phase 1 PK / PD study comparing CHS-1420 to Humira in healthy volunteers. This Phase 1 PK study met the primary endpoint and demonstrated bioequivalence for all prospectively defined endpoints and was conducted under an IND application in the United States. We plan to initiate Phase 3 clinical trials in psoriasis or rheumatoid arthritis during the first half of 2015 to support the planned filing of a marketing application in the United States in 2016 and the E.U. in 2017. We are in the process of reaching concurrence with regulatory authorities in United States, Europe and Japan with the objective of designing a harmonized global Phase 3 program to support registration in these territories. If approved, we believe we will be able to extrapolate the data from our trials in rheumatoid arthritis and psoriasis to gain approval for CHS-1420 in all the indications included in the label for Humira.



# Step 1: Cell Line Development and Manufacturing

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

## Step 2: Analytical Characterization and In Vitro Comparability

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

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

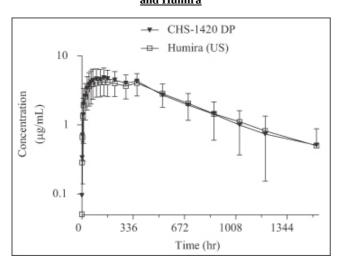
# Step 3: In Vivo Animal Comparability

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

# Step 4: Pivotal Phase 1 Human Pharmacokinetic and Pharmacodynamic Study

In April 2014, we initiated a Phase 1 pivotal PK study in human subjects. This is a single dose,

# Mean Serum Concentration Over Time for CHS-1420 and Humira



double-blind parallel group study designed to demonstrate bioequivalence between CHS-1420 and Humira. A secondary objective was to assess the safety and tolerability of CHS-1420 in this population. The study has been successfully completed and met the primary endpoint and demonstrated bioequivalence with respect to the three prospectively defined PK endpoints. CHS-1420 and Humira were both well tolerated in this singledose study in healthy adult volunteers.

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# Step 5: Phase 3 Confirmatory Safety and Efficacy Clinical Trials

We plan to execute a multi-center, global, randomized, double-blind, active-controlled, Phase 3 clinical trial in psoriasis or rheumatoid arthritis. This study would be considered the primary confirmatory safety and efficacy study to support a registration filing. We plan to begin the new study in the first half of 2015.

We plan to execute a multi-center, global, randomized, double-blind, active-controlled, Phase 3 clinical trial in psoriasis or rheumatoid arthritis. This study would be considered the primary confirmatory safety and efficacy study to support a registration filing. We plan to begin the new study in the first half of 2015.

#### Long Acting G-CSF Pipeline Opportunity

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

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

- *Large market opportunity.* The combined opportunity for both short- and long-acting G-CSF therapies worldwide is estimated to exceed \$5 billion in 2017 (please see figure below), and pegfilgrastim therapies are expected to capture over 70% of worldwide market revenues in the G-CSF class. It is estimated that the worldwide opportunity for Neulasta, the reference product for CHS-1701, will exceed \$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. These percentage shares are based on sales of all short-acting G-CSF products in the E.U., which totaled approximately 1.4 million units in Q3 2013. This total was comprised of Neupogen, Granocyte and biosimilar filgrastim sales of 0.2 million units, 0.4 million units, and 0.7 million units, respectively.

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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.



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

#### Product Overview

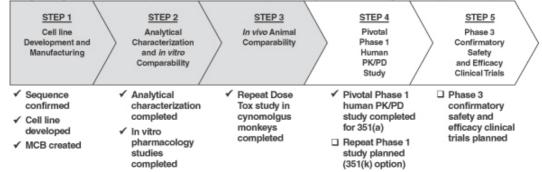
Pegfilgrastim (Neulasta), the reference product for CHS-1701, is a pegylated form of the recombinant human G-CSF analog, filgrastim. Filgrastim produced from *E. coli* is not glycosylated. We have performed extensive analytical characterization of CHS-1701 and have determined that its basic and higher-order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

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

Analysts project the worldwide market for Neulasta in 2017 will exceed \$3.9 billion, of which approximately \$3.0 billion would be in the United States. We have concluded that patent expiration in major markets offers a near-term opportunity to introduce biosimilar competitors in the United States after October 2015 and in Europe after February 2018.

# Current Development Status and Data

The diagram below summarizes the current development status of CHS-1701. Under the 351(a) (novel biologic) pathway, we have successfully advanced CHS-1701 through steps 1 through 4, including completion of a Phase 1 PK / PD study in healthy volunteers. This study was conducted under an Investigational New Drug application in the United States. We are currently preparing for the initiation of future studies as described below. Assuming positive results, we plan to file a BLA application for CHS-1701 in the United States in 2016 under the 351(a) (novel biologic) pathway which does not require demonstration of bioequivalence to the originator drug. However, to preserve the option to change from the 351(a) (novel biologic) pathway to the 351(k) (biosimilar) pathway, we are also planning a repeat pivotal Phase 1 PK / PD study in healthy volunteers. We have not yet decided whether to proceed with this additional study. Phase 3 registration clinical trial requirements and development plans are currently under discussion with regulatory agencies, and we plan to begin the study in the first half of 2015.



### Step 1: Cell Line Development and Manufacturing

As with our other product candidates, we confirmed that the amino acid sequence of CHS-1701 is identical to the originator molecule. CHS-1701 is manufactured in *E. coli* and PEGylation occurs as a subsequent step in the manufacturing process. For PEGylation of CHS-1701, we used the same polyethylene glycol, or PEG, molecule as Neulasta and established that chemistry and site of attachment of the PEG molecule was the same. We expect to manufacture commercial supply of CHS-1701 at a U.S. CMO.

## Step 2: Analytical Characterization and In Vitro Comparability

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

#### Step 3: In Vivo Animal Comparability

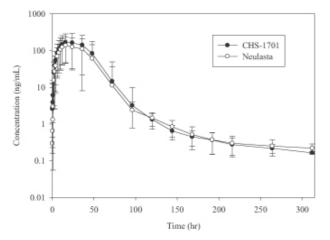
With CHS-1701, we have performed two preclinical pharmacology/toxicology studies: a two-week study in rats and a four-week study in monkeys. We performed a two-week rat study to characterize the toxicity and pharmacodynamics of CHS-1701 administered every four days for two weeks, with a recovery period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

We designed a second pharmacology/toxicology study in animals to characterize PK and PD profiles as well as the potential for harmful antibody responses to CHS-1701 or other toxic effects, in order to compare these attributes observed for CHS-1701 with those we observed for Neulasta. We administered either CHS-1701 or Neulasta at dose levels of 0.075, 0.25 and 0.75 mg/kg once weekly for 4 weeks. We found that CHS-1701 performed in a manner similar to Neulasta in that it increased the production of white blood cells in the bone marrow and resulted in an increase in the amount of white blood cells in the blood, in the bone marrow and in lymphoid tissues such as spleen and thymus tissue. Moreover, we found no differences between CHS-1701 and Neulasta in terms of potentially harmful antibody responses or other toxicities, nor in terms of PK and PD.

# Step 4: Pivotal Phase 1 Human Pharmacokinetic and Pharmacodynamic Study

We conducted a Phase 1, randomized, double-blind, single-dose, two-period crossover study to assess the PK profile, safety and activity of a single subcutaneous 6 mg dose of CHS-1701 compared to Neulasta in 79

#### Mean Serum Concentration Over Time of CHS-1701 and Neulasta



healthy human subjects between November 2012 and March 2013. There was a 28-day washout interval after each drug administration. Bioequivalence of CHS-1701 and Neulasta was measured based on  $AUC_{ogt}$ ,  $AUC_{ogtinf}$  and  $C_{max}$  of the molecule.

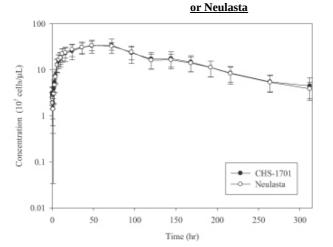
Pegfilgrastim mean exposure ( $C_{max}$ , AUC<sub>0gt</sub> and AUC<sub>0ginf</sub>) and standard deviation values were overlapping after subcutaneous administration of CHS-1701 or Neulasta, independent of the day of dosing or the treatment sequence, with notable variability observed. However, the study did not meet bioequivalence due to geometric mean values (i.e., a type of calculation that compares the measured values) ranging slightly above the allowed upper confidence interval (125%) on all three variables. Under the 351(a) (novel biologic) pathway, demonstration of

pharmacokinetic bioequivalence of CHS-1701 to Neulasta is not required and the FDA has indicated that our development program may proceed to Phase 3. However, to preserve the option to change from a 351(a) (novel biologic) pathway to a 351(k) (biosimilar) pathway, we are also making necessary preparations for a new pivotal Phase 1 PK / PD study in healthy volunteers for purposes of demonstrating PK bioequivalence to the originator drug (Neulasta), which is required under the 351(k) pathway. We have not yet decided whether to proceed with this additional study.

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Importantly, with respect to the PD marker, the absolute neutrophil count, or ANC, mean exposure  $(AUC_{0gt})$ , the study demonstrated that CHS-1701 mobilization of neutrophils was comparable to that observed with Neulasta. Although we did not power the study to define bioequivalence for this endpoint, a post-hoc

### Mean Absolute Neutrophil Count (ANC) Over Time after single dose of CHS-1701



analysis of this secondary endpoint revealed that this endpoint would have met bioequivalence criteria. This further suggests that the variations observed in the study that resulted in missing PK bioequivalence had little to no effect on the PD response (i.e., mean increase in ANC over time) and that CHS-1701 functioned as anticipated, as well as similarly to Neulasta.

Overall, we demonstrated that the adverse event profile was similar between the two treatments. Adverse events reports in both treatment arms included upper respiratory infection, back pain, pain in extremity, arthralgia, musculoskeletal chest pain, neck pain and headache. In this study, CHS-1701 and Neulasta had essentially the same safety profile. Anti-drug antibodies were similar between CHS-1701 and Neulasta and did not appear to

affect drug exposure. Neutralizing antibodies were not evaluated in this study.

The Phase 1 study described above met its primary endpoint for purposes of enabling us to pursue a 351(a) (novel biologic) approval pathway, but did not establish bioequivalence necessary to support a 351(k) (biosimilar) pathway. To preserve our option to change from a 351(a) (novel biologic) pathway to a 351(k) (biosimilar) pathway, we are planning a repeat pivotal Phase 1 PK / PD study to measure the bioequivalence of CHS-1701 and Neulasta. If we decide to proceed with this additional Phase 1 study, we will design the study to address variability that we observed in our first PK study, which we believe led to the lack of bioequivalence.

We are also planning to perform a single-dose, dose-proportionality study in the United States. This study will assess the PK and ANC profile over time for CHS-1701 compared to Neulasta. The doses are the 6 mg dose that is the approved dose of Neulasta and at least one additional dose level below the 6 mg dose. This study will be performed in parallel with the Phase 3 clinical trial.

We are also planning to perform a multi-dose PK study at the 6 mg dose as part of the Phase 3 clinical trials described below.

### Step 5: Phase 3 Confirmatory Safety and Efficacy Clinical Trials

We are planning to initiate two Phase 3 clinical trials in the first half of 2015. The primary objective of these trials will be to compare the efficacy of CHS-1701 versus Neulasta in reducing the duration of severe neutropenia in the first cycle of chemotherapy. We also intend to compare the safety profiles of CHS-1701 and Neulasta and to explore other measures of efficacy.

These will be studies in patients with advanced breast cancer receiving chemotherapy with CHS-1701 or Neulasta administered 24 hours after each dose of chemotherapy for the first four cycles. In each of these trials, we plan to enroll approximately 369 subjects randomized 2:1 to CHS-1701 or Neulasta. In both studies, the primary endpoint will be the days of severe neutropenia, a surrogate marker for febrile neutropenia, following the first dose of CHS-1701 in comparison to Neulasta.

### **Early-Stage Biosimilar Pipeline**

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

We have performed a product opportunity review of additional biosimilar pipeline candidates in conjunction with our Scientific Advisory Board. Accordingly, we are advancing the development of several undisclosed product candidates through various steps. One or more of these products is expected to form the basis of our Phase 3 clinical trial pipeline between 2017 and 2020.

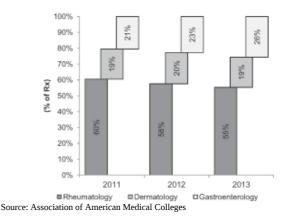
#### Sales and Marketing

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

### **Target Physician Numbers**

Specialty	U.S. Physicians
Rheumatology	4,069
Dermatology	10,101
Gastroenterology	11,550





Source: IMS Health; Association of American Medical Colleges Physician Specialty Data Book 2012; AMA Physician Master File (December 2010)

### Manufacturing

We have entered into agreements with CMOs including Cook Pharmica LLC, or Cook, Rentschler Biotechnologie GmbH, or Rentschler, and Cytovance Biologics, Inc., or Cytovance, for the manufacture and clinical drug supply for our lead products candidates. We continue to screen other contract manufacturers to meet our clinical, commercial and regulatory supply requirements on a product-by-product basis. We have not yet entered into commercial supply agreements with any contract manufacturers, but we will commence negotiations as appropriate based on development of our lead product candidates.

#### Competition

The development and commercialization of protein-based therapeutics is highly competitive. While we believe that our biologics platform, knowledge, experience and scientific resources provide us with competitive advantages, we face potential competition from many different sources. Such competition includes larger and

better-funded pharmaceutical, generic pharmaceutical, specialty pharmaceutical and biotechnology companies, as well as innovator companies and any other firms developing the biosimilars that would compete with the product candidates in our pipeline and other novel products with similar indications. For example, CHS-0214 may compete with products developed by Pfizer (which holds ex-North America rights to Enbrel, the reference product of CHS-0214), Sandoz (as a biosimilar company), Bioepis and Merck & Co., Inc., or Merck, (through their collaboration to develop and commercialize etanercept (Enbrel) biosimilar candidates) and Hanwha. Similarly, CHS-1420 may face competition from AbbVie (the holder of rights to Humira, the reference product of CHS-1420), Sandoz (as a biosimilar company), Amgen, Actavis, Plc, or Actavis, Pfizer and Boehringer Ingelheim (as biosimilar companies and as developers of novel products). CHS-1701 may face competition from Amgen (which holds rights to Neulasta, the reference product of CHS-1701), Sandoz (as a biosimilar company) and Hospira and Teva (as developers of novel products).

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

Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. These competitors also compete with

us in recruiting and retaining qualified scientific and management personnel and establishing clinical study sites and subject registration for clinical studies, as well as in acquiring technologies complementary to or necessary for our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

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

### **Collaboration and License Agreements**

### License Agreement with Daiichi Sankyo Company, Limited

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

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

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

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

### License Agreement with Baxter International, Inc., Baxter Healthcare Corporation and Baxter Healthcare SA

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

Upon execution of the license agreement, we received an upfront payment in cash of \$30.0 million. We are eligible to receive from Baxter tiered royalties, based on the manufacturing cost as a percentage of net sales of licensed products, ranging from the mid-single digits to the high teens on a country-by-country basis. These royalties are subject to certain offsets and reductions. We are also eligible to receive milestone payments for achievement of specified development and regulatory milestones totaling up to \$216.0 million. In February 2014, we amended the license agreement to increase the eligible milestone payments by \$5.3 million to an aggregate amount of \$221.3 million. Contingent payments intended to cover development-related expenses are potentially reimbursable, in part, to Baxter in certain limited circumstances. The amounts that are potentially reimbursable to

Baxter contain a claw-back feature that, in the event that we commercialize a biosimilar version of etanercept (Enbrel) in the United States, as opposed to Baxter opting-in to commercialize the molecule in the United States, fifty percent (50%) of those contingent payments are refundable to Baxter.

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

#### Distribution Agreement with Orox Pharmaceuticals B.V.

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

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

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

#### License Agreement with Genentech, Inc.

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

We may terminate the agreement at any time upon sixty days prior written notice to Genentech. Genentech may terminate the agreement for any material breach by Coherus that is not cured within a specified time period

or in the event of our insolvency. Genentech may also terminate the agreement if we challenge the licensed patents. Absent earlier termination, the agreement with Genentech will expire on a country-by-country basis on the expiration of the last valid patent claim.

### License Agreements with Selexis SA

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

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

#### **Intellectual Property**

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

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

In the normal course of business, we pursue patent protection directed primarily to protein manufacture and formulation. We are the sole owners of a portfolio of pending patent applications, none of which have yet issued, and all of which pertain to our lead product candidates CHS-0214 and CHS-1420. We have 104 pending patent applications the United States and in other countries covering formulations and manufacture of CHS-0214, which if granted are expected to expire in 2032 and 2033. We have eight pending patent applications in the United States and in other countries covering formulations of CHS-1420, which if granted are expected to expire in 2032.

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

We have a non-exclusive license from Genentech under two U.S. patents which are commonly known as the "Cabilly" patents. The Cabilly patents cover key steps of therapeutic antibody manufacturing methods. One of

the Cabilly patent covers a process for producing an immunoglobulin molecule (Ig) in a single host cell; the second Cabilly patent covers a method for making an antibody heavy chain and antibody light chain in a recombinant host cell. Both licensed patents are expected to expire in December 2018.

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

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

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

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

InteKrin has an exclusive license from Amgen under 122 patents and patent applications granted or filed in the United States and other countries that cover PPAR gamma inhibitor molecules and therapeutic product compositions that are expected to expire in 2020 and 2021, as well as certain salt forms and polymorphic forms of PPAR gamma inhibitor molecules that are expected to expire in 2024. Additionally, InteKrin owns ten pending patent applications filed in the United States and other countries that cover solid forms of PPAR gamma pharmaceutical compositions that, if granted, are expected to expire in 2029, 2031 and 2034.

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

### Regulatory

#### Government Regulation and Product Approval

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

## FDA Approval Process

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

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

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

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

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

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

The FDA may order the temporary or permanent discontinuation of a clinical trial at any time or impose other sanctions if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The study protocol and informed

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consent information for patients in clinical trials must also be submitted to an institutional review board, or IRB, for approval. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements or may impose other conditions. The study sponsor may also suspend a clinical trial at any time on various grounds, including a determination that the subjects or patients are being exposed to an unacceptable health risk.

Clinical trials to support BLAs for marketing approval of an originator biologic under the 351(a) pathway are typically conducted in three sequential phases, but the phases may overlap or be combined. In Phase 1, the biologics are initially introduced into healthy human subjects or patients and the biologic is tested to assess pharmacokinetics, pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence of effectiveness. In the case of some products for severe or life-threatening diseases, such as cancer treatments, initial human testing may be conducted in the intended patient population. Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the biologic for a particular indication, dosage tolerance and optimum dosage and to identify common adverse effects and safety risks. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 clinical trials are undertaken to obtain additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites. These Phase 3 clinical trials are intended to establish data sufficient to demonstrate substantial evidence of the efficacy and safety of the product to permit the FDA to evaluate the overall benefit-risk relationship of the biologic and to provide adequate information for the labeling of the biologic. Trials conducted outside of the United States under similar, GCP-compliant conditions in accordance with local applicable laws may also be acceptable to the FDA in support of product licensing.

Sponsors of clinical trials for investigational drugs must publicly disclose certain clinical trial information, including detailed trial design and trial results in the FDA public databases. These requirements are subject to specific timelines and apply to most controlled clinical trials of FDA-regulated products. Phase 1, Phase 2 and Phase 3 trials may not be completed successfully within a specified period, if at all, and there can be no assurance that the data collected will support FDA approval or licensure of the product.

After successful completion of the required clinical testing in accordance with all applicable regulatory requirements, detailed information regarding the investigational product is prepared and submitted to the FDA in the form of a BLA requesting approval to market the product for one or more indications. FDA review and approval of the BLA is required before marketing of the product may begin in the United States. The BLA must include the results of all pre-clinical, clinical and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture and controls and must demonstrate the safety and efficacy of the product based on these results. The BLA must also contain extensive manufacturing information. The cost of preparing and submitting a BLA is substantial. Under federal law, the submission of most BLAs is additionally subject to a substantial application user fee, as well as annual product and establishment user fees, which may total several million dollars and are typically increased annually.

The FDA has 60 days from its receipt of a BLA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of BLAs. The FDA's stated goal is to review most such applications for standard review biologics within ten months from the date the application is accepted for filing. Although the FDA can meet its user fee performance goals, the review process is often significantly extended by requests for additional information or clarification, and FDA review may not occur on a timely basis at all. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed or held meets standards designed to assure the product's continued safety, purity and potency. The FDA usually refers applications for novel biologics which present difficult questions of safety or efficacy, to an advisory committee — typically a panel that includes clinicians and other experts — for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving a BLA, the FDA will typically inspect one or more clinical sites to assure

compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the biologic is manufactured. The FDA will not approve the product unless it verifies that compliance with current GMP – a quality system regulating manufacturing — is satisfactory and the BLA contains data that provide substantial evidence that the biologic is safe and effective in the indication studied.

After the FDA evaluates the BLA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the BLA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. The FDA approval is never guaranteed, and the FDA may refuse to approve a BLA if applicable regulatory criteria are not satisfied.

Under the PHSA, the FDA may approve a BLA if it determines that the product is safe, pure and potent and the facility where the product will be manufactured meets standards designed to ensure that it continues to be safe, pure and potent. An approval letter authorizes commercial marketing of the biologic with specific prescribing information for specific indications. The approval for a biologic may be significantly more limited than requested in the application, including limitations on the specific diseases and dosages or the indications for use, which could restrict the commercial value of the product. The FDA may also require that certain contraindications, warnings or precautions be included in the product labeling. In addition, as a condition of BLA approval, the FDA may require a risk evaluation and mitigation strategy, or REMS, to help ensure that the benefits of the biologic outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patient registries. The requirement for a REMS or use of a companion diagnostic with a biologic can materially affect the potential market and profitability of the biologic. Moreover, product approval may require, as a condition of approval, substantial post-approval testing and surveillance to monitor the biologic's safety or efficacy. Such post-approval testing may include Phase 4 trials and surveillance to further assess and monitor the product's safety and effectiveness after commercialization. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

After a BLA is approved, the product may also be subject to official lot release. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official lot release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA may also perform certain confirmatory tests on lots of some products, such as viral vaccines, before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency and effectiveness of biological products. After approval of biologics, manufacturers must address any safety issues that arise, are subject to recalls or a halt in manufacturing and are subject to periodic inspection after approval.

Because biologically sourced raw materials are subject to unique contamination risks, their use may be restricted in some countries.

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

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

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studies, as compared with the requirement for three study phases under the 351(a) (novel biologics) approval pathway. Thus, under the 351(k) (biosimilar) approval pathway, an application for licensure of a biosimilar product must include information demonstrating biosimilarity based upon the following, unless the FDA determines otherwise:

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

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

- the proposed biosimilar product and reference product utilize the same mechanism of action for the condition(s) of use prescribed, recommended or suggested in the proposed labeling, but only to the extent the mechanism(s) of action are known for the reference product;
- the condition or conditions of use prescribed, recommended or suggested in the labeling for the proposed biosimilar product have been previously
  approved for the reference product;
- the route of administration, the dosage form and the strength of the proposed biosimilar product are the same as those for the reference product; and
- the facility in which the biological product is manufactured, processed, packed or held meets standards designed to assure that the biological product continues to be safe, pure and potent.

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

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

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

the active ingredients are the same or to demonstrate that any impurities or differences in active ingredients do not affect the safety, purity or potency of the biosimilar product. In addition, as with BLAs, biosimilar product applications will not be approved unless the product is manufactured in facilities designed to assure and preserve the biological product's safety, purity and potency.

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

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

The first biological product determined to be interchangeable with a branded product for any condition of use is also entitled to a period of exclusivity, during which time the FDA may not determine that another product is interchangeable with the reference product for any condition of use. This exclusivity period extends until the earlier of: (1) one year after the first commercial marketing of the first interchangeable product; (2) 18 months after resolution of a patent infringement suit instituted under 42 U.S.C. § 262(1)(6) against the applicant that submitted the application for the first interchangeable product, if a patent infringement suit instituted under 42 U.S.C. § 262(1)(6) against the approval of the first interchangeable product, if a patent infringement suit instituted under 42 U.S.C. § 262(1)(6) against the approval of 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(1)(6).

### Advertising and Promotion

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

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

#### Adverse Event Reporting and GMP Compliance

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

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

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

### Other Healthcare Laws and Compliance Requirements

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

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

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

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

The shifting commercial compliance environment and the need to build and maintain robust systems to comply with different compliance and/or reporting requirements in multiple jurisdictions increase the possibility that a healthcare company may violate one or more of the requirements. If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to

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penalties, including, without limitation, civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to operate our business and our financial results.

### **International Regulation**

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

#### Pharmaceutical Coverage, Pricing and Reimbursement

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

#### Employees

As of June 30, 2014, we had 46 full-time employees, 28 of whom were primarily engaged in research and development activities and 13 of whom had an M.D. or Ph.D. degree.

### Facilities

Our headquarters are located in Redwood City, California, where we occupy office space in five suites under a lease that will expire in April 2017. Our analytical and process development laboratories are located in Camarillo, California under a lease that expires in June 2017.

### Legal Proceedings

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

### MANAGEMENT

## **Executive Officers and Directors**

The following table sets forth information regarding our executive officers and directors, as of June 30, 2014:

Name	Age	Position(s)		
Executive Officers				
Dennis M. Lanfear	58	President, Chief Executive Officer and Chairman of the Board		
George G. Montgomery	53	Chief Financial Officer		
Barbara K. Finck, M.D.	67	Chief Medical Officer		
Alan C. Herman, Ph.D.	66	Chief Scientific Officer		
Michael A. Nazak	55	Senior Vice President Finance & Administration		
Peter K. Watler, Ph.D.	52	Chief Technical Officer		
Non-Employee Directors				
James I. Healy, M.D., Ph.D. <sup>(1)(2)</sup>	49	Director		
V. Bryan Lawlis, Ph.D. <sup>(2).</sup>	62	Director		
Christos Richards <sup>(3)</sup>	56	Director		
Ali J. Satvat <sup>(1)</sup>	36	Director		
August J. Troendle, M.D.	57	Director		
Mats Wahlström <sup>(1)(3)</sup>	59	Director		
Mary T. Szela <sup>(2)(3)</sup>	51	Director		
(1) Member of the audit committee.				

(1) Member of the audit committee.(2) Member of the compensation committee.

(3) Member of the nominating and corporate governance committee.

#### **Executive Officers**

**Dennis M. Lanfear** is our co-founder and has served as our President and Chief Executive Officer and as a member of our board of directors since our inception in September 2010. Mr. Lanfear previously was President of InteKrin Therapeutics Inc., a biopharmaceutical company, from 2005 to May 2010. Prior to that, Mr. Lanfear served in various senior leadership roles at Amgen Inc., a biopharmaceutical company from 1986 to 1999. While at Amgen, Mr. Lanfear had key leadership positions in the Process Development department, which under his management became an area of key strategic advantage for Amgen. Mr. Lanfear has also held senior leadership roles in several product development programs including those for growth factors, somatotrophins and neurotrophins and directed efforts from preclinical studies to Phase 3 clinical trials at Amgen. Mr. Lanfear holds B.S. degrees in Chemical Engineering and Biochemistry from Michigan State University and an M.B.A. from the Anderson School of Management at the University of California, Los Angeles. We believe Mr. Lanfear is qualified to serve on our board of directors because of his background and various leadership roles in the biopharmaceutical field.

**George G. Montgomery** has served as our Chief Financial Officer since August 2012. Mr. Montgomery previously served as Managing Director of Sagent Advisors, Inc., an investment banking firm, from February 2011 to October 2012. Prior to that, from July 2008 to January 2011, he served as Managing Director of Montgomery, Marshall Healthcare Partners, LLC, an investment banking firm. Mr. Montgomery also previously served as a Managing Director at JPMorgan H&Q, an investment banking firm. Mr. Montgomery was Managing Director of Montgomery, Marshall Healthcare Partners has a B.A. in Political Science from Yale University and an M.B.A. from the Wharton School at the University of Pennsylvania. As described above, Mr. Montgomery was Managing Director of Montgomery, Marshall Healthcare Partners LLC filed a voluntary petition for bankruptcy in December 2012. Except as described in the preceding sentence, no other event has occurred during the past 10 years requiring disclosure pursuant to Item 401(f) of Regulation S-K of the Securities Act of 1933, as amended, or the Securities Act.

**Barbara K. Finck, M.D.** has served as our Chief Medical Officer since July 2013 and served as Senior Vice President from July 2012 to July 2013. Dr. Finck previously served as Senior Vice President and Chief Medical Officer of NKT Therapeutics Inc., a biopharmaceutical company, from September 2010 to July 2012. Prior to that, from June 2007 to June 2010, Dr. Finck served as Senior Vice President of Research and Development and Chief Medical Officer at Osprey Pharmaceuticals U.S.A., Inc., a biopharmaceutical company. Prior to that, Dr. Finck served as an executive for various biopharmaceutical companies. Dr. Finck has a B.A. in Physiological Psychology from the University of California, Santa Barbara and received her M.D. from the University of California, San Francisco School of Medicine. She is board certified in internal medicine and rheumatology.

Alan C. Herman, Ph.D. has served as our Chief Scientific Officer since April 2011. Dr. Herman previously founded and served as Chief Executive Officer of WindRose Analytica, Inc., a contract analytical laboratory. In May 2009, WindRose Analytica was acquired by Althea Technologies, Inc., a biologic manufacturing company. Dr. Herman served as Chief Scientific Officer and Vice President of Product Development at Althea Technologies from May 2009 to April 2011. Prior to that, Dr. Herman served as Senior Director of Quality Control for Tercica, Inc., a biopharmaceutical company. In 1989 Dr. Herman joined Amgen where he started the Analytical Research and Development Department until May 2009. In 1984, he joined Genentech where he worked first in process development and later in pharmaceutics. During his time at Genentech, Dr. Herman worked on a number of products, including human growth hormone, tissue plasminogen activator and interferon. Dr. Herman started his career at Merck, where he worked on a recombinant hepatitis B vaccine. Dr. Herman received his B.S. and M.S. degrees in Biology at Indiana University of Pennsylvania. He received a Ph.D. in Microbiology from Duke University and did his post-doctoral work in oncogenic virus structure at Duke University Medical Center under Dr. Dani Bolognesi.

Michael A. Nazak is our Senior Vice President of Finance & Administration and has been employed by us since April 2011. Mr. Nazak was previously the Senior Director of Finance & Accounting at InteKrin Therapeutics Inc., a biopharmaceutical company, from April 2008 to April 2011. Prior to that, Mr. Nazak also served as the Corporate Controller for Reliant Technologies, Inc., a developer and manufacturer of medical laser devices, from May 2005 to April 2008 and as a Senior Director of Finance & Corporate Controller at Connetics Corporation, a then publicly-traded specialty pharmaceutical company, from February 2001 to January 2005. Mr. Nazak also held Corporate Controller and other finance and accounting positions at Cygnus Solutions (a Red Hat company), Raychem Corporation and MIPS Computer Systems, and was previously an auditor with Coopers & Lybrand LLP. Mr. Nazak holds a B.S. degree in Business Administration with a Concentration in Accounting from San Jose State University.

**Peter K. Watler, Ph.D.** has served as our Chief Technical Officer since June 2014. Dr. Watler also has served as our Senior Vice President of Process Sciences since March 2012. Dr. Watler was previously the Principal Consultant and Chief Technology Officer of Hyde Engineering Consulting, a global process system design and consulting organization, from January 2007 to May 2012. Previously, Dr. Watler also held various process engineering roles at VaxGen, a biopharmaceutical company, serving as its Vice President of Manufacturing Operations from January 2006 to January 2007 and Senior Director of Manufacturing from August 2002 to December 2005. Prior to that, Dr. Watler worked at Amgen as an Associate Director of Pilot Plant Engineering from June 2000 to August 2002 and an Engineer and Manager from June 1990 to June 2000. Dr. Watler received his B.S. and M.S. degrees in Chemical Engineering from the University of Toronto and a Ph.D. in Chemical Engineering from Yamaguchi University.

#### **Board Composition**

James I. Healy, M.D., Ph.D. has been a member of our board of directors since February 2014. Dr. Healy has been a General Partner of Sofinnova Ventures, a venture capital firm, since June 2000. Prior to June 2000, Dr. Healy held various positions at Sanderling Ventures, Bayer Healthcare Pharmaceuticals (as successor to Miles Laboratories) and ISTA Pharmaceuticals, Inc. Dr. Healy is currently on the board of directors of Amarin Corporation plc, Hyperion Therapeutics, Inc., InterMune, Inc., and several private companies. Previously, he

served as a board member of Anthera Pharmaceuticals, Inc., Durata Therapeutics, Inc., CoTherix, Inc., Movetis NV and several private companies. Dr. Healy holds an M.D. and a Ph.D. in Immunology from the Stanford University School of Medicine and holds a B.A. in Molecular Biology and a B.A. in Scandinavian Studies from the University of California, Berkeley. We believe Dr. Healy is qualified to serve on our board of directors due to his extensive experience investing and working in the pharmaceuticals industry and extensive service on the boards of directors of other life sciences companies.

V. Bryan Lawlis, Ph.D. has served on our board of directors since May 2014 and prior to that he served as the chairman of our Scientific Advisory Board from November 2012 until he joined the board in May 2014. Since August 2011 he has served as the President and Chief Executive Officer of ltero Biopharmaceuticals, LLC, a privately held limited liability holding company which has held the assets of ltero Biopharmaceuticals, Inc., or Itero Biopharmaceuticals, since August 2011. Dr. Lawlis co-founded and served as President and Chief Executive Officer of Itero Biopharmaceuticals, from 2006 until it discontinued operations in August 2011. Prior to that, he served as President and Chief Executive Officer of Aradigm Corporation, a pharmaceutical company, from August 2004, and served on its board of directors from February 2005, continuing in both capacities until August 2006. Dr. Lawlis served as Aradigm Corporation's President from June 2003 to August 2004 and as its Chief Operating Officer from November 2001 to June 2003. Previously, Dr. Lawlis co-founded Covance Biotechnology Services, Inc., a contract biopharmaceutical manufacturing company, served as its President and Chief Executive Officer from 1996 to 1999, and served as Chairman from 1999 to 2001 when it was sold to Diosyth RTP, Inc., a division of Akzo Nobel, NV. From 1981 to 1996, Dr. Lawlis was employed at Genencor, Inc., a biotechnology company, and Genentech. His last position at Genentech was Vice President of Process Sciences. Dr. Lawlis has served on the boards of directors of two privately held companies, Sutro Biopharmaceuticals, Inc. since 2003 and Reform Biologics, LL since February. He has also served on the boards of directors at BioMarin Pharmaceutical Inc., a public biopharmaceutical company since June 2007, Geron Corporation, a public biopharmaceutical company, since March 2012 and Kalobios Pharmaceuticals, Inc., a public biopharmaceutical company, since August 2013. Dr. Lawlis holds a B.A. in Microbiology from the University of Texas at Austin and a Ph.D. in Biochemistry from Washington State University. We believe Dr. Lawlis is qualified to serve on our board of directors due to his longtime involvement in the biotechnology industry and extensive service as a director or officer of other life sciences companies.

**Christos Richards** has served as a member of our board of directors since March 2011. Mr. Richards has been partner at Catalyst Advisors LLC, an executive search firm, since January 2014. Prior to that, from October 1998 to January 2014, Mr. Richards held positions of increasing responsibility at Levin and Company, an executive search and consulting firm. From January 2009 to January 2014, Mr. Richards served as Chief Executive Officer of Levin and Company. Mr. Richards served as a Principal of Stanton Chase International from July 1996 to October 1998. From 1987 to July 1996, Mr. Richards founded and served as Chief Executive Officer of Career Connection/Nexium Inc. Mr. Richards was educated in Switzerland and is fluent in German and Swiss German. Mr. Richards brings to the board experience in the recruitment of numerous executive level professionals, including a diverse range of C-level and VP-level executives. We believe Mr. Richards is qualified to serve on our board of directors based on his extensive senior management experience and expertise.

Ali J. Satvat has served as a member of our board of directors since May 2014. Mr. Satvat has been a Director on the Health Care industry team within KKR's Private Equity platform since January 2012. Mr. Satvat has served as a member of the board of directors of PRA Health Sciences, Inc. since September 2013. Prior to joining KKR, Mr. Satvat was a Principal with Apax Partners, where he invested in healthcare from 2006 to 2012, served as a director of Chiron Holdings (Kinetic Concepts, Inc. and LifeCell Corporation) from 2011 to 2012 and TZ Holdings (The TriZetto Group, Inc.) from 2008 to 2012 and was actively involved with many of the firm's successful growth investments. Previously, Mr. Satvat held various positions with Johnson & Johnson Development Corporation, Audax Group and The Blackstone Group, where he was involved in a broad range of transactions. Mr. Satvat holds an A.B. in History and Science from Harvard College and an M.B.A. in Health Care Management and Entrepreneurial Management from the Wharton School of the University of Pennsylvania. Mr. Satvat also serves on the board of directors of the Healthcare Private Equity Association. We believe Mr. Satvat is qualified to serve on our board of directors based on his extensive investment experience in the health care industry.

August J. Troendle, M.D. has served as a member of our board of directors since March 2011. Dr. Troendle has been the Chief Executive Officer, President and Chairman of Medpace, Inc., a clinical research organization, since its inception in 1992. Dr. Troendle previously worked for Sandoz (Novartis) where he was responsible for the clinical development of lipid altering agents. His experience as Medical Review Officer in the Division of Metabolic and Endocrine Drug Products at the FDA give him insight into the regulatory environment for development of drugs in the metabolic and cardiovascular fields. He also formerly served on the board of directors of Xenon Pharmaceuticals Inc. from 2009 to 2010. Dr. Troendle received his M.D. from the University of Maryland, School of Medicine. We believe Dr. Troendle is qualified to serve on our board of directors based on his experience in clinical research and expertise in regulatory oversight.

**Mats Wahlström** has served as a member of our board of directors since January 2012. He currently serves as the Chief Executive Officer and Chairman of KMG Capital Partners, LLC since April 2012, Chairman of PCI | HealthDev since August 2010 and Chairman of Caduceus Medical Holdings, LLC since August 2010. He has served on the boards of directors of Getinge AB since March 2012 and Alteco Medical AB since October 2012. He served as a director of Health Grades, Inc., a NASDAQ-listed healthcare ratings company, from March 2009 through its sale to a private equity firm in October 2010, and as a director of Zynex Inc., an over-the-counter medical device manufacturer, from October 2010 through January 2014. From January 2004 to December 2009, Mr. Wahlström served as co-CEO of Fresenius Medical Care North America and a member of the management board at Fresenius Medical Care AG & Co. KGAA. From November 2002 to December 2009, he served as President and CEO of Fresenius Medical Services, which operates more than 1,700 dialysis clinics in the U.S. Prior to joining Fresenius Medical Care in 2002, he held various positions at Gambro AB in Sweden, including President of Gambro North America and Chief Executive Officer of Gambro Healthcare Inc. as well as Chief Financial Officer of the Gambro Group. Mr. Wahlström has a B.S. degree in Economics and Business Administration from University of Lund, Sweden. We believe Mr. Wahlström is qualified to serve on our board of directors because of his extensive management and director experience in the life sciences and healthcare sectors.

**Mary T. Szela** has served as a member of our board of directors since July 2014. Ms. Szela has served as the Chief Executive Officer of Melinta Therapeutics, Inc., an antibiotic development company, since April 2013. She has also served on the board of directors of Melinta since January 2013. Previously, Ms. Szela joined Abbott Laboratories in 1987 and has held several leadership positions, including Senior Vice President of Global Strategic Marketing from January 2010 to May 2012 and Senior Vice President of U.S. Pharmaceuticals from September 2008 to December 2009. Prior to Abbott, Ms. Szela worked for the University of Illinois Hospital. She has served on the board of directors of Suneva Medical, Inc. since July 2012. Ms. Szela earned a B.S. in Nursing and an M.B.A. from the University of Illinois. We believe Ms. Szela is qualified to serve on our board of directors because of her extensive management experience and expertise in pharmaceutical company operations.

### **Scientific Advisory Board**

We maintain a scientific advisory board consisting of the members identified below. Our scientific advisory board meets on a quarterly basis and is comprised of industry and academic experts that have extensive experience in the analysis, research and development, manufacture, regulatory approval and commercialization of complex biological therapeutics, including experience relating to clinical and preclinical evaluation of these therapeutics. We consult with our scientific advisory board on a variety of matters pertaining to our lead and future pipeline product candidates, including, for example, formulation development, upstream and downstream protein manufacture, clinical or preclinical development, protein analysis, regulatory matters and intellectual property evaluation.

## V. Bryan Lawlis, Ph.D. is also a member of our board of directors.

**Tsutomu Arakawa, Ph.D.** is the President and Director of Protein Chemistry of Alliance Protein Laboratories. Before co-founding Alliance Protein Laboratories in 1998, Dr. Arakawa spent over 14 years in Protein Chemistry at Amgen as Research Scientist and Lab Head. Prior to working at Amgen, Dr. Arakawa was a postdoctoral fellow at Washington University studying tubulin self-assembly and its interactions with actin.

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During his earlier postdoctoral studies with Serge Timasheff at Brandeis, he studied mechanisms of solvent effects on protein stability and solubility and helped to develop the preferential interaction theory to explain the stabilizing effects of excipients such as sugars. He received his Ph.D. in Biochemistry in 1977 from Osaka Prefectural University.

William F. Bennett, Ph.D. is a Principal of Bioscope Associates LLC. Until 2009, he was Sr. Director of Regulatory Policy at Genentec and led the Genentech Biosimilars working group. He was at Genentech for 18 years altogether, having held high-level positions in Research, Bioprocess Development and Regulatory Affairs. He helped guide Genentech over many years through his participation on the Research Review, Product Development, Process Development Review and Appointments and Promotions Committees. During a period away from Genentech, as CSO at Sensus Corporation, he led the research and development of Somavert (a treatment for acromegaly) and was the Vice President of Research at Cor Therapeutics and the Senior Vice President of R&D at Hyseq/Nuvelo. He returned to Genentech in 2003. Dr. Bennett has a B.A. in Chemistry from TCU and a Ph.D. in Biochemistry from the University of Texas Southwestern Medical School. He was named a Distinguished Alumnus of TCU in 2010 and serves on the TCU Science & Engineering Advisory Board.

Andrew J.S. Jones, D. Phil. spent 23 years from 1981 to 2004 at Genentech, initially as a scientist in the Protein Biochemistry Department and the Medical and Analytical Chemistry Department, of which he was the founding Director, from 1983 to 1987. He was also in the Pharmaceutical R&D Department from 1987 to 1994. Since 2004, Dr. Jones has worked as a consultant to various biopharmaceutical companies. He was the Head of the Scientific Advisory Board for Itero Biopharmaceuticals from 2009 to 2011. Dr. Jones obtained his B.A. (Honors) degree in Biochemistry from St. John's College, Oxford University. He received his D. Phil. degree in Biology from the University of York and performed postdoctoral research at McMaster University, under a Multiple Sclerosis Society of Canada Postdoctoral Research Fellowship and also at Cornell University.

**Christos Mantzoros, M.D., D.Sc., Ph.D. h.c. mult.** is a Professor of Medicine at Harvard Medical School and at the Boston University School of Medicine. He serves as the Chief of Endocrinology, Diabetes and Metabolism at the Boston VA Healthcare System. Dr. Mantzoros obtained an M.D. and D. Sc. from the University of Athens Medical School, a Master's in Clinical Epidemiology from Harvard School of Public Health and a Master's in Medical Sciences (Clinical Investigation) from Harvard Medical School. Dr. Mantzoros was also awarded two honorary Ph.D. degrees from Aristotle University of Thessaloniki in 2012 and the University of Patras in 2014. He has received board certification in Internal Medicine, Endocrinology, Diabetes and Metabolism and in Clinical Nutrition. Dr. Mantzoros is the scientific co-founder of InteKrin Metabolic Therapeutics. He serves as the Editor-in-Chief of Metabolism, Clinical and Experimental, and is on the Editorial Board of several journals.

James A. Miller, Ph.D. is currently an independent consultant to the biopharmaceutical industry. Dr. Miller was recently Vice President of Process Development at Insmed, Inc., where he was involved with the sale of the company to Merck, Inc., with whom he continued to work as Senior Director of Process Development at the newly formed entity, Merck Boulder. From 2000 to 2003, Dr. Miller was Executive Vice President and co-founder of Saronyx, Inc., a company that developed web-enabled interfaces for data exchange between pharmaceutical development specialists and contract research organizations. From 1998 to 2000, he was Senior Director of Preclinical Development at Regeneron Pharmaceuticals, Inc., where he was responsible for the departments of pharmacology, pharmacokinetics, analytical assay and drug formulation/stability. From 1987 to 1998, Dr. Miller worked at Amgen in a number of roles, including founding the neurobiology department and undertaking leadership of the BDNF development team. Dr. Miller received his B.S. degree in Biology from the University of Oregon and a Ph.D. in Chemistry from the California Institute of Technology. He also received postdoctoral training in Physiology at the University of Colorado Medical School and the Yale University School of Medicine.

**Carl Ware, Ph.D.** is a Director and Professor at the Infectious and Inflammatory Disease Center at the Sanford-Burnham Medical Research Institute. Dr. Ware is a leading immunologist and virologist internationally recognized for his scientific discoveries and advances in the study of the immune system that are leading to new therapeutics for autoimmune and viral diseases and cancer. Dr. Ware attended the University of California,

Irvine, where he began his scientific research career by studying tumor destroying cytokines with Professor Gale A. Granger. From 1979 to 1981, Dr. Ware studied membrane biochemistry and the complement system with Dr. W. Kolb at the University of Texas Health Science Center in San Antonio. In 1981, Dr. Ware joined the research groups of Dr. Jack Strominger and Dr. Tim Springer at Dana-Farber Cancer Institute, Harvard Medical School. Dr. Ware established his own research laboratory in 1982 as an assistant professor of Immunology in the Biomedical Sciences Program at the University of California, Riverside, advancing to full professor in 1993. In 1996, Dr. Ware joined the prestigious La Jolla Institute for Allergy and Immunology as head of the Division of Molecular Immunology. Dr. Ware holds a joint appointment as professor in the Department of Biology at the University of California, San Diego. In 2010, Dr. Ware was recruited to the Sanford Burnham Medical Research Institute in La Jolla as director of the Infectious and Inflammatory Diseases Center. Dr. Ware received his Ph.D. in Molecular Biology and Biochemistry in 1979 from University of California, Irvine.

### **Director Independence**

Our board of directors currently consists of eight members. Our board of directors has determined that all of our directors, other than Messrs. Lanfear and Richards and Dr. Troendle, qualify as "independent" directors in accordance with The NASDAQ Global Market, or NASDAQ, listing requirements. Mr. Lanfear is not considered independent because he is an employee of our company. Mr. Richards is not considered independent because he has served as an executive officer of Catalyst Advisors, LP and Levin & Company which provided executive search services to us. Dr. Troendle is not considered independent because he is a founder and chief executive officer of Medpace, Inc., a company that has provided clinical research services to us. The NASDAQ independence definition includes a series of objective tests, such as that the director is not, and has not been for at least three years, one of our employees and that neither the director nor any of his family members has engaged in various types of business dealings with us. In addition, as required by NASDAQ rules, our board of directors has made a subjective determination as to each independent director that no relationships exist, which, in the opinion of our board of directors, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In making these determinations, our board of directors reviewed and discussed information provided by the directors and us with regard to each director's business and personal activities and relationships as they may relate to us and our management. There are no family relationships among any of our directors or executive officers.

### **Classified Board of Directors**

In accordance with our amended and restated certificate of incorporation to be in effect immediately prior to the consummation of this offering, our board of directors will be divided into three classes with staggered, three-year terms. At each annual meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. Effective upon the consummation of this offering, our directors will be divided among the three classes as follows:

- the Class I directors will be , and , and their terms will expire at the annual meeting of stockholders to be held in 2015;
- the Class II directors will be , and , and their terms will expire at the annual meeting of stockholders to be held in 2016; and
- the Class III directors will be , and , and their terms will expire at the annual meeting of stockholders to be held in 2017.

Our amended and restated certificate of incorporation will provide that the authorized number of directors may be changed only by resolution of the board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change in control of our company.

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## **Voting Arrangements**

Pursuant to an amended and restated voting agreement that we entered into with certain holders of our common stock and certain holders of our convertible preferred stock:

- the holders of a majority of our Series A convertible preferred stock, voting separately as a single class, have the right to elect two directors to our board of directors;
- Sofinnova Venture Partners VII, L.P. has the right to nominate one director to our board of directors for so long as Sofinnova Venture Partners VII, L.P. (or its affiliates) hold shares of our Series B convertible preferred stock;
- KMG Capital Partners, LLC has the right to nominate one director to our board of directors for so long as KMG Capital Partners, LLC (or its affiliates) hold shares of our Series B convertible preferred stock;
- KKR Biosimilar L.P. has the right to nominate one director to our board of directors for so long as KKR Biosimilar L.P. (or its affiliates) hold shares of our Series C convertible preferred stock;
- Lilly Ventures Fund I, LLC has the right to nominate one director to our board of directors;
- our then-incumbent Chief Executive Officer has the right to be nominated to serve on our board of directors;
- two directors must be acceptable to the majority of the other then-serving directors; and
- the holders of a majority of our common stock, voting separately as a single class, have the right to elect one director to our board of directors who shall be the then-current Chief Executive Officer.

The holders of our common stock and convertible preferred stock who are parties to the third amended and restated voting agreement are obligated to vote for such designees. The provisions of this voting agreement will terminate upon the consummation of this offering and there will be no further contractual obligations regarding the election of our directors. Our directors hold office until their successors have been elected and qualified or appointed, or the earlier of their death, resignation or removal.

#### Leadership Structure of the Board

Our bylaws and corporate governance guidelines provide our board of directors with flexibility to combine or separate the positions of Chairman of the Board and Chief Executive Officer and/or the implementation of a lead director in accordance with its determination that utilizing one or the other structure would be in the best interests of our company. Mr. Lanfear currently serves as the Chairman of the Board and Mr. Wahlström currently serves as the lead independent director of the board. All of our directors are encouraged to make suggestions for board of director's agenda items of pre-meeting materials. In addition, in his role as lead independent director, Mr. Wahlström presides over the executive sessions of the board of directors in which Mr. Lanfear, as the Chief Executive Officer, does not participate and serves as a liaison to management on behalf of the independent members of the board of directors.

Our board of directors has concluded that our current leadership structure is appropriate at this time. However, our board of directors will continue to periodically review our leadership structure and may make such changes in the future as it deems appropriate.

### **Role of Board in Risk Oversight Process**

Risk assessment and oversight are an integral part of our governance and management processes. Our board of directors encourages management to promote a culture that incorporates risk management into our corporate strategy and day-to-day business operations. Management discusses strategic and operational risks at regular management meetings and conducts specific strategic planning and review sessions during the year that include a focused discussion and analysis of the risks facing us. Throughout the year, senior management reviews these

risks with the board of directors at regular board meetings as part of management presentations that focus on particular business functions, operations or strategies and presents the steps taken by management to mitigate or eliminate such risks.

Our board of directors does not have a standing risk management committee, but rather administers this oversight function directly through our board of directors as a whole, as well as through various standing committees of our board of directors that address risks inherent in their respective areas of oversight. In particular, our board of directors is responsible for monitoring and assessing strategic risk exposure. Our audit committee is responsible for overseeing our major financial risk exposures and the steps our management has taken to monitor and control these exposures and considers and approves or disapproves any related-persons transactions. The audit committee also monitors compliance with legal and regulatory requirements. Our nominating and governance committee monitors the effectiveness of our corporate governance guidelines. Our compensation committee assesses and monitors whether any of our compensation policies and programs has the potential to encourage excessive risk-taking.

## **Board Committees**

Audit Committee

Our audit committee oversees our corporate accounting and financial reporting process. Among other matters, the audit committee:

- appoints our independent registered public accounting firm;
- evaluates the independent registered public accounting firm's qualifications, independence and performance;
- · determines the engagement of the independent registered public accounting firm;
- reviews and approves the scope of the annual audit and the audit fee;
- discusses with management and the independent registered public accounting firm the results of the annual audit and the review of our quarterly consolidated financial statements;
- approves the retention of the independent registered public accounting firm to perform any proposed permissible audit and non-audit services;
- monitors the rotation of partners of the independent registered public accounting firm on our engagement team as required by law;
- is responsible for reviewing our consolidated financial statements and our management's discussion and analysis of financial condition and results of
  operations to be included in our annual and quarterly reports to be filed with the Securities and Exchange Commission, or SEC;
- reviews our critical accounting policies and estimates; and
- · annually reviews the audit committee charter and the committee's performance.

The current members of our audit committee are Mats Wahlström, James I. Healy, M.D., Ph.D. and Ali J. Satvat. Mr. Wahlström serves as the chairperson of the committee. All members of our audit committee meet the requirements for financial literacy under the applicable rules and regulations of the SEC and The NASDAQ Global Market. Our board of directors has determined that Mats Wahlström is an audit committee financial expert as defined under the applicable rules of the SEC and has the requisite financial sophistication as defined under the applicable rules and regulations of The NASDAQ Global Market. Under the rules of the SEC and The NASDAQ Global Market, members of the audit committee must also meet heightened independence standards. However, a minority of the members of the audit committee may be exempt from the heightened audit committee independence standards for one year from the date of effectiveness of the registration statement of which this prospectus forms a part. Our board of directors has determined that each of Messrs. Wahlström and Satvat and

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Dr. Healy are independent under the applicable rules of the SEC and The NASDAQ Global Market. The audit committee operates under a written charter that satisfies the applicable standards of the SEC and The NASDAQ Global Market.

### **Compensation Committee**

Our compensation committee reviews and recommends policies relating to compensation and benefits of our officers and employees. The compensation committee reviews and recommends corporate goals and objectives relevant to compensation of our President and Chief Executive Officer and other executive officers, evaluates the performance of these officers in light of those goals and objectives and recommends to our board of directors the compensation of these officers based on such evaluations. The compensation committee also recommends to our board of directors the issuance of stock options and other awards under our stock plans. The compensation committee will review and evaluate, at least annually, the performance of the compensation committee and its members, including compliance by the compensation committee with its charter. The current members of our compensation committee are James I. Healy, M.D., Ph.D., V. Bryan Lawlis, Ph.D. and Mary T. Szela. Dr. Healy serves as the chairperson of the committee. Each of the members of our compensation committee is independent under the applicable rules and regulations of The NASDAQ Global Market, is a "non-employee director" as defined in Rule 16b-3 promulgated under the Exchange Act and is an "outside director" as that term is defined in Section 162(m) of the U.S. Internal Revenue Code of 1986, as amended, or Section 162(m). The compensation committee operates under a written charter.

#### Nominating and Corporate Governance Committee

The nominating and corporate governance committee is responsible for making recommendations to our board of directors regarding candidates for directorships and the size and composition of our board of directors. In addition, the nominating and corporate governance committee is responsible for overseeing our corporate governance policies and reporting and making recommendations to our board of directors concerning governance matters. The current members of our nominating and corporate governance committee are Mats Wahlström, Christos Richards and Mary T. Szela. Mr. Wahlström serves as the chairperson of the committee. Each of Mr. Wahlström and Ms. Szela is an independent director under the applicable rules and regulations of The NASDAQ Global Market relating to nominating and corporate governance committee independence. The nominating and corporate governance committee operates under a written charter.

#### **Compensation Committee Interlocks and Insider Participation**

During 2013, our compensation committee consisted of Christos Richards, Graham K. Crooke, MB.BS. and August J. Troendle, M.D. Mr. Richards served as the chairperson of the compensation committee. None of the members of our compensation committee have at any time been one of our officers or employees. None of our executive officers currently serves, or has in the past fiscal year served, as a member of the board of directors or compensation committee of any entity that has one or more executive officers on our board of directors or compensation committee.

### **Board Diversity**

Upon consummation of this offering, our nominating and corporate governance committee will be responsible for reviewing with the board of directors, on an annual basis, the appropriate characteristics, skills and experience required for the board of directors as a whole and its individual members. In evaluating the suitability of individual candidates (both new candidates and current members), the nominating and corporate governance committee, in recommending candidates for election, and the board of directors, in approving (and, in the case of vacancies, appointing) such candidates, will take into account many factors, including the following:

- personal and professional integrity;
- ethics and values;

- experience in corporate management, such as serving as an officer or former officer of a publicly held company;
- experience in the industries in which we compete;
- experience as a board member or executive officer of another publicly held company;
- diversity of expertise and experience in substantive matters pertaining to our business relative to other board members;
- conflicts of interest; and
- practical and mature business judgment.

Currently, our board of directors evaluates, and following the consummation of this offering will evaluate, each individual in the context of the board of directors as a whole, with the objective of assembling a group that can best maximize the success of the business and represent stockholder interests through the exercise of sound judgment using its diversity of experience in these various areas.

#### **Code of Business Conduct and Ethics**

Prior to the consummation of this offering, we will have adopted a code of business conduct and ethics that applies to all of our employees, officers and directors, including those officers responsible for financial reporting. Following the consummation of this offering, the code of business conduct and ethics will be available on our website. We expect that any amendments to the code, or any waivers of its requirements, will be disclosed on our website.

### Limitation on Liability and Indemnification Matters

Our amended and restated certificate of incorporation, which will become effective immediately prior to the consummation of this offering, 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 amended and restated bylaws, which will become effective immediately prior to the consummation of this offering, 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 are obligated to 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.

In addition to the indemnification required in our amended and restated certificate of incorporation and amended and restated bylaws, we have entered or intend to enter into indemnification agreements with each of our directors, officers and certain employees before the completion of this offering. These agreements will provide for the indemnification of our directors, officers and certain employees for all reasonable expenses and liabilities incurred in connection with any action or proceeding brought against them by reason of the fact that they are or were our agents. We believe that these provisions in our amended and restated certificate of

incorporation and amended and restated bylaws and indemnification agreements are necessary to attract and retain qualified persons as directors and officers. This description of the limitation of liability and indemnification provisions of our amended and restated certificate of incorporation, amended and restated bylaws and indemnification agreements is qualified in its entirety by reference to these documents, each of which is attached as an exhibit to the registration statement, of which this prospectus is a part. We will 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 directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might benefit us and our stockholders. A stockholder's investment may be harmed to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have 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. There is no pending litigation or proceeding naming any of our directors or officers as to which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any director or officer.

#### **Director Compensation**

The following table presents the total compensation for each person who served as a non-employee member of our board of directors during 2013. Other than as set forth in the table and described more fully below, in 2013 we did not pay any compensation, reimburse any expense of, make any equity awards or non-equity awards to, or pay any other compensation to any of the other non-employee members of our board of directors.

In 2013, we paid a cash retainer to Michael Lazarus, M.D., in the amount of \$25,000. In connection with S. Edward Torres' appointment to our board of directors, in July 2013, we awarded him an option to purchase 50,000 shares of our common stock, which vests as to 1/48th of the shares subject to the option monthly. None of our other non-employee directors received any compensation from us in 2013.

## 2013 Director Compensation Table

The following table sets forth information for the year ended December 31, 2013 regarding the compensation awarded to, earned by or paid to our nonemployee directors:

Name <sup>(1)</sup> Christos Richards	Fees Earned or Paid in Cash(\$)	Option Awards <sup>(2)(3)</sup> (\$)	All Other Compensation(\$)	Total(\$)
Christos Richards		—	—	—
Michael Lazarus, M.D. <sup>(4)</sup>	\$25,000	—	—	\$25,000
Graham K. Crooke, MB.BS. <sup>(4)</sup>	—	—	—	
S. Edward Torres <sup>(4)</sup>		63,806	—	63,806
August J. Troendle, M.D.		—		
Mats Wahlström		—	—	—

(1) Mr. Lanfear, who is President and Chief Executive Officer, receives no compensation for his service as a director and, consequently, is not included in this table. The compensation received by Mr. Lanfear as an employee during 2013 is presented in the 2013 Summary Compensation Table in "Executive Compensation."
(2) The comparison of the c

(2) The amounts reported in the Option Awards column represent the grant date fair value of the stock options granted to the non-employee members of our board of directors during 2013 as computed in accordance with ASC 718. The assumptions used in calculating the grant date fair value of the stock options reported in the Option Awards column are set forth in Note 10 to the audited consolidated financial statements included in this prospectus. The amounts reported in this column exclude the impact of estimated forfeitures related to service-based vesting conditions. Note that the amounts reported in this column reflect the accounting cost for these stock options and do not correspond to the actual economic value that may be received by the non-employee members of our board of directors from the options.

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- (3)As of December 31, 2013, Michael Lazarus, M.D., Christos Richards, S. Edward Torres, August J. Troendle, M.D., Graham K. Crooke, MB.BS. and Mats Wahlström held options covering 50,000 shares each of our common stock, respectively. (4)
- Resigned from the board of directors prior to June 30, 2014.

, 2014, our board of directors approved a compensation policy for our non-employee directors to be effective in connection with the consummation of In this offering, or the Post-IPO Director Compensation Program. Pursuant to the Post-IPO Director Compensation Program, our non-employee directors will receive cash compensation as follows:

- Each non-employee director will receive an annual cash retainer in the amount of **\$** per year.
- The chairperson of the audit committee will receive additional annual cash compensation in the amount of \$ per year for such chairperson's service on the audit committee. Each non-chairperson member of the audit committee will receive additional annual cash compensation in the amount of \$ per year for such member's service on the audit committee.
- The chairperson of the compensation committee will receive additional annual cash compensation in the amount of \$ per year for such chairperson's service on the compensation committee. Each non-chairperson member of the compensation committee will receive additional annual cash compensation in the amount of \$ per year for such member's service on the compensation committee.
- The chairperson of the nominating and corporate governance committee will receive additional annual cash compensation in the amount of \$ per year for such chairperson's service on the nominating and corporate governance committee. Each non-chairperson member of the nominating and corporate governance committee will receive additional annual cash compensation in the amount of \$ per year for such member's service on the nominating and corporate governance committee.

Under the Post-IPO Director Compensation Program, each non-employee director serving on our board of directors upon the consummation of this offering shares of our common stock. In addition, non-employee directors will receive a stock option grant covering will receive a stock option grant covering shares of our common stock upon a director's initial appointment or election to our board of directors and an annual stock option grant covering shares of our common stock on the date of each annual stockholder's meeting thereafter, beginning in 2015. We expect each stock option granted under the Post-IPO Director Compensation Program will vest in substantially equal annual installments on each anniversary of the applicable grant date, subject to continued service on our board of directors.

### EXECUTIVE COMPENSATION

The following is a discussion and analysis of compensation arrangements of our named executive officers, or NEOs. This discussion contains forward looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs. Actual compensation programs that we adopt may differ materially from currently planned programs as summarized in this discussion. As an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, we are not required to include a Compensation Discussion and Analysis section and have elected to comply with the scaled disclosure requirements applicable to emerging growth companies.

We seek to ensure that the total compensation paid to our executive officers is reasonable and competitive. Compensation of our executives is structured around the achievement of individual performance and near-term corporate targets as well as long-term business objectives.

Our NEOs for fiscal year 2013 were as follows:

- Dennis M. Lanfear, President, Chief Executive Officer and Chairman of the Board;
- Barbara K. Finck, M.D., Chief Medical Officer;
- Alan C. Herman, Ph.D., Chief Scientific Officer;
- Douglas H. Farrar, former Chief Technology Officer; and
- Stephen C. Glover, former Chief Business Officer.

#### **Summary Compensation**

The following table shows information regarding the compensation of our named executive officers for services performed in the year ended December 31, 2013.

Name and Principal Position	Year	Salawy (\$)	Bonus (\$)	Stock Awards (\$)	Option Awards(\$)	All Other Compensation (\$) <sup>(1)</sup>	Total (\$)
Dennis M. Lanfear	2013	<u>Salary (\$)</u> \$400,000	<u>Bonus (\$)</u> \$337,625	<u>Awarus (\$)</u>	\$638,063 <sup>(2)</sup>	\$ 3,921	\$1,379,609
President, Chief Executive Officer and							
Chairman of the Board							
Barbara K. Finck, M.D.	2013	330,375	112,625	—	394,554 <sup>(2)</sup>	321	837,875
Chief Medical Officer							
Alan C. Herman, Ph.D.	2013	296,120	105,115	—	121,232 <sup>(2)</sup>	321	522,788
Chief Scientific Officer							
Douglas H. Farrar	2013	290,926	75,480	—	179,041(2)	311	545,758
Former Chief Technology Officer <sup>(5)</sup>							
Stephen C. Glover	2013	103,846	83	\$795,285 <sup>(3)</sup>	1,267(4)	188,543	1,089,024
Former Chief Business Officer <sup>(6)</sup>							

(1)Amounts in this column consist of the following:

	Non- cash holiday gifts (\$)	cash holiday Tax gross up for gifts non-cash holiday		Reimbursement of Company- sponsored health club membership fees (\$)		Reimbursement for personal concierge physician services (\$)		Separation- related payments (\$)	
Dennis M. Lanfear	\$ 212	\$	109	\$	1,800	\$	1,800		
Barbara K. Finck, M.D.	212		109		_		_	_	
Alan C. Herman, Ph.D.	212		109		—		_		
Douglas H. Farrar	212		99		_		_		
Stephen C. Glover	—		—		450			\$ 188,093	

For Mr. Glover, separation-related payments include: (i) \$150,000 in consulting fees paid to Mr. Glover's company MedicaRX pursuant to a consulting agreement entered into between the Company and MedicaRX in connection with Mr. Glover's termination; (ii) \$16,638 representing continued healthcare payments pursuant to Mr. Glover's separation agreement; and (iii) \$21,455 representing the forgiveness of the unpaid principal balance of a promissory note entered into between the Company and Mr. Glover.

(2) Amount represents the grant date fair value of options granted during year 2013 as calculated in accordance with ASC Topic 718. See Note 10 of the audited consolidated financial statements included in this prospectus for the assumptions used in calculating these amounts. Amount represents the fair value attributable to stock award acceleration pursuant to Mr. Glover's separation agreement.

(3) (4)

Amount represents the fair value attributable to the extended exercisability of stock options pursuant to Mr. Glover's separation agreement. Mr. Farrar's employment with the Company terminated on June 30, 2014. Mr. Glover's employment with the Company terminated on March 31, 2013.

(5) (6)

#### **Outstanding Equity Awards at 2013 Fiscal Year End**

The following table sets forth all outstanding equity awards held by each of the named executive officers as of December 31, 2013.

			Option Awa	Stock	Awards		
Name	Vesting Commencement Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise <u>Price (\$)</u>	Option Expiration Date	Number of Shares of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested (\$)
Dennis M. Lanfear	10/12/2010(3)(4)	50,000		\$0.005	10/11/2020		
	10/15/2010(5)					708,334	\$1,276,417(6)
	04/19/2011	367,912	183,956	0.25	07/17/2021		
	07/20/2013(4)	52,083	447,917	0.85	11/21/2023		
Barbara K. Finck, M.D.	07/02/2012	71,541	130,459	1.25	02/27/2023		
	07/30/2013(4)	15,625	134,375	0.85	11/21/2023		
Alan C. Herman, Ph.D.	04/19/2011	117,274	58,638	0.25	07/17/2021		
	07/30/2013(4)	9,895	85,105	0.85	11/21/2023		
Douglas H. Farrar	04/19/2011	128,769	64,385	0.25	07/17/2021(7)		
	07/30/2013(4)	14,614	125,686	0.85	11/21/2023(7)		
Stephen C. Glover	04/19/2011	92,552		0.25	09/30/2014		

(1) (2)

Each stock option was granted pursuant to our 2010 Equity Incentive Plan. Unless otherwise noted, options vest as to 25% of the total number of shares subject to the option on the first anniversary of the vesting commencement date and as to 1/48<sup>th</sup> of the total number of shares subject to the option in monthly installments over the three year period thereafter, subject to continued service with our company through the applicable vesting dates and accelerated vesting under certain circumstances, as described under the section entitled "Terms and Conditions of Employee Arrangements with our NEOs" below.

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- (3) Contains an early exercise provision permitting the executive to exercise the option prior to vesting, with any unvested shares subject to repurchase by us at the exercise price paid until the shares vest in accordance with the vesting schedule of the option. The option will become fully vested as of immediately prior to the consummation of an acquisition of the Company.
- Vests as to 1/48<sup>th</sup> of the total number of shares subject to the option in monthly installments over four years measured from the applicable vesting dates.
- (5) The Company's right of repurchase with respect to these shares lapses as to 1/48th of the total number of shares issued on each monthly anniversary of October 15, 2010 and shall fully lapse upon a change in control of the Company.
   (6) Because our common stock was not traded on a public market on December 31, 2013, the market value has been determined based on a per-share common stock value of \$1.802, which was the latest per
- because our common stock was not raded on a public infance on potential of 31, 2013, the market value has been determined based on a per-share common stock value of \$1,002, which was the fatest per share value of our common stock determined by our board of directors as of December 31, 2013.
   (7) Represents the term of the option as of December 31, 2013. Pursuant to Mr. Farrar's separation agreement, the option will remain exercisable until no later than June 30, 2015.
- () Represents the term of the option as of December 51, 2015, Fulstant to Mr. Fartar 5 separation agreement, the option will remain exercisable until to fater than sume 50,

#### Narrative to 2013 Summary Compensation Table and Outstanding Equity Awards at 2013 Fiscal Year End

#### Terms and Conditions of Employee Arrangements with our NEOs

### Offer Letter Agreements

We have entered into agreements with each of the NEOs in connection with his or her employment with us. These agreements set forth the terms and conditions of employment of each NEO, including base salary, annual bonus, initial equity award grants and standard employee benefit plan participation. Our board of directors or the compensation committee reviews each NEO's base salary from time to time to ensure compensation adequately reflects the NEO's qualifications, experience, role and responsibilities.

For fiscal year 2013, Messrs. Lanfear and Farrar, and Dr. Herman received annual base salaries of \$400,000, \$275,000 and \$287,500, respectively. Prior to his termination of employment with us on March 31, 2013, Mr. Glover's annual base salary in effect was \$300,000. In addition, Messrs. Lanfear and Farrar, and Dr. Herman were eligible for annual bonuses targeted at 50%, 25%, and 25%, respectively. In connection with her promotion from Senior Vice President, Clinical Development Inflammatory Diseases to Chief Medical Officer effective as of July 2013, Dr. Finck's annual base salary was increased from \$300,000 to \$325,000. For 2013, Dr. Finck's annual bonus target was 25% of base salary.

While we do not have a formal bonus program, our board of directors may award discretionary bonuses to reward outstanding performance and continued dedication of our employees. In June 2014, we awarded annual bonuses to our NEOs, other than Mr. Glover, for their contributions to us in 2013 as shown in the "Bonus" column of the Summary Compensation Table above.

Under Mr. Lanfear's offer letter, in the event Mr. Lanfear is terminated without "Cause" (as defined below), other than during the 12-month period commencing upon a "Change of Control" (as defined below), he will receive: (i) 12 months' continuation of base salary, paid in accordance with the Company's normal payroll practices commencing on the 60th day following such termination; (ii) a sum equal to the product of (A) the per month medical and dental coverage premium pursuant to COBRA and (B) 12, to be paid on the 60th day following such termination; (iii) acceleration of vesting of such number of shares subject to any stock options and equity awards that would have become vested in the 12 months immediately following such termination had Mr. Lanfear remained employed with the Company through such period; and (iv) 12 months following such termination in which to exercise vested options. In the event that Mr. Lanfear is terminated without Cause or resigns for "Good Reason" (as defined below), in either case, within the 12-month period commencing upon a Change of Control, then in addition to the foregoing severance payments and benefits, Mr. Lanfear will receive full accelerated vesting of all stock options and equity awards and he will be entitled to six months following such termination in which to exercise vested options. All such severance payments and benefits are subject to the execution and nonrrevocation of a general release of claims against the Company that becomes effective and irrevocable within 60 days of Mr. Lanfear's termination.

Under Dr. Herman's and Mr. Farrar's offer letters, in the event the executive is terminated without Cause, other than during the 12-month period commencing upon a Change of Control, he will receive: (i) six months'

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continuation of base salary, paid in accordance with the Company's normal payroll practices commencing on the 60th day following such termination; (ii) a sum equal to the product of (A) the per month medical and dental coverage premium pursuant to COBRA and (B) six, to be paid on the 60th day following such termination; (iii) acceleration of vesting of such number of shares subject to any stock options and equity awards that would have vested in the six months immediately following such termination had the executive remained employed with the Company through such period; and (iv) six months following such termination in which to exercise vested options. In the event that Dr. Herman or Mr. Farrar is terminated without Cause or resigns for Good Reason, in either case, within the 12-month period commencing upon a Change of Control, then in addition to the foregoing severance payments and benefits, he will receive full accelerated vesting of all stock options and equity awards and he will be entitled to six months following such termination in which to exercise vested options. All such severance payments and benefits are subject to the execution of a general release of claims against the Company that becomes effective and irrevocable within 60 days of the executive's termination.

For the purposes of Messrs. Lanfear's and Farrar's and Dr. Herman's offer letters, "Cause" generally means the executive's (i) repeated unexplained or unjustified absence from the Company or gross negligence, willful misconduct or repeated, willful and flagrant insubordination in the performance of the executive's duties to the Company as directed by the board of directors, which behavior remains uncured more than 30 days following written notice from the board of directors of its reasonable belief that there is Cause for the executive's termination under this clause (i); (ii) commission of any act of fraud that is related to the executive's personal gain with respect to the Company; (iii) commission of a felony or a crime causing material harm to the standing and reputation to the Company or affecting the Company in a materially financial way (each of (i), (ii) or (iii) as determined by a unanimous vote of the board of directors); or (iv) the executive's continued failure, 60 days after the board of directors provides written notice to him, to meet performance standards within the executive's control and achievable within the Company's resources, each as reasonably determined by the board of directors and specifying the areas in which the executive's performance must improve.

For the purposes of Messrs. Lanfear's and Farrar's and Dr. Herman's offer letters, "Good Reason" for each of them to resign means the executive's resignation of employment because any of the following occurs without the executive's written consent: (i) the material diminution of the executive's duties and responsibilities; (ii) the material reduction of the executive's base salary (defined as a greater than a ten percent reduction), but excluding reductions in connection with an across-the-board reduction of all executive officers' annual base salaries potential by a percentage at least equal by which the executive's base salary is reduced; or (iii) the material transfer of the executive's principal place of employment with the Company (defined as more than 40 miles from the executive's principal place of employment immediately preceding such change); provided, that a resignation is not with Good Reason unless he gives the Company written notice describing such Good Reason event within 30 days after the event first occurs, such event is not corrected by the Company within 30 days after the Company's receipt of such notice and he terminates the executive's employment no later than 180 days after the expiration of such correction period.

For the purposes of Messrs. Lanfear's and Farrar's and Dr. Herman's offer letters, "Change of Control" means the date of the consummation of (i) the merger or consolidation of the Company by means of any transaction or series of related transactions, provided that the applicable transaction shall not be deemed a Change of Control unless the Company's stockholders constituted immediately prior to such transaction do not hold more than 50% of the voting power of the surviving or acquiring entity (or its parent) immediately following such transaction; (ii) any transaction or series of related transactions to which the Company is a party in which more than 50% of the Company's voting power is transferred (taking into account only voting power resulting from stock held by such stockholders prior to such transaction); or (iii) a sale, lease, transfer, exclusive license or other disposition of substantially all of the assets of the Company; provided, however, that a Change of Control shall not include (x) a merger or consolidation with a wholly-owned subsidiary of the Company, (y) a merger effected exclusively for the purpose of changing the domicile of the Company or (z) any transaction or series of transactions principally for bona fide equity financing purposes in which the Company is the surviving corporation.

### Glover Separation Agreement

On March 31, 2013, we entered into a Transition and Separation Agreement with Mr. Glover in connection with his termination of employment with us. Pursuant to the separation agreement, in exchange for a general release of claims against the Company and continued compliance with Mr. Glover's confidentiality agreement, Mr. Glover received: (i) acceleration of 531,250 shares of restricted stock effective on the last day of his consulting agreement which was on September 30, 2013; (ii) the extension of the exercisability of an option to purchase 92,552 shares of Company common stock until September 30, 2014; and (iii) forgiveness of the unpaid principal balance of a promissory note entered into between the Company and Mr. Glover.

Under the separation agreement, Mr. Glover also transitioned into a consulting role with the Company through his company MedicaRX effective April 1, 2013 for a term of six months. Pursuant to the consulting agreement between the Company and MedicaRX, as compensation for the consulting services, MedicaRX received a monthly retainer of \$25,000 paid in bi-monthly installments over the course of the consulting period. In return for the consulting services, we also paid to Mr. Glover a lump sum equal to six months of continued healthcare premiums under COBRA.

#### Farrar Separation Agreement

On June 30, 2014, in connection with his termination of employment, we entered into a letter agreement with Mr. Farrar providing for certain separation benefits in exchange for a general release of claims against the Company and continued compliance with his confidentiality agreement. In accordance with the terms of the letter agreement, the Company entered into a consulting agreement with Flatirons Biotech, Inc. for Mr. Farrar to provide consulting services to the Company from July 1, 2014 to December 31, 2014. The consulting agreement between the Company and Flatirons Biotech, Inc. provides that as compensation for Mr. Farrar's consulting services, Flatirons Biotech, Inc. will receive a monthly retainer of \$27,917 over the course of the consulting period.

In addition, Mr. Farrar will continue to vest in his outstanding equity awards while providing consulting services or, if he is terminated without cause, through December 31, 2014, and he will have until six months following the termination of the consulting period to exercise his then-vested equity awards. The Company will reimburse Mr. Farrar's healthcare premiums under COBRA through the earliest of: (i) the last day of the month in which Mr. Farrar terminates the consulting period or the Company terminates the consulting period for cause; (ii) June 30, 2015; (iii) the date Mr. Farrar obtains healthcare coverage through another employer; or (iv) the date Mr. Farrar is otherwise no longer eligible for COBRA.

### Terms and Conditions of Equity Award Grants

Certain of our NEOs received options to purchase our common stock in fiscal 2013. The table above entitled "Outstanding Equity Awards at 2013 Fiscal Year End" describes the material terms of other option awards made in past fiscal years to our NEOs.

In February 2013, our board of directors granted a stock option award to Dr. Finck covering 202,000 shares of our common stock in connection with her commencement of employment with us in 2012. These options vest as to 25% of the vesting commencement date the shares subject to the option on the first anniversary, and 1/48th of the shares subject to the option on each monthly anniversary thereafter, subject to Dr. Finck's continuous services to the Company on each applicable vesting date.

In November 2013 our board of directors granted an option award to Dr. Finck covering 150,000 shares of our common stock in connection with her promotion to Chief Medical Officer. In November 2013, our board of directors also granted stock option awards to Messrs. Lanfear and Farrar and Dr. Herman covering 500,000, 140,300 and 95,000 shares of our common stock, respectively. These options vest as to 1/48th of the shares subject to the option on each monthly anniversary of the vesting commencement date, such that 100% of the shares subject to the option will be vested and exercisable on the fourth anniversary of the vesting commencement date, subject to the executive's continuous service to the Company on each applicable vesting date.

In March 2014, our board of directors granted stock option awards to Messrs. Lanfear and Farrar and Dr. Herman, covering 1,499,262, 157,661 and 245,066 shares of our common stock, respectively. These options vest as to 1/48th of the shares subject to the option on each monthly anniversary of the vesting commencement date, such that 100% of the shares subject to the option will be vested and exercisable on the fourth anniversary of the vesting commencement date, subject to the executive's continuous service to the Company on each applicable vesting date.

### Terms and Conditions of 401(k) Plan

All employees who meet eligibility requirements may elect to participate in our 401(k) Plan. Enrollment in the 401(k) Plan is optional. The maximum contribution to the 401(k) Plan is \$17,500 for 2013 and 2014 tax years based on IRS guidelines for all employees with an additional \$5,500 for additional catchup contributions for plan participants age 50 and older, subject to regulatory and plan limitations. Under the 401(k) plan, employees may elect to contribute up to a maximum of 90% of his or her salary compensation, not to exceed the contribution amount allowed by the IRS.

#### **Equity Compensation Plans**

### 2014 Equity Incentive Award Plan

We have adopted the 2014 Equity Incentive Award Plan, or 2014 Plan, which will be effective on the closing of this offering. The principal purpose of the 2014 Plan is to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards and cash-based performance bonus awards. The material terms of the 2014 Plan, as it is currently contemplated, are summarized below. Our board of directors is still in the process of developing, approving and implementing the 2014 Plan and, accordingly, this summary is subject to change.

### Share Reserve

Under the 2014 Plan, shares of our common stock will be initially reserved for issuance pursuant to a variety of stock-based compensation awards, including stock options, stock appreciation rights, or SARs, restricted stock awards, restricted stock unit awards, deferred stock awards, deferred stock unit awards, dividend equivalent awards, stock payment awards and performance awards, plus the number of shares remaining available for future awards under our 2010 Equity Incentive Plan, as amended, or the 2010 Plan, as of the consummation of this offering. The number of shares initially reserved for issuance or transfer pursuant to awards under the 2014 Plan will be increased by (i) the number of shares represented by awards outstanding 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), if approved by our board of directors or the compensation committee of our board of directors, an annual increase on the first day of each fiscal year beginning in 2015 and ending in 2024, equal to

percent ( .0%) of the shares of stock outstanding on the last day of the immediately preceding fiscal year or such smaller number of shares of stock as shares of stock may be issued upon the exercise of incentive stock options.

The following counting provisions will be in effect for the share reserve under the 2014 Plan:

- to the extent that an award terminates, expires or lapses for any reason or an award is settled in cash without the delivery of shares, any shares subject to the award at such time will be available for future grants under the 2014 Plan;
- to the extent shares are tendered or withheld to satisfy the grant, exercise price or tax withholding obligation with respect to any award under the 2014 Plan, such tendered or withheld shares will be available for future grants under the 2014 Plan;
- shares purchased on the open market with cash proceeds from the exercise of options will not be available for future grants under the 2014 Plan;

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- to the extent that shares of our common stock are repurchased by us prior to vesting so that shares are returned to us, such shares will be available for future grants under the 2014 Plan;
- the payment of dividend equivalents in cash in conjunction with any outstanding awards will not be counted against the shares available for issuance under the 2014 Plan; and
- to the extent permitted by applicable law or any exchange rule, shares issued in assumption of, or in substitution for, any outstanding awards of any entity acquired in any form of combination by us or any of our subsidiaries will not be counted against the shares available for issuance under the 2014 Plan.

In addition, the maximum aggregate value of awards that may be granted to any non-employee director pursuant to the 2014 Plan during any calendar year .

### Administration

is

The compensation committee of our board of directors is expected to administer the 2014 Plan unless our board of directors assumes authority for administration. Unless otherwise determined by our board of directors, the compensation committee will consist of at least two members of our board of directors, each of whom is intended to qualify as an "outside director," within the meaning of Section 162(m) of the U.S. Internal Revenue Code of 1986, or amended, or the Code, a "non-employee director" for purposes of Rule 16b-3 under the Exchange Act and an "independent director" within the meaning of the rules of the applicable stock exchange or other principal securities market on which shares of our common stock are traded. The 2014 Plan provides that the board or compensation committee may delegate its authority to grant awards to employees other than executive officers and certain senior executives of the Company to a committee consisting of one or more members of our board of directors or one or more of our officers, other than awards made to our non-employee directors, which must be approved by our full board of directors.

Subject to the terms and conditions of the 2014 Plan, the administrator has the authority to select the persons to whom awards are to be made, to determine the number of shares to be subject to awards and the terms and conditions of awards and to make all other determinations and to take all other actions necessary or advisable for the administration of the 2014 Plan. The administrator is also authorized to adopt, amend or rescind rules relating to administration of the 2014 Plan. Our board of directors may at any time remove the compensation committee as the administrator and revest in itself the authority to administer the 2014 Plan. The full board of directors will administer the 2014 Plan with respect to awards to non-employee directors.

### Eligibility

Options, SARs, restricted stock and all other stock-based and cash-based awards under the 2014 Plan may be granted to individuals who are then our officers, employees or consultants or are the officers, employees or consultants of certain of our affiliates. Such awards also may be granted to our directors. Only employees of our company or certain of our affiliates may be granted incentive stock options, or ISOs.

### Awards

The 2014 Plan provides that the administrator may grant or issue stock options, SARs, restricted stock, restricted stock units, deferred stock, deferred stock units, dividend equivalents, performance awards and stock payments, or any combination thereof. Each award will be set forth in a separate agreement with the person receiving the award and will indicate the type, terms and conditions of the award.

Nonstatutory Stock Options, or NSOs, will provide for the right to purchase shares of our common stock at a specified price which may not be less
than fair market value on the date of grant and usually will become exercisable (at the discretion of the administrator) in one or more installments
after the grant date, subject to the participant's continued employment or service with us and/or subject to the satisfaction of corporate performance
targets and individual performance targets established by the administrator. NSOs may be granted for any term specified by the administrator that
does not exceed ten years.

- Incentive Stock Options, or ISOs, will be designed in a manner intended to comply with the provisions of Section 422 of the Code and will be subject to specified restrictions contained in the Code. Among such restrictions, ISOs must have an exercise price of not less than the fair market value of a share of common stock on the date of grant, may only be granted to employees and must not be exercisable after a period of ten years measured from the date of grant. In the case of an ISO granted to an individual who owns (or is deemed to own) at least 10% of the total combined voting power of all classes of our capital stock, the 2014 Plan provides that the exercise price must be at least 110% of the fair market value of a share of common stock on the date of grant and the ISO must not be exercisable after a period of five years measured from the date of grant.
- *Restricted Stock* may be granted to any eligible individual and made subject to such restrictions as may be determined by the administrator. Restricted stock, typically, may be forfeited for no consideration or repurchased by us at the original purchase price if the conditions or restrictions on vesting are not met. In general, restricted stock may not be sold or otherwise transferred until restrictions are removed or expire. Purchasers of restricted stock, unlike recipients of options, will have voting rights and will have the right to receive dividends, if any, prior to the time when the restrictions lapse, however, extraordinary dividends will generally be placed in escrow and will not be released until restrictions are removed or expire.
- Restricted Stock Units may be awarded to any eligible individual, typically without payment of consideration, but subject to vesting conditions based on continued employment or service or on performance criteria established by the administrator. Like restricted stock, restricted stock units may not be sold, or otherwise transferred or hypothecated, until vesting conditions are removed or expire. Unlike restricted stock, stock underlying restricted stock units will not be issued until the restricted stock units have vested, and recipients of restricted stock units generally will have no voting or dividend rights prior to the time when vesting conditions are satisfied.
- Deferred Stock Awards represent the right to receive shares of our common stock on a future date. Deferred stock may not be sold or otherwise
  hypothecated or transferred until issued. Deferred stock will not be issued until the deferred stock award has vested, and recipients of deferred stock
  generally will have no voting or dividend rights prior to the time when the vesting conditions are satisfied and the shares are issued. Deferred stock
  awards generally will be forfeited, and the underlying shares of deferred stock will not be issued, if the applicable vesting conditions and other
  restrictions are not met.
- *Deferred Stock Units* are denominated in unit equivalent of shares of our common stock and vest pursuant to a vesting schedule or performance criteria set by the administrator. The common stock underlying deferred stock units will not be issued until the deferred stock units have vested, and recipients of deferred stock units generally will have no voting rights prior to the time when vesting conditions are satisfied.
- Stock Appreciation Rights, or SARs, may be granted in connection with stock options or other awards, or separately. SARs granted in connection with stock options or other awards typically will provide for payments to the holder based upon increases in the price of our common stock over a set exercise price. The exercise price of any SAR granted under the 2014 Plan must be at least 100% of the fair market value of a share of our common stock on the date of grant. Except as required by Section 162(m) of the Code with respect to a SAR intended to qualify as performance-based compensation as described in Section 162(m) of the Code, there are no restrictions specified in the 2014 Plan on the exercise of SARs or the amount of gain realizable therefrom, although restrictions may be imposed by the administrator in the SAR agreements. SARs under the 2014 Plan will be settled in cash or shares of our common stock, or in a combination of both, at the election of the administrator.
- *Dividend Equivalents* represent the value of the dividends, if any, per share paid by us, calculated with reference to the number of shares covered by the award. Dividend equivalents may be settled in cash or shares and at such times as determined by the compensation committee or board of directors, as applicable.

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- Performance Awards may be granted by the administrator on an individual or group basis. Generally, these awards will be based upon specific
  performance targets and may be paid in cash or in common stock or in a combination of both. Performance awards may include "phantom" stock
  awards that provide for payments based upon the value of our common stock. Performance awards may also include bonuses that may be granted by
  the administrator on an individual or group basis and which may be payable in cash or in common stock or in a combination of both.
- *Stock Payments* may be authorized by the administrator in the form of common stock or an option or other right to purchase common stock as part of a deferred compensation or other arrangement in lieu of all or any part of compensation, including bonuses, that would otherwise be payable in cash to the employee, consultant or non-employee director.

### Change in Control

In the event of a change in control where the acquiror does not assume or replace awards granted, prior to the consummation of such transaction, awards issued under the 2014 Plan, other than performance awards, will be subject to accelerated vesting such that 100% of such awards will become vested and exercisable or payable, as applicable. Performance awards will vest in accordance with the terms and conditions of the applicable award agreement. The administrator may also make appropriate adjustments to awards under the 2014 Plan and is authorized to provide for the acceleration, cash-out, termination, assumption, substitution or conversion of such awards in the event of a change in control or certain other unusual or nonrecurring events or transactions. Under the 2014 Plan, a change in control is generally defined as:

- the transfer or exchange in a single transaction or series of related transactions by our stockholders of more than 50% of our voting stock to a person or group;
- a change in the composition of our board of directors over a two-year period such that the members of the board of directors who were approved by at least two-thirds of the directors who were directors at the beginning of the two year period or whose election or nomination was so approved cease to constitute a majority of the board of directors;
- the consummation of a merger, consolidation, reorganization or business combination, sale or disposition of all or substantially all of our assets or acquisition of assets or stock of another entity, in each case, other than a transaction that results in our outstanding voting securities immediately before the transaction continuing to represent a majority of the voting power of the acquiring company's outstanding voting securities and after which no person or group beneficially owns 50% or more of the outstanding voting securities of the surviving entity immediately after the transaction; or
- stockholder approval of our liquidation or dissolution.

### Adjustments of Awards

In the event of a nonreciprocal transaction between the Company and its stockholders, such as a stock dividend, stock split, spin-off, rights offering or recapitalization affecting the number of outstanding shares of our common stock or the share price of our common stock, the administrator will make appropriate, proportionate adjustments to:

- the aggregate number and type of shares subject to the 2014 Plan;
- the number and kind of shares subject to outstanding awards and terms and conditions of outstanding awards (including, without limitation, any
  applicable performance targets or criteria with respect to such awards); and
- the grant or exercise price per share of any outstanding awards under the 2014 Plan.

In the event of certain other corporate transactions, in order to prevent dilution or enlargement of the potential benefits intended to be made available under the 2014 Plan, the administrator has the discretion to make such equitable adjustments and may also:

provide for the termination or replacement of an award in exchange for cash or other property;

- provide that any outstanding award cannot vest, be exercised or become payable after such event;
- provide that awards may be exercisable, payable or fully vested as to shares of common stock covered thereby; or
- provide that any surviving corporation will assume or substitute outstanding awards under the 2014 Plan.

#### Amendment and Termination

Our board of directors or the compensation committee (with board approval) may terminate, amend or modify the 2014 Plan at any time and from time to time. However, we must generally obtain stockholder approval:

- to increase the number of shares available under the 2014 Plan (other than in connection with certain corporate events, as described above);
- reduce the price per share of any outstanding option or stock appreciation right granted under the 2014 Plan; or
- cancel any option or stock appreciation right in exchange for cash or another award when the option or stock appreciation right price per share exceeds the fair market value of the underlying shares.

No awards may be granted pursuant to the 2014 Plan after the tenth anniversary of the effective date of the 2014 Plan. Any award that is outstanding on the termination date of the 2014 Plan will remain in force according to the terms of the 2014 Plan and the applicable award agreement.

We intend to file with the SEC a registration statement on Form S-8 covering the shares of our common stock issuable under the 2014 Plan.

## 2010 Equity Incentive Plan

Our board of directors adopted the 2010 Plan effective as of October 12, 2010 and our stockholders approved the 2010 Plan on February 28, 2011. The 2010 Plan was subsequently amended on March 27, 2014. The 2010 Plan provided for the grants of stock options, including ISOs and NSOs, and stock purchase rights. As of June 30, 2014, options to purchase 9,251,560 shares of our common stock at a weighted-average exercise price per share of \$0.97 were outstanding under the 2010 Plan. No other awards have been granted under the 2010 Plan. As of June 30, 2014, 991,414 shares of our common stock were available for future issuance pursuant to awards granted under the 2010 Plan. Following the completion of this offering and in connection with the effectiveness of our 2014 Plan, the 2010 Plan will terminate and no further awards will be granted under the 2010 Plan. However, all outstanding awards will continue to be governed by their existing terms.

#### Administration

Our board of directors, or a committee thereof appointed by our board of directors, has the authority to administer the 2010 Plan and the awards granted under it. Following the date upon which our common stock is first listed on any securities exchange or designated as a national market security on an interdealer quotation system, the committee administering the plan will consist solely of two or more independent directors, each of whom is an "outside director" within the meaning of 162(m) of the Code, a "non-employee director" within the meaning of Rule 16b-3 of the Exchange Act and qualifies as "independent" within the meaning of any applicable stock exchange listing requirements. The administrator has the authority to select the service providers to whom awards will be granted under the 2010 Plan, the number of shares to be subject to those awards under the 2010 Plan and the terms and conditions of the awards granted. In addition, the administrator has the authority to construe and interpret the 2010 Plan and to adopt rules for the administration, interpretation and application of the 2010 Plan that are consistent with the terms of the 2010 Plan.

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## Eligibility

Awards other than ISOs may be granted to any of our employees, consultants or directors or any employees or consultants of an affiliate of our company. Only employees of our company or of an affiliate of our company may be granted ISOs.

#### Awards

The 2010 Plan provides that the administrator may grant or issue options, including ISOs and NSOs, and stock purchase rights. Each award will be set forth in a separate agreement with the person receiving the award and will indicate the type, terms and conditions of the award.

The exercise price of ISOs granted to employees who at the time of grant own stock representing more than 10% of the voting power of all classes of our common stock may not be less than 110% of the fair market value per share of our common stock on the date of grant. The exercise price of all other options granted under the 2010 Plan may not be less than 100% of the fair market value per share of our common stock on the date of grant. Shares subject to options under the 2010 Plan generally vest in a series of installments over the participant's period of service. In general, the maximum term of options granted is ten years, provided that the maximum term of an ISO granted to an employee who owns stock representing more than 10% of the voting power of all classes of our common stock is five years.

We may also issue stock purchase rights under the 2010 Plan pursuant to which participants may accept an offer to purchase our common stock by execution of a restricted stock purchase agreement. The restricted stock purchase agreement shall generally grant the Company the right to repurchase shares acquired upon exercise of a stock purchase right upon the purchaser's termination of service. Once a stock purchase right is exercised, the purchaser will have rights equivalent to those of a stockholder.

#### Transferability

Generally, options may not be sold or otherwise transferred in any manner other than by will or the laws of descent and distribution and may be exercised only by the participant during the lifetime of the participant.

### Adjustments Upon Changes in Capitalization

In the event of certain changes in capitalization, including, but not limited to, any dividend or distribution, reorganization, merger or consolidation, that affects our common stock such that an adjustment is determined to be appropriate in order to prevent dilution or enlargement of the benefits or potential benefits intended by the Company to be made available under the 2010 Plan or with respect to any award thereunder, the administrator may make certain adjustments, including to: (i) the number and kind of common stock with respect to which awards may be granted; (ii) the number and kind of common stock subject to outstanding options, stock purchase rights or restricted stock; or (iii) the grant or exercise price with respect to any option or stock purchase right. The administrator may also take one or more of the following actions in order to prevent such enlargement or dilution of benefits: (i) provide for the purchase, realization or replacement of any award; (ii) to provide for the acceleration of vesting of any award; (iii) to provide for the assumption or substitution of any award by a successor corporation; (iv) to provide for the termination of an award upon the consummation of the corporate event following a period during which all awards shall be exercisable and all restrictions shall lapse. Notwithstanding anything to the contrary, in the event of an "Equity Restructuring" (as defined in the 2010 Plan), the number and type of securities that may be issued under the plan, the number and type of securities subject to each outstanding award and the exercise or grant price of outstanding awards shall be proportionately adjusted.

## Acquisition

If the Company undergoes an Acquisition (as defined in the 2010 Plan), then any acquiring corporation may assume any awards outstanding under the 2010 Plan or may substitute similar stock awards (including an award to acquire the same consideration paid to the stockholders) for those outstanding under the 2010 Plan. In the event any surviving corporation or entity or acquiring corporation or entity in an Acquisition, or affiliate of such

corporation or entity, does not assume such awards or does not substitute similar stock awards for those outstanding under the 2010 Plan, then with respect to (i) awards held by participants who have not terminated their service with us prior to such event, that number of awards that would have otherwise vested (and, if applicable, the time during which the awards may be exercised) will be accelerated and made exercisable at least ten days prior to the closing of the Acquisition (and, if applicable, the awards terminated if not exercised prior to the closing of such Acquisition) and (ii) any other awards outstanding under the 2010 Plan, such awards will be terminated if not exercised, prior to the closing of the Acquisition.

#### Amendment and Termination

Our board of directors may amend or terminate the 2010 Stock Option Plan at any time, provided that the board of directors will obtain stockholder approval for any amendment to the extent necessary to comply with applicable law. No amendment or termination of the 2010 Plan or award granted thereunder may impair the rights under options already granted to a participant unless mutually agreed to in writing by the participant and the Administrator. Following this offering and in connection with the effectiveness of our 2014 Plan, the 2010 Plan will terminate and no further awards will be granted under the 2010 Plan.

We intend to file with the SEC a registration statement on Form S-8 covering our shares of common stock issuable under the 2010 Plan.

#### **Employee Stock Purchase Plan**

We intend to adopt an Employee Stock Purchase Plan, which we refer to as our ESPP, which will be effective upon the effectiveness of the registration statement to which this prospectus relates. The ESPP is designed to allow our eligible employees to purchase shares of our common stock, at semi-annual intervals, with their accumulated payroll deductions. The ESPP is intended to qualify under Section 423 of the Code.

### Plan Administration

Subject to the terms and conditions of the ESPP, our compensation committee will administer the ESPP. Our compensation committee can delegate administrative tasks under the ESPP to the services of an agent and/or employees to assist in the administration of the ESPP. The administrator will have the discretionary authority to administer and interpret the ESPP. Interpretations and constructions of the administrator of any provision of the ESPP or of any rights thereunder will be conclusive and binding on all persons. We will bear all expenses and liabilities incurred by the ESPP administrator.

#### Shares Available Under ESPP

The maximum number of our shares of our common stock which will be authorized for sale under the ESPP is equal to the sum of (a) shares of common stock and (b), if approved by our board of directors or the compensation committee of our board of directors, an annual increase on the first day of each year beginning in 2015 and ending in 2024, equal to the lesser of (i) percent (%) of the shares of common stock outstanding (on an as converted basis) on the last day of the immediately preceding fiscal year and (ii) such number of shares of common stock as determined by our board of directors; provided, however, no more than shares of our common stock may be issued under the ESPP. The shares made available for sale under the ESPP may be authorized but unissued shares or reacquired shares reserved for issuance under the ESPP.

## Eligible Employees

Employees eligible to participate in the ESPP for a given offering period generally include employees who are employed by us or one of our subsidiaries on the first day of the offering period, or the enrollment date. Our employees and any employees of our subsidiaries who customarily work less than five months in a calendar year or are customarily scheduled to work less than 20 hours per week will not be eligible to participate in the ESPP. Finally, an employee who owns (or is deemed to own through attribution) 5% or more of the combined voting power or value of all our classes of stock or of one of our subsidiaries will not be allowed to participate in the ESPP.

### Participation

Employees will enroll under the ESPP by completing a payroll deduction form permitting the deduction from their compensation of at least 1% of their compensation but not more than the lesser of % of their compensation and \$25,000 per offering period. Such payroll deductions may be expressed as either a whole number percentage or a fixed dollar amount and the accumulated deductions will be applied to the purchase of shares on each semi-annual purchase date. However, a participant may not purchase more than shares in each offering period and may not subscribe for more than \$25,000 in fair market value of shares our common stock (determined at the time the option is granted) during any calendar year. The ESPP administrator has the authority to change these limitations for any subsequent offering period.

### Offering

Under the ESPP, participants are offered the option to purchase shares of our common stock at a discount during a series of successive offering periods, which will normally commence on and of each year. The initial offering period will commence and end on dates as determined by the ESPP administrator. Unless otherwise determined by the ESPP administrator, each offering period will have a duration of six months. However, in no event may an offering period be longer than 27 months in length.

The option purchase price will be the lower of 85% of the closing trading price per share of our common stock on the first trading date of an offering period in which a participant is enrolled or 85% of the closing trading price per share on the semi-annual purchase date, which will occur on the last trading day of each offering period.

Unless a participant has previously canceled his or her participation in the ESPP before the purchase date, the participant will be deemed to have exercised his or her option in full as of each purchase date. Upon exercise, the participant will purchase the number of whole shares that his or her accumulated payroll deductions will buy at the option purchase price, subject to the participation limitations listed above.

A participant may cancel his or her payroll deduction authorization at any time prior to the end of the offering period. Upon cancellation, the participant will have the option to either (a) receive a refund of the participant's account balance in cash without interest or (b) exercise the participant's option for the current offering period for the maximum number of shares of common stock on the applicable purchase date, with the remaining account balance refunded in cash without interest. Following at least one payroll deduction, a participant may also decrease (but not increase) his or her payroll deduction authorization once during any offering period. If a participant wants to increase or decrease the rate of payroll withholding, he or she may do so effective for the next offering period by submitting a new form before the offering period for which such change is to be effective.

A participant may not assign, transfer, pledge or otherwise dispose of (other than by will or the laws of descent and distribution) payroll deductions credited to a participant's account or any rights to exercise an option or to receive shares of our common stock under the ESPP, and during a participant's lifetime, options in the ESPP shall be exercisable only by such participant. Any such attempt at assignment, transfer, pledge or other disposition will not be given effect.

### Adjustments upon Changes in Recapitalization, Dissolution, Liquidation, Merger or Asset Sale

In the event of any increase or decrease in the number of issued shares of our common stock resulting from a stock split, reverse stock split, stock dividend, combination or reclassification of the common stock, or any other increase or decrease in the number of shares of common stock effected without receipt of consideration by us, we will proportionately adjust the aggregate number of shares of our common stock offered under the ESPP, the number and price of shares which any participant has elected to purchase pursuant under the ESPP and the maximum number of shares which a participant may elect to purchase in any single offering period.

If there is a proposal to dissolve or liquidate us, then the ESPP will terminate immediately prior to the consummation of such proposed dissolution or liquidation, and any offering period then in progress will be

shortened by setting a new purchase date to take place before the date of our dissolution or liquidation. We will notify each participant of such change in writing at least ten business days prior to the new exercise date. If we undergo a merger with or into another corporation or sale of all or substantially all of our assets, each outstanding option will be assumed or an equivalent option substituted by the successor corporation or the parent or subsidiary of the successor corporation. If the successor corporation refuses to assume the outstanding options or substitute equivalent options, then any offering period then in progress will be shortened by setting a new purchase date to take place before the date of our proposed sale or merger. We will notify each participant of such change in writing at least ten business days prior to the new exercise date.

## Amendment and Termination

Our board of directors may amend, suspend or terminate the ESPP at any time. However, the board of directors may not amend the ESPP without obtaining stockholder approval within 12 months before or after such amendment to the extent required by applicable laws.

We intend to file with the SEC a registration statement on Form S-8 covering our shares issuable under the ESPP.

## CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following is a description of transactions since January 1, 2011 to which we have been a party, in which the amount involved exceeds \$120,000 and in which any of our directors, executive officers or holders of more than 5% of our capital stock, or an affiliate or immediate family member thereof, had or will have a direct or indirect material interest.

## Sales and Purchases of Securities

### Series C Convertible Preferred Stock Financing

In May 2014, we issued an aggregate of 9,149,993 shares of our Series C convertible preferred stock at a price per share of \$6.00 for aggregate net proceeds of \$54.7 million to 35 accredited investors and 1,763,848 shares of Series C convertible preferred stock which were issued pursuant to a conversion from \$10.6 million aggregate principal and associated accrued interest in convertible notes issued in our 2013 bridge financing. In addition, we issued 16,667 shares of Series C convertible preferred stock in exchange for services. The table below sets forth the number of shares of Series C convertible preferred stock sold to our directors, executive officers or holders of more than 5% of our common stock, or an affiliate or immediate family member thereof:

Name	Number of Shares of Series C Convertible Preferred Stock	Aggregate Purchase Price(\$)
KKR Biosimilar L.P. <sup>(1)</sup>	4,166,666	\$ 24,999,996
Venrock Associates VI, L.P. <sup>(2)</sup>	1,852,517	11,115,102
Lilly Ventures Fund I, LLC <sup>(3)</sup>	905,351	5,432,106
MX II Associates, LLC <sup>(4)</sup>	444,259	2,665,554
Sofinnova Venture Partners VII, L.P. <sup>(5)</sup>	250,000	1,500,000
Helix Founders' Fund, L.P. <sup>(6)</sup>	88,851	533,106
KMG Capital Partners, LLC <sup>(7)</sup>	133,277	799,662
Caduceus Medical Holdings, LLC <sup>(7)</sup>	44,425	266,550
Leonard Capital, LLC <sup>(7)</sup>	17,625	105,750
Barbara K. Finck, M.D.	8,812	52,872
Lanfear Capital Advisors, LLC <sup>(8)</sup>	8,812	52,872
Surazal Limited Partnership <sup>(9)</sup>	4,406	26,436
Christos Richards	4,375	26,250
George G. Montgomery	4,406	26,436

(1)

Ali J. Satvat, who is a member of our board of directors, is an executive of Kohlberg Kravis Roberts & Co. L.P., which is an entity affiliated with KKR Biosimilar L.P. Includes 74,196 shares purchased by Venrock Partners VI, L.P., 704,467 shares purchased by Venrock Healthcare Capital Partners, L.P. and 128,866 shares purchased by VHCP Co-Investment Holdings, (2) LLC

(3) S. Edward Torres, who was previously on our board of directors, is a Managing Director of Lilly Ventures Management Company, LLC, which is an entity affiliated with Lilly Ventures Fund I, LLC.

August J. Troendle, M.D. who is a member of our board of directors, is Chief Executive Officer, President and Chairman of Medpace, Inc., and is the Managing Member of MX II Associates, LLC. James I. Healy, M.D., Ph.D. who is a member of our board of directors, is a managing member of Sofinnova Management VII, L.L.C., which is the general partner of Sofinnova Venture Partners VII, L.P. (4)

(5) (6) Graham K. Crooke, MB.BS., who was formerly on our board of directors, is a General Partner of Helix Founders Fund, L.P.

(7) Mats Wahlström, who is a member of our board of directors, is Chairman of Caduceus Medical Holdings, LLC and Chief Executive Officer and Chairman of KMG Capital Partners, LLC and of Leonard Capital, LLC.

(8) Dennis M.C. Lanfear, who is our Chief Executive Officer and Chairman of our board of directors, is President of Lanfear Capital Advisors, LLC. Michael Lazarus, M.D. who was previously on our board of directors, is affiliated with Surazal Limited Partnership.

(9)

## **Repurchase of Common Stock**

In March 2014, we repurchased shares of our common stock from certain of our directors, executive officers or holders of more than 5% of our common stock at a repurchase price per share equal to the original issuance price of \$0.005 per share, as set forth below:

Name	Number of Shares of Series B Preferred Stock	Aggregate Purchase Price
Dennis M. Lanfear	200,000	\$ 1,000
Stephen C. Glover	100,000	500
Douglas H. Farrar	100,000	500

### InteKrin Therapeutics Inc. Acquisition

In February 2014, we acquired InteKrin Therapeutics Inc. Total consideration for the acquisition of InteKrin was \$5.0 million and consisted of: (a) the issuance of 1,194,686 shares of Series B convertible preferred stock with a fair value of \$2.7 million, (b) the assumption of a convertible note of InteKrin payable to Sofinnova Venture Partners VII, L.P., which was concurrently paid off by issuing 406,483 shares of our Series B convertible preferred stock with a fair value of \$1.0 million, (c) a cash payment of \$1,485 and (d) contingent consideration with a fair value of \$1.3 million at the acquisition date. Shareholders of InteKrin include Dennis M. Lanfear, Sofinnova Venture Partners VII, L.P. and Vivo Ventures Fund V, L.P. and its affiliated funds. At the time of our acquisition of InteKrin, Dennis M. Lanfear was a director of InteKrin, and Dennis M. Lanfear, Michael A. Nazak and Graham K. Crooke, MB.BS., were directors of ZAO InteKrin, a subsidiary of InteKrin.

The table below sets forth the number of shares of Series B convertible preferred stock issued as consideration in the acquisition to our directors, executive officers or holders of more than 5% of our common stock, or an affiliate or immediate family member thereof:

Name	Number of Shares of Series B Convertible Preferred Stock
<u>Name</u> Sofinnova Venture Partners VII, L.P. <sup>(1)</sup>	640,783
Dennis M. Lanfear <sup>(2)</sup>	10,883
James I. Healy, M.D., Ph.D.	80

James I. Healy, M.D., Ph.D. who is a member of our board of directors, is a managing member of Sofinnova Management VII, L.L.C., which is the general partner of Sofinnova Venture Partners VII, L.P.
 Includes 5,523 shares received by Dennis M. Lanfear, 5,324 shares received by Dennis M. Lanfear, as Trustee of the Lanfear Revocable Trust, dated January 27, 2004, as restated and 36 shares received by Lanfear Capital Advisors, LLC.

### 2013 Issuance of Warrants to Purchase Series B Convertible Preferred Stock

In July, August and September 2013, as part of a bridge financing, we issued warrants to purchase up to a maximum of 7,134,149 shares of our Series B convertible preferred stock at a price per share of \$0.01 to the below directors, executive officers or holders of more than 5% of our capital stock, or an affiliate or immediate family member thereof in connection with a convertible note financing. In May 2014, all of the principal and accrued interest under the convertible notes issued in this financing converted into shares of our Series C convertible preferred stock and all of the warrants were exercised for shares of Series B convertible preferred stock.

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The table below sets forth the number of shares of Series B convertible preferred stock issued to our directors, executive officers or holders of more than 5% of our common stock, or an affiliate or immediate family member thereof pursuant to their exercise of the warrants:

	Number of Shares of Series B Convertible Preferred Stock
Name	from Warrants
Lilly Ventures Fund I, LLC <sup>(1)</sup>	1,971,750
MX II Associates, LLC <sup>(2)</sup>	1,792,500
Venrock Associates VI, L.P.	1,433,999
KMG Capital Partners, LLC <sup>(3)</sup>	537,750
Helix Founders' Fund, L.P. <sup>(4)</sup>	358,500
Caduceus Medical Holdings, LLC <sup>(3)</sup>	179,250
Leonard Capital, LLC <sup>(3)</sup>	71,700
Barbara K. Finck, M.D.	35,850
Lanfear Capital Advisors, LLC <sup>(5)</sup>	35,850
Christos Richards	17,925
George G. Montgomery	17,925
Surazal Limited Partnership <sup>(6)</sup>	17,925

S. Edward Torres, who was previously on our board of directors, is a Managing Director of Lilly Ventures Management Company, LLC, which is an entity affiliated with Lilly Ventures Fund I, LLC. August J. Troendle, M.D., who is a member of our board of directors, is Chief Executive Officer, President and Chairman of Medpace, Inc. and is the Managing Member of MX II Associates, LLC. (1)

(2) (3) Mats Wahlström, who is a member of our board of directors, is Chairman of Caduceus Medical Holdings, LLC and Chief Executive Officer and Chairman of KMG Capital Partners, LLC and of Leonard

Capital, LLC. (4)

Graham K. Crooke, MB.BS, who was previously on our board of directors, is a General Partner of Helix Founders' Fund, L.P. Dennis M. Lanfear, who is our Chief Executive Officer and Chairman of our board of directors, is President of Lanfear Capital Advisors, LLC. Michael Lazarus, M.D., who was previously on our board of directors, is affiliated with Surazal Limited Partnership. (5)

(6)

## Series B Convertible Preferred Stock Financing

In January 2012, we issued an aggregate of 5,377,500 shares of our Series B convertible preferred stock at a price per share of \$4.1841 for aggregate net proceeds of approximately \$20.3 million to 18 accredited investors and 2,540,742 shares of Series B convertible preferred stock which we issued pursuant to a conversion from \$10.6 million aggregate principal and accrued interest in convertible notes issued in our 2011 bridge financing. In addition, we issued 836,500 shares of Series B convertible preferred stock in exchange for services. In December 2012, we issued an additional 4,788,365 shares of our Series B convertible preferred stock in additional closings, of which 2,876,365 shares were issued in exchange for services. The table below sets forth the number of shares of Series B convertible preferred stock sold to our directors, executive officers or holders of more than 5% of our capital stock, or an affiliate or immediate family member thereof:

Name	Number of Shares of Series B Preferred Stock	Aggregate Purchase Price
Daiichi Sankyo Company, Limited	4,780,000	\$ 19,999,999
Cook Pharmica LLC	3,585,000	14,999,999
Medpace, Inc. <sup>(1)</sup>	1,219,696	5,103,330
Lilly Ventures Fund I, LLC <sup>(2)</sup>	1,203,763	5,036,666
Oasis Investing Limited <sup>(3)</sup>	956,000	3,999,999
Olsen International Limited <sup>(4)</sup>	956,000	3,999,999
Helix Founders' Fund, L.P. <sup>(5)</sup>	246,676	1,032,117
Leonard Capital, LLC <sup>(1)</sup>	124,439	520,665
Caduceus Medical Holdings, LLC <sup>(1)</sup>	121,730	509,330
Dennis M. Lanfear	18,665	78,096
Douglas H. Farrar	14,932	62,476
Stephen C. Glover	14,932	62,476
Alan C. Herman Ph.D.	8,710	36,443
Stuart E. Builder, Ph.D. <sup>(6)</sup>	7,466	31,240
Christos Richards	2,487	10,405
Surazal Limited Partnership <sup>(7)</sup>	2,383	9,970

(1)Includes 622,196 shares purchased by MX II Associates LLC and 597,500 shares purchased by Medpace, Inc. August J. Troendle, M.D., who is a member of our board of directors, is Chief Executive Officer, President and Chairman of Medpace, Inc. and is the Managing Member of MX II Associates, LLC. S. Edward Torres, who was previously on our board of directors, is a Managing Director of Lilly Ventures Management Company, LLC, which is an entity affiliated with Lilly Ventures Fund I, LLC.

(2) (3)

Oasis Investing Limited is an affiliated entity of Orox Pharmaceuticals B.V. (4) Olsen International Limited is an affiliated entity of Orox Pharmaceuticals B.V.

(5) Graham K. Crooke, MB.BS, who was previously on our board of directors, is a General Partner of Helix Founders' Fund, L.P.

(6) Stuart E. Builder, Ph.D. was previously on our board of directors

(7) Michael Lazarus, M.D., who was previously on our board of directors, is affiliated with Surazal Limited Partnership.

## **Issuance of Unsecured Promissory Notes**

In December 2011, we issued unsecured promissory notes bearing interest at 0.2% per annum to certain of our directors, executive officers or holders of more than 5% of our common stock in approximately the amounts set forth below in connection with, and to facilitate, their purchase of our common stock:

	Principal
	Amount
	of Unsecured Duranicas
Name	Promissory Note
<u>Name</u> Alan C. Herman, Ph.D.	Note \$ 51,032
Dennis M. Lanfear	35,151
Stephen C. Glover	21,380
Douglas H. Farrar	25,122

In March 2013, our board of directors approved the forgiveness of all outstanding principal and accrued interest under the unsecured promissory note issued to Mr. Glover. In May 2014, our board of directors approved the forgiveness of all outstanding principal and accrued interest under the unsecured promissory notes issued Messrs. Lanfear and Farrar and Dr. Herman.

## 2011 Issuance of Warrants to Purchase Series B Convertible Preferred Stock

In July, August and December 2011, as part of a bridge financing, we issued warrants to purchase up to a maximum of 587,543 shares of our Series B convertible preferred stock at a price per share of \$0.01 to the below directors, executive officers or holders of more than 5% of our capital stock, or an affiliate or immediate family member thereof in connection with a convertible note financing. In January 2012, all of the principal and accrued interest under the convertible notes issued in this financing were converted into shares of our Series B convertible preferred stock.

The table below sets forth the number of shares of Series B convertible preferred stock subject to the warrants issued to our directors, executive officers or holders of more than 5% of our common stock, or an affiliate or immediate family member thereof:

Name	Number of Shares of Series B ConvertiblePreferred Stock Exercisable Under Warrants
Lilly Ventures Fund I, LLC <sup>(1)</sup>	239,000
MX II Associates, LLC <sup>(2)</sup>	179,250
Helix Founders' Fund, L.P. <sup>(3)</sup>	47,795
Leonard Capital <sup>(4)</sup>	35,850
Caduceus Medical Holdings LLC <sup>(4)</sup>	23,900
Dennis M. Lanfear	5,377
Douglas H. Farrar	4,302
Stephen C. Glover	4,302
Alan C. Herman, Ph.D.	2,509
Stuart E. Builder, Ph.D. <sup>(5)</sup>	2,151
Christos Richards	716
Surazal Limited Partnership <sup>(6)</sup>	686

(1) S. Edward Torres, who was previously on our board of directors, is a Managing Director of Lilly Ventures Management Company, LLC, which is an entity affiliated with Lilly Ventures Fund I, LLC.

(2) August J. Troendle, M.D., who is a member of our board of directors, is Chief Executive Officer, President and Chairman of Medpace, Inc. and is the Managing Member of MX II Associates, LLC.
 (3) Graham K. Crooke, MB.BS, who was previously on our board of directors, is a General Partner of Helix Founders' Fund, L.P.
 (4) Mats Wahlström, who is a member of our board of directors, is Chairman of Caduceus Medical Holdings, LLC and Chief Executive Officer and Chairman of KMG Capital Partners, LLC and of J

<sup>4)</sup> Mats Wahlström, who is a member of our board of directors, is Chairman of Caduceus Medical Holdings, LLC and Chief Executive Officer and Chairman of KMG Capital Partners, LLC and of Leonard Capital, LLC.

(5) Stuart E. Builder, Ph.D. was previously on our board of directors.

<sup>(6)</sup> Michael Lazarus, M.D., who was previously on our board of directors, is affiliated with Surazal Limited Partnership.

## Series A Convertible Preferred Stock Financing

In March 2011, we issued an aggregate of 1,406,663 shares of our Series A convertible preferred stock at a price per share of \$0.75 for aggregate net proceeds of approximately \$1.0 million to 13 accredited investors and 214,225 shares of Series A convertible preferred stock which were issued pursuant to a conversion from \$160,699 aggregate principal and accrued interest in convertible notes from our 2011 bridge financing.

Name	Number of Shares of Series A Convertible Preferred Stock	Aggregat	e Purchase Price
MX II Associates, LLC <sup>(1)</sup>	533,333	\$	400,000
Helix Founders' Fund, L.P. <sup>(2)</sup>	400,000		300,000
Lanfear Capital Advisors, LLC <sup>(3)</sup>	66,946		50,210
Christos Richards	66,666		50,000
Alan C. Herman, Ph.D.	66,666		50,000
Douglas H. Farrar	33,473		25,105
Surazal Limited Partnership <sup>(4)</sup>	13,387		10,040

(1) August J. Troendle, M.D., who is a member of our board of directors, is Chief Executive Officer, President and Chairman of Medpace, Inc. and is the Managing Member of MX II Associates, LLC.

(2) Graham K. Crooke, MB.BS, who was previously on our board of directors, is a General Partner of Helix Founders' Fund, L.P.
 (3) Dennis M. Lanfear, who is our Chief Executive Officer and Chairman of our board of directors, is President of Lanfear Capital Additional Control of Capital Additional Capital Additional Capital Additional Capital Additional Capital Additional Capital Additional Capital Capi

(3) Dennis M. Lanfear, who is our Chief Executive Officer and Chairman of our board of directors, is President of Lanfear Capital Advisors, LLC.
 (4) Michael Lazarus M.D. who was previously on our board of directors is affiliated with Surzal Limited Partnership.

<sup>(4)</sup> Michael Lazarus, M.D., who was previously on our board of directors, is affiliated with Surazal Limited Partnership.

#### 2011 Issuance of Warrants to Purchase Series A Convertible Preferred Stock

In January 2011, as part of a bridge financing, we issued warrants to purchase up to a maximum of 106,560 shares of our Series A convertible preferred stock at a price per share of \$0.75 to the below directors, executive officers or holders of more than 5% of our common stock, or an affiliate or immediate family member thereof:

	Number of Shares of Series A Convertible Preferred Stock
Name	Exercisable Under Warrants
Lanfear Capital Advisors, LLC <sup>(1)</sup>	33,300
Stephen C. Glover	33,300
Douglas H. Farrar	16,650
Stuart E. Builder, Ph.D. <sup>(2)</sup>	16,650
Surazal Limited Partnership <sup>(3)</sup>	6,660

(1) Dennis M. Lanfear, who is our Chief Executive Officer and Chairman of our board of directors, is President of Lanfear Capital Advisors, LLC.

Stuart E. Builder, Ph.D. was previously on our board of directors.

(3) Michael Lazarus, M.D., who was previously on our board of directors, is affiliated with Surazal Limited Partnership.

### Daiichi Sankyo Company, Limited License Agreement

Under the Daiichi License Agreement, we granted Daiichi Sankyo Company, Limited, or Daiichi Sankyo, exclusive rights to CHS-0214 (our etanercept (Enbrel) biosimilar candidate) and a rituximab (Rituxan) biosimilar candidate in the territory of Japan, Taiwan and South Korea, with an option to expand the licensed rights to include China, and an option to manufacture the products for these licensed territories. In exchange for these rights, Daiichi Sankyo made an upfront equity investment of \$20.0 million in the company, paid us an upfront fee, and agreed to pay us royalties based on a percentage of net sales of licensed products in the licensed territory. If we are manufacturing product for Daiichi Sankyo, we are eligible to receive an increased royalty reflecting our manufacturing costs. Daiichi Sankyo terminated its rights to CHS-0214 in Taiwan and South Korea in May 2012, declined to expand its licensed rights to China in August 2012 and terminated its rights to a rituximab biosimilar candidate in July 2014.

Under the memoranda of understanding, we agreed to specific cost sharing responsibilities with Daiichi Sankyo based upon percentages of estimated costs. See "Business — Collaboration and License Agreements — License Agreement with Daiichi Sankyo Company, Limited" for more information about our collaboration with Daiichi Sankyo.

### Engagements with Catalyst Advisors LP and Levin & Company

Christos Richards, a member of our board of directors and our compensation committee, is a partner in Catalyst Advisors LP, or Catalyst, an executive search firm. We retained Catalyst in 2014 to perform executive search and recruiting services. During the period from January 1, 2014 through July 14, 2014, the total amount invoiced to us by Catalyst for these services was approximately \$432,000 including expense reimbursement, and the total amount paid by us to Catalyst for these services during this period was approximately \$366,000. Prior to 2014, Mr. Richards was Chief Executive Officer of Levin & Company, or Levin, an executive search firm. We retained Levin during the period of January 1, 2011 through December 31, 2013 to perform executive search and recruiting services. The total amount paid by us to Levin for these services in this period, including expense reimbursement, was approximately \$254,000.

In March 2014, we issued to Mr. Richards a warrant exercisable for up to 44,184 shares of our common stock, with an exercise price of \$1.00 per share, as additional consideration for services provided to us by Mr. Richards in connection with these engagements.

#### Medpace, Inc. Master Services Agreement

In January 2012, we entered into a Master Services Agreement with Medpace, Inc., or Medpace, a contract research organization, or CRO, under which we engage Medpace to perform certain CRO services related to the design and execution of clinical development programs. August J. Troendle, M.D., who is a member of our board of directors, is Chief Executive Officer, President and Chairman of Medpace, Inc. and is the Managing Member of MX II Associates, LLC. Prior to the consummation of this offering, MX II Associates, LLC is a beneficial owner of more than 5% of our common stock. In August 2014 we executed a task order with Medpace to cover the in life management of the Phase 3 rheumatoid arthritis study (a Phase 3, double-blind, randomized, parallel-group, active-control study to compare the efficacy and safety of CHS-0214 versus Enbrel in subjects with rheumatoid arthritis and inadequate response to treatment with methotrexate). To date, under the Master Services Agreement we have entered into commitments with Medpace for clinical development services having an aggregate value of \$51 million. As of June 30, 2014, we have expensed approximately \$14.5 million of this amount for our CHS-1420, CHS-0214 and CHS-1701 clinical development programs.

## **Cook Pharmica LLC Clinical Supply Agreement**

In January 2012, we entered into a Clinical Supply Agreement with Cook Pharmica LLC, or Cook, a contract manufacturing organization, or CMO, under which Cook agreed to perform certain manufacturing services related to supplying products for use in our clinical studies, in exchange for up to \$10 million of Series B convertible preferred stock. We have entered into commitments to use Cook to meet our initial commercial supply needs for certain of our products, including one of our lead products, CHS-1420. Cook was a beneficial owner of more than 5% of our common stock for a portion of the period beginning January 1, 2011.

#### **Orox Pharmaceuticals B.V. Distribution Agreement**

In December 2012, we entered into a distribution agreement with Orox Pharmaceuticals B.V., or Orox, in which we granted Orox an exclusive license to distribute CHS-0214, CHS-1420, CHS-1701 and a rituximab biosimilar candidate, as well as options to purchase future products, in certain Caribbean and Latin American countries. The agreement requires us to develop the licensed products and achieve regulatory approval for such products outside of the specified territory in order to facilitate Orox's ability to secure regulatory approvals within the licensed territory. We are eligible to receive from Orox a percentage of gross profits from the sale of

licensed products, on a product-by-product basis. See "Business — Collaboration and License Agreements —

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Distribution Agreement with Orox Pharmaceuticals B.V." for more information about our collaboration with Orox. Oasis Investing Limited and Olsen International Limited are affiliated entities of Orox and each was a beneficial owner of more than 5% of our common stock for a portion of the period beginning January 1, 2011.

### **Investor Rights Agreement**

We and the holders of our preferred stock have entered into a third amended and restated investor rights agreement pursuant to which these stockholders and warrantholders will have, among other things, registration rights under the Securities Act of 1933, as amended, or the Securities Act, with respect to their shares of common stock following this offering. Prior to the completion of this offering, all outstanding shares of our convertible preferred stock will be converted into common stock. See "Description of Capital Stock — Registration Rights" for more information about the investors rights agreement.

### **Voting Agreement**

We have entered into a voting agreement with certain holders of our common stock and holders of our preferred stock. The voting agreement provides for a right of first offer in favor of certain holders of preferred stock with regard to certain issuances of our capital stock. Upon the closing of this offering, the voting agreement will terminate.

For a description of the voting arrangements in the voting agreement, see the section titled "Management — Board Composition — Voting Arrangements."

## **Right of First Refusal and Co-Sale Agreement**

We have entered into a right of first refusal and co-sale agreement with certain holders of our common stock and holders of our preferred stock. This agreement provides for rights of first refusal and co-sale relating to the shares of our common stock held by certain key holders of our common stock. Upon the consummation of this offering, the third amended and restated right of first refusal and co-sale agreement as currently in effect will terminate.

#### **Indemnification Agreements**

We have entered or intend to enter into indemnification agreements with each of our directors, executive officers and certain other employees. These agreements, among other things, will require us to indemnify each individual to the fullest extent permitted by Delaware law, including indemnification of expenses such as attorneys' fees, judgments, fines and settlement amounts incurred by the individual in any action or proceeding, including any action or proceeding by or in right of us, arising out of the person's services as a director, officer or other employee. For additional information, see "Management — Limitation of Liability and Indemnification Matters."

## **Policies and Procedures for Related Party Transactions**

Our board of directors has adopted a written related person transaction policy, to be effective upon the consummation of this offering, setting forth the policies and procedures for the review and approval or ratification of related person transactions. This policy will cover, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we were or are to be a participant, where the amount involved exceeds \$120,000 and a related person had or will have a direct or indirect material interest, including, without limitation, purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness and employment by us of a related person. As provided by our audit committee charter to be effective upon completion of this offering, our audit committee will be responsible for reviewing and approving any related person transaction and in doing so will consider all relevant facts and circumstances, including, but not limited to, whether the transaction is on terms comparable to those that could be obtained in an arm's length transaction and the extent of the related person's interest in the transaction. All of the transactions described in this section occurred prior to the adoption of this policy.

## PRINCIPAL STOCKHOLDERS

The following table sets forth information relating to the beneficial ownership of our common stock as of August 31, 2014, 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 Securities and Exchange Commission, or 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 August 31, 2014 through the exercise of any stock option, warrants 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.

The percentage of shares beneficially owned is computed on the basis of 42,934,776 shares of our common stock outstanding as of August 31, 2014, which reflects the assumed conversion of all of our outstanding shares of preferred stock into an aggregate of 35,225,839 shares of common stock. Shares of our common stock that a person has the right to acquire within 60 days of August 31, 2014 are deemed outstanding for purposes of computing the percentage ownership of the person holding such rights, but are not deemed outstanding for purposes of computing the percentage ownership of any other person, except with respect to the percentage ownership of all directors and executive officers as a group. 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.

Beneficial Ownershin

	Beneficial Ownership Prior to this Offering			Beneficial Ownership After this Offering		
Name and Address of Beneficial Owner	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
5% and Greater Stockholders		<u>`</u>		<b>_</b>		
Daiichi Sankyo Company, Limited <sup>(1)</sup>	4,780,000		4,780,000	11.13%		
Lilly Ventures Fund I, LLC <sup>(2)</sup>	4,796,055		4,796,055	11.17%		
Entities affiliated with MX II Associates, LLC <sup>(3)</sup>	3,989,788	179,250	4,169,038	9.67%		
KKR Biosimilar L.P. <sup>(4)</sup>	4,166,666		4,166,666	9.70%		
Sofinnova Venture Partners VII, L.P. <sup>(5)</sup>	3,553,766		3,553,766	8.28%		
Entities affiliated with Venrock Associates VI, L.P. <sup>(6)</sup>	3,286,516		3,286,516	7.65%		
Named Executive Officers and Directors						
Douglas H. Farrar <sup>(7)</sup>	1,648,405	256,796	1,905,201	4.41%		
Barbara K. Finck, M.D. <sup>(8)</sup>	44,662	160,499	205,161	*		
Stephen C. Glover <sup>(9)</sup>	1,331,878	130,154	1,462,032	3.39%		
James I. Healy, M.D., Ph.D. <sup>(10)</sup>	3,553,846	8,333	3,562,179	8.30%		
Alan C. Herman, Ph.D. <sup>(11)</sup>	500,376	621,857	1,122,233	2.58%		
Dennis M. Lanfear <sup>(12)</sup>	2,491,156	946,452	3,437,608	7.83%		
V. Bryan Lawlis, Ph.D. <sup>(13)</sup>	—	15,625	15,625	*		
Christos Richards <sup>(14)</sup>	91,453	113,650	205,103	*		
Ali J. Satvat <sup>(15)</sup>	4,166,666	—	4,166,666	9.70%		
Mary T. Szela <sup>(16)</sup>	—	2,083	2,083	*		
S. Edward Torres <sup>(17)</sup>	4,796,055	50,000	4,846,055	11.27%		
August J. Troendle, M.D. <sup>(18)</sup>	4,026,246	186,542	4,212,788	9.77%		
Mats Wahlström <sup>(19)</sup>	1,450,235	89,061	1,539,296	3.58%		
Peter K. Watler, Ph.D. <sup>(20)</sup>	—	181,013	181,013	*		
All directors and executive officers as a group (16 persons) <sup>(21)</sup>	24,148,309	3,682,534	27,830,843	59.70%		

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

(1) 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.

<sup>(2)</sup> 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

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with respect to shares owned by Lilly Ventures Fund I, LLC. Mr. Torres is a non-managing member of Lilly Ventures Fund I LLC and has shared voting and shared investment power over such shares, and may be deemed the indirect beneficial owner of such shares. Mr. Torres disclaims beneficial ownership over such shares, except to the extent of any pecuniary interest therein. The address of Lilly Ventures Fund I, LLC is 115 West Washington Street, Suite 1680 — South, Indianapolis, IN 46204.

- (3) Includes (i) 597,500 shares held prior to this offering by Medpace Investors, LLC, or Medpace Investors, (ii) 3,392,288 shares held prior to this offering by MX II Associates LLC, or MX II Associates, and (iii) 179,250 shares that may be acquired pursuant to the exercise of a warrant held by MX II Associates prior to this offering. 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.
- (4) 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 Fund Holdings GP Limited, KKR Group Holdings 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.
- <sup>(5)</sup> 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.
- <sup>(6)</sup> Consists of (i) 2,274,592 shares held prior to this offering by Venrock Associates VI, L.P., or VA VI, (ii) 178,591 shares held prior to this offering by Venrock Partners VI, L.P., or VP VI, (iii) 704,467 shares held prior to this offering by Venrock Healthcare Capital Partners, L.P., or VHCP, and (iv) 128,866 shares held prior to this offering 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 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.
- <sup>(7)</sup> Consists of (i) 1,648,405 shares held prior to this offering, (ii) 20,952 shares that may be acquired pursuant to the exercise of warrants and (iii) 235,844 shares that may be acquired pursuant to the exercise of stock options within 60 days of August 31, 2014 by Mr. Farrar.
- (8) Consists of (i) 44,662 shares held prior to this offering and (ii) 160,499 shares that may be acquired pursuant to the exercise of stock options within 60 days of August 31, 2014 by Dr. Finck.
- <sup>(9)</sup> Consists of (i) 1,331,878 shares held prior to this offering, (ii) 37,602 shares that may be acquired pursuant to the exercise of warrants and (iii) 92,552 shares that may be acquired pursuant to the exercise of stock options within 60 days of August 31, 2014 by Mr. Glover.
- (10) 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) 80 shares held prior to this offering and (ii) 8,333 shares that may be acquired pursuant to the exercise of stock options within 60 days of August 31, 2014.

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- <sup>(11)</sup> Consists of (i) 500,376 shares held prior to this offering by Alan C. Herman, Ph.D. and Margaret R. Herman, Trustees of the Herman Trust dated March 16, 2001, (ii) 402,509 shares that may be acquired pursuant to the exercise of warrants held prior to this offering and (iii) 219,348 shares that may be acquired pursuant to the exercise of stock options within 60 days of August 31, 2014 by Dr. Herman.
- (12) Consists of (i) 2,270,324 shares held prior to this offering by Dennis M. Lanfear, as Trustee of the Lanfear Revocable Trust, dated January 27, 2004, as restated, (ii) 111,644 shares held prior to this offering by Lanfear Capital Advisors, LLC, (iii) 109,188 shares held prior to this offering by Dennis M. Lanfear, (iv) 33,300 shares that may be acquired pursuant to the exercise of a warrant held prior to this offering by Lanfear Capital Advisors, LLC, (v) 5,377 shares that may be acquired pursuant to the exercise of a warrant by Mr. Lanfear and (vi) 907,775 shares that may be acquired pursuant to the exercise of stock options within 60 days of August 31, 2014 by Mr. Lanfear.
- <sup>(13)</sup> Consists of 15,625 shares that may be acquired pursuant to the exercise of stock options within 60 days of August 31, 2014 by Dr. Lawlis.
- <sup>(14)</sup> Consists of (i) 91,453 shares held prior to this offering, (ii) 44,900 shares that may be acquired pursuant to the exercise of warrants and (iii) 68,750 shares that may be acquired pursuant to the exercise of stock options within 60 days of August 31, 2014 by Mr. Richards.
- <sup>(15)</sup> 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.
- (16) Consists of 2,083 shares that may be acquired pursuant to the exercise of stock options within 60 days of August 31, 2014 by Ms. Szela.
- Consists of the shares held by Lilly Ventures Fund I, LLC. Mr. Torres disclaims beneficial ownership of the shares held by Lilly Ventures Fund I, LLC, except to the extent of his pecuniary interest therein. Also includes 50,000 shares that may be acquired pursuant to the exercise of stock options within 60 days of August 31, 2014 by Mr. Torres. Mr. Torres resigned from our board of directors effective May 29, 2014.
- (18) Consists of the shares described in Note (3) above. Dr. Troendle disclaims beneficial ownership of the shares held by Medpace Investors, LLC and MX II Associates, LLC as described in Note (3) above, except to the extent of his pecuniary interest therein. Also includes 7,292 shares that may be acquired pursuant to the exercise of stock options within 60 days of August 31, 2014 by Dr. Troendle.
- (19) Consists of the shares held by Caduceus Medical Holdings, LLC, KMG Capital Partners, LLC and Leonard Capital, LLC. Mr. Wahlström disclaims beneficial ownership of the shares held by Caduceus Medical Holdings, LLC, KMG Capital Partners, LLC and Leonard Capital, LLC, except to the extent of his pecuniary interest therein. Also includes 89,061 shares that may be acquired pursuant to the exercise of stock options within 60 days of August 31, 2014 by Mr. Wahlström.
- <sup>(20)</sup> Consists of 181,013 shares that may be acquired pursuant to the exercise of stock options within 60 days of August 31, 2014 by Dr. Watler.
- <sup>(21)</sup> Includes (i) 17,956,510 shares held by entities affiliated with certain of our directors and (ii) 24,148,309 shares beneficially owned by our executive officers and directors, which includes the 17,956,510 shares held by such entities and 3,682,534 shares that may be acquired pursuant to the exercise of stock options and warrants within 60 days of August 31, 2014.

## 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, which will become effective immediately prior to the consummation of this offering, 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 have been filed as exhibits to the registration statement of which this prospectus is part.

#### General

Immediately prior to the consummation of this offering, we will file our amended and restated certificate of incorporation that authorizes shares of common stock, \$0.0001 par value per share, and shares of preferred stock, \$0.0001 par value per share. As of June 30, 2014, there were outstanding:

- 42,934,776 shares of our common stock, on an as converted basis, held by approximately 86 stockholders of record;
- 1,234,017 shares of our common stock issuable upon cash exercise of outstanding warrants; and
- 9,251,560 shares of our common stock issuable upon cash exercise of outstanding stock options.

## **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.

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## **Preferred Stock**

Immediately prior to the consummation of this offering, all outstanding shares of our preferred stock will be converted into shares of our common stock. See Note in the notes to our consolidated audited financial statements included elsewhere in this prospectus for a description of our currently outstanding preferred stock. Immediately prior to the consummation of this offering, our amended and restated certificate of incorporation will be amended and restated to delete all references to such shares of preferred stock. Upon the consummation of this offering, our board of directors will have the authority, without further action by our stockholders, to issue up to 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. Immediately after consummation of this offering, no shares of preferred stock will be outstanding, and we have no present plan to issue any shares of preferred stock.

#### Warrants

The following table sets forth information about outstanding warrants to purchase shares of our stock as of June 30, 2014. Immediately prior to the consummation of this offering, the warrants to purchase shares of our preferred stock will convert into warrants to purchase our common stock based on the conversion ratio of the preferred stock.

Class of Stock Underlying Warrants Common stock, par value \$0.0001 <sup>(1)</sup>	Number of Shares Exercisable Prior to This Offering	Number of Shares of Common Stock Exercisable Following this Offering	Exercise Price Per <u>Share(\$)</u> \$ 1.00	Expiration Dates 3/28/2024
-	922,309	—	\$ 1.00	5/20/2024
Series A convertible preferred stock, par value \$0.0001 <sup>(1)</sup>	106,560	—	\$ 0.75	1/26/2016
Series B convertible preferred stock, par value \$0.0001 <sup>(1)</sup>	205,148	_	\$ 0.01	7/21/2018 and 11/29/2018
Total	1,234,017			

(1) In connection with our initial public offering, these warrants will net exercise into shares of common stock if not otherwise exercised prior to the consummation of this offering.

## **Registration Rights**

Under our third amended and restated investor rights agreement, following the closing of this offering, the holders of approximately 42.9 million shares of common stock, including shares issuable upon exercise of warrants, or their transferees, have the right to require us to register their shares under the Securities Act of 1933, as amended, or 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 June 30, 2014, after the consummation of this offering, the holders of approximately 42.9 million shares of our common stock, including shares issuable upon exercise of warrants, or their transferees, will be entitled to certain demand registration rights. Beginning 180 days following the effectiveness of the registration statement of which this prospectus is a part, 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 June 30, 2014, after the consummation of this offering, the holders of approximately 42.9 million shares of our common stock, including shares issuable upon exercise of warrants, or their transferees, will be entitled to certain Form S-3 registration rights. Following the effectiveness of the registration statement of which this prospectus is a part, 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 June 30, 2014, after the consummation of this offering, 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 42.9 million shares of our common stock, including shares issuable upon exercise of warrants, or their transferees, will be 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 this offering or when that stockholder can sell all of its shares under Rule 144 of the Securities Act.

### 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 that will be in effect immediately prior to the consummation of this offering

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contain provisions that 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.

#### **Undesignated Preferred Stock**

The ability to authorize undesignated preferred stock makes it possible for our board of directors to issue "blank check" 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 the 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). For more information on the classified board, see "Management — Board Composition." 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 will provide 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 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

For a discussion of liability and indemnification, please see "Management—Limitation on Liability and Indemnification Matters."

## NASDAQ Listing

We intend to apply for the listing of our common stock on The NASDAQ Global Market under the symbol "CHRS."

## **Transfer Agent and Registrar**

Upon the completion of this offering, the transfer agent and registrar for our common stock will be . The transfer agent and registrar's address is

### SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our common stock. Future sales of our common stock, including shares issued upon the exercise of outstanding options or warrants, 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 June 30, 2014, upon the closing of this offering and assuming (1) the conversion of our outstanding preferred stock into common stock, assuming an initial public offering price of \$ per share (the mid-point of the price range set forth on the cover page of this prospectus), (2) no exercise of the underwriters' option to purchase additional shares of common stock to cover over-allotments and (3) no exercise of outstanding options or warrants, we will have outstanding an aggregate of approximately shares of common stock. Of these shares, all of the shares of common stock to be sold in this offering and any shares sold upon exercise of the underwriters' option to purchase additional shares to cover over-allotments will be freely tradable in the public market without restriction or further registration under the Securities Act of 1933, as amended, or the Securities Act, unless the shares are held by any of our "affiliates" as such term is defined in Rule 144 of the 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.

As a result of the lock-up agreements referred to below and the provisions of Rule 144 and Rule 701 under the Securities Act, based on the number of shares of our common stock outstanding as of June 30, 2014, the shares of our common stock (excluding the shares sold in this offering) that will be available for sale in the public market are as follows:

Approximate Number of Shares

shares

#### First Date Available for Sale into Public Market

180 days after the date of this prospectus, or longer if the lock-up period is extended, upon expiration of the lock-up agreements referred to below, subject in some cases to applicable volume limitations under Rule 144

### Lock-Up Agreements

In connection with this offering, we, our directors, our executive officers and holders of substantially all of our other outstanding shares of common stock or securities convertible into or exchangeable for shares of our 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 lockup agreement continuing through the date 180 days after the date of this prospectus, except with the prior written consent of J.P. Morgan Securities LLC and Credit Suisse Securities (USA) LLC.

Prior to the completion of the offering, certain of our employees, including our executive officers, and/or directors may enter into written trading plans that are intended to comply with Rule 10b5-1 under the Exchange Act. Sales under these trading plans would not be permitted until the expiration of the lock-up agreements relating to the offering described above.

Following the lock-up periods set forth in the agreements described above, and assuming that the representatives of the underwriters do not release any parties from these agreements and that there is no extension of the lock-up period, all of the shares of our common stock that are restricted securities or are held by our affiliates as of the date of this prospectus will be eligible for sale in the public market in compliance with Rule 144 under the Securities Act.

## Rule 144

In general, under Rule 144, as currently in effect, once we have been subject to the public company reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, for at least 90 days, 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 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) to the lock-up agreement referred to above, if applicable, and the 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 June 30, 2014 on the basis of the assumptions described above and assuming no exercise of the underwriter's option to purchase additional shares and no exercise of outstanding options or warrants); or
- the average weekly trading volume of our common stock on The NASDAQ Global Market, or NASDAQ, 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 the registration statement of which this prospectus is a part (to the extent such common stock is not subject to a lock-up agreement) is entitled to rely on Rule 701 to resell such shares beginning 90 days after we become subject to the public company reporting requirements of the Exchange Act in reliance on Rule 144, but without compliance with the holding period requirements contained in Rule 144. Accordingly, subject to any applicable lock-up agreements, beginning 90 days after we become subject to the public company reporting requirements of the Exchange Act, under Rule 701 persons who are not our "affiliates," as defined in Rule 144, may resell those shares without complying with the minimum holding period requirements of Rule 144, and persons who are our "affiliates" may resell those shares without compliance with Rule 144's minimum holding period requirements (subject to the terms of the lock-up agreement referred to below, if applicable).

## **Registration Rights**

Based on the number of shares outstanding as of June 30, 2014, after the consummation of this offering, the holders of approximately 42.9 million shares of our common stock, including shares issuable upon exercise of warrants, or their transferees, will, subject to any lock-up agreements they have entered into, be 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.

#### **Equity Incentive Plans**

We intend to file with the SEC a registration statement under the Securities Act covering the shares of common stock that we may issue upon exercise of outstanding options reserved for issuance under our 2010 Equity Incentive Plan, as amended, our 2014 Equity Incentive Award Plan and our 2014 Employee Stock Purchase Plan. Such registration statement is expected to be filed and become effective as soon as practicable after the consummation of this offering. Accordingly, shares registered under such registration statement will be available for sale in the open market following its effective date, 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 that 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 of our common stock 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);

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- 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 U.S. 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. 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 agent receives the certification described above or the holder otherwise establishes an exemption. Proceeds of a disposition of our common stock conducted through 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.

Backup withholding is not an additional tax. Any amounts withhold 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:

Name	Number of Shares
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 initial 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 initial 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 over-allotment option. If any shares are purchased with this over-allotment 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.

	Without Over-allotment Exercise	With Over-allotment Exercise
	Exercise	Exercise
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 \$ .

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.

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

## **Index to Financial Statements**

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 180 days after the date of this prospectus, other than the shares of our common stock to be sold hereunder and any shares of our common stock issued upon the exercise of options granted under our existing plans.

Our directors and executive officers and substantially all of our equity holders 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 180 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 directors and executive officers or other employees from entering into 10b5-1 trading plans provided that (1) any shares that may be sold under such plans will be subject to the restrictions described above and (2) 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.

We intend to apply to have our common stock approved for listing/quotation 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' over-allotment 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 over-allotment 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 over-allotment 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.

Prior to this offering, there has been no public market for our common stock. The initial public offering price will be determined by negotiations between us and the representatives of the underwriters. In determining the initial public offering price, we and the representatives of the underwriters expect to consider a number of factors including:

- the information set forth in this prospectus and otherwise available to the representatives;
- our prospects and the history and prospects for the industry in which we compete;
- an assessment of our management;
- our prospects for future earnings;
- the general condition of the securities markets at the time of this offering;
- the recent market prices of, and demand for, publicly traded common stock of generally comparable companies; and
- other factors deemed relevant by the underwriters and us.

Neither we nor the underwriters can assure investors that an active trading market will develop for our common shares, or that the shares will trade in the public market at or above the initial public offering price.

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(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 beneficiaries 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. Certain legal matters in connection with this offering will be passed upon for the underwriters by Davis Polk & Wardwell LLP, Menlo Park, California. Latham & Watkins LLP and certain attorneys and investment funds affiliated with the firm collectively own shares of our Series B and Series C convertible preferred stock which will be converted into an aggregate of 8,551 shares of common stock immediately prior to the completion of this offering.

### EXPERTS

Ernst & Young LLP, independent registered public accounting firm, has audited our consolidated financial statements at December 31, 2013 and 2012, and for each of the two years in the period ended December 31, 2013, as set forth in their report. We have included our financial statements in this 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 Securities and Exchange Commission, or SEC, a registration statement on Form S-1 under the Securities Act of 1933, as amended, or 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. 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. 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 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.

Upon consummation of this offering, we will become subject to the information and periodic reporting requirements of the Exchange Act and, in accordance therewith, will file periodic reports, proxy statements and other information with the SEC. Such periodic reports, proxy statements and other information will be 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. Upon consummation of this offering, you may access our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the 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.

## **Coherus BioSciences, Inc.**

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#### **Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders Coherus BioSciences, Inc.

We have audited the accompanying consolidated balance sheets of Coherus BioSciences, Inc. as of December 31, 2012 and 2013, and the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders' deficit, and cash flows for each of the two years in the period ended December 31, 2013. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Coherus BioSciences, Inc. at December 31, 2012 and 2013, and the consolidated results of its operations and its cash flows for each of the two years in the period ended December 31, 2013, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

Redwood City, California August 4, 2014

### Coherus BioSciences, Inc.

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

		mber 31,
Assets	2012	2013
Current assets:		
Cash	\$ 14,548	\$ 39,554
Restricted cash	50	50
Receivables from related parties	158	278
Notes receivable from related parties	_	107
Prepaid assets	9,983	5,688
Other current assets	60	
Total current assets	24,799	45,677
Property and equipment, net	1,605	1,743
Notes receivable from related parties — non-current	123	_
Other assets	6	27
Total assets	\$ 26,533	\$ 47,447
Liabilities, Convertible Preferred Stock and Stockholders' Deficit	<u> </u>	<u> </u>
Current liabilities:		
Accounts payable	\$ 2,209	\$ 3,302
Accounts payable — related parties	1,693	383
Accrued and other liabilities	3,588	7,279
Deferred revenue	2,025	14,283
Convertible notes		14,205
Convertible notes — related parties		3,092
Convertible preferred stock warrant liability	1,738	24,251
Total current liabilities	11,253	53,701
Deferred revenue — non-current	6,076	28,567
Contingent liability to collaborator	0,070	7,500
Other liabilities — non-current	12	61
Total liabilities	17,341	89,829
Commitments and contingencies (Note 6)		
Series A convertible preferred stock, \$0.0001 par value: Shares authorized: 1,800,000 at December 31, 2012 and 2013		
Shares issued and outstanding: 1,620,888 at December 31, 2012 and 2013	1,191	1,191
Liquidation preference: \$1,216 at December 31, 2012 and 2013 Series B convertible preferred stock, \$0.0001 par value:	1,191	1,191
Shares authorized: 14,692,297 and 26,290,997 at December 31, 2012 and 2013, respectively		
Shares issued and outstanding: 13,638,707 at December 31, 2012 and 2013		
	53,504	53,504
Liquidation preference: \$57,066 at December 31, 2012 and 2013 Stockholders' deficit:	55,504	55,504
Common stock, \$0.0001 par value: Shares authorized: 35,000,000 and 46,598,700 at December 31, 2012 and 2013, respectively		
Shares issued and outstanding: 8,059,063 and 8,064,479 at December 31, 2012 and 2013, respectively	1	1
Additional paid-in capital	453	2,514
Accumulated deficit	(45,957)	(99,592)
Total stockholders' deficit		
	(45,503)	(97,077)
Total liabilities, convertible preferred stock and stockholders' deficit	\$ 26,533	\$ 47,447

See accompanying notes to consolidated financial statements.

### **Coherus BioSciences, Inc.**

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

	Year Ended December 31,	
	2012	2013
Revenue:		
Collaboration and license revenue — related party	\$ 1,899	\$ 2,025
Collaboration and license revenue		726
Total revenue	1,899	2,751
Operating expenses:		
Research and development (includes related party of \$16,777 and \$9,471 for the years ended December 31,		
2012 and 2013, respectively)	34,886	31,279
General and administrative	5,531	7,465
Total operating expenses	40,417	38,744
Loss from operations	(38,518)	(35,993)
Interest expense (includes related party of \$1,059 and \$4,026 for the years ended December 31, 2012 and 2013,		
respectively)	(1,514)	(5,293)
Other income (expense), net	7,014	(12,349)
Net loss and comprehensive loss	\$ (33,018)	\$ (53,635)
Net loss per share, basic and diluted	\$ (9.51)	\$ (9.66)
Weighted-average number of shares used in computing net loss per share, basic and diluted	3,471,731	5,554,477
Pro forma net loss per share, basic and diluted (unaudited)		\$ (1.68)
Weighted-average number of shares used in computing pro forma net loss per share, basic and diluted (unaudited)		24,488,112

See accompanying notes to consolidated financial statements.

### **Coherus BioSciences, Inc.**

# Consolidated Statements of Convertible Preferred Stock and Stockholders' Deficit

(in thousands, except share and per share data)

	Series Convert Preferred	ible	Series Convert Preferred	ible	Common	Stock	Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Shares			Capital Deficit	
Balances at December 31, 2011	1,620,888	\$1,191		\$ —	8,500,000	<b>\$</b> 1	\$ 5,658	\$ (7,966)	\$ (2,307)
Beneficial conversion feature related to 2011 Notes		_					(5,658)	(4,973)	(10,631)
Issuance of Series B convertible preferred stock							(0,000)	(,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	(,)
at \$4.1841 per share net of issuance costs of									
\$3,562			7,289,500	26,938			_		
Issuance of Series B convertible preferred stock			, ,	,					
at \$4.1841 per share upon conversion of									
convertible promissory notes		_	2,540,742	10,631		_	_	_	_
Issuance of Series B convertible preferred stock				-					
at \$4.1841 per share in exchange for services			3,712,865	15,535			_		
Issuance of Series B convertible preferred stock									
upon exercise of warrants, including the									
reclassification of the associated convertible									
preferred stock warrant liability			95,600	400		_	_	_	_
Issuance of common stock upon exercise of									
options for cash	_	_	_	_	37,188	_	_	_	
Repurchase of unvested founders shares	_		_	—	(478,125)	_	_	_	
Vesting of restricted common stock issued to									
founders		_	—	—			10		10
Stock-based compensation expense				—			443		443
Net loss			—	—			—	(33,018)	(33,018)
Balances at December 31, 2012	1,620,888	1,191	13,638,707	53,504	8,059,063	1	453	(45,957)	(45,503)
Issuance of common stock upon exercise of									
options for cash	_	_	_	_	5,416	_	6	_	6
Vesting of restricted common stock issued to									
founders		_	_	—		_	10		10
Stock-based compensation expense	_		_			_	2,045		2,045
Net loss		_						(53,635)	(53,635)
Balances at December 31, 2013	1,620,888	\$1,191	13,638,707	\$53,504	8,064,479	<b>\$</b> 1	\$ 2,514	\$ (99,592)	\$ (97,077)

See accompanying notes to consolidated financial statements.

# Coherus BioSciences, Inc.

# **Consolidated Statements of Cash Flows**

# (in thousands)

	Year I Decem	
	2012	2013
Operating activities Net loss	¢(22.010)	¢(E2 62E)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:	\$(33,018)	\$(53,635)
Depreciation and amortization	221	404
Remeasurement of convertible preferred stock warrant and embedded derivative liabilities	(639)	4,557
Fair value of warrants in excess of debt proceeds recognized at issuance	(055)	3,669
Fair value of embedded derivative in excess of debt proceeds recognized at issuance		4,096
Preferred stock issued in exchange for services	7,956	7,579
Gain on extinguishment of 2011 Notes	(6,369)	
Noncash interest expense	1,514	5,293
Stock-based compensation expense	443	2,045
Changes in operating assets and liabilities:		2,045
Notes receivable from related parties	(5)	16
Receivables from related parties	(158)	(120)
Prepaid assets	(1,999)	(3,284)
Other current assets	(1,555)	60
Other assets	207	(21)
Accounts payable	1,685	924
Accounts payable — related parties	1,693	(1,310)
Accrued and other liabilities	2,176	2,845
Deferred revenue	8,101	34,749
Contingent liability to collaborator		7,500
Other liabilities — non-current	(9)	56
Net cash (used in) provided by operating activities	(18,251)	15,423
Investing activities	(10,201)	10,420
Purchases of property and equipment	(1,783)	(373)
Increase in restricted cash	(40)	(3/3)
Net cash used in investing activities	(1,823)	(373)
Financing activities	(1,023)	(373)
Proceeds from issuances of Series B convertible preferred stock, net of issuance costs	26,938	_
Proceeds from issuances of series D convertible preferred stock, net of issuance costs	20,550	2,900
Proceeds from issuance of convertible notes — related parties	_	7,050
Proceeds from issuance of common stock upon exercise of stock options		6
Net cash provided by financing activities	26,938	9,956
Net increase in cash	6,864	25,006
Cash at beginning of year	7,684	14,548
Cash at end of year	\$ 14,548	\$ 39,554
Supplemental disclosures of cash flow information		
Noncash investing and financing activities		
Conversion of 2011 Notes and accrued interest into Series B convertible preferred stock	\$ 10,631	<u>\$                                    </u>
Reaquisition of beneficial conversion feature as a result of the conversion of 2011 Notes	\$ 10,631	\$ —
Issuance of Series B convertible preferred stock in consideration for prepaid services	\$ 15,535	\$
Vesting of restricted common stock	<u>\$ 10</u>	\$ 10
Reclassification of fair value of convertible preferred stock warrants to Series B preferred stock upon exercise	\$ 400	<u>\$                                    </u>
Purchase of equipment in accounts payable	\$ —	\$ 169

See accompanying notes to consolidated financial statements.

### Coherus BioSciences, Inc.

#### **Notes to Consolidated Financial Statements**

#### 1. Organization and Operations

#### **Description of the Business**

Coherus BioSciences, Inc. (the "Company" or "Coherus") was incorporated in the state of Delaware as BioGenerics, Inc. in September 2010 and changed its name to Coherus BioSciences, Inc. in April 2012. The Company is a late-stage clinical biologics platform company focused on the global biosimilar market. The Company's headquarters and laboratory are located in Redwood City, California and in Camarillo, California, respectively. The Company operates in one segment.

#### Need to Raise Additional Capital

The Company has incurred net operating losses since its inception and expects to continue to incur losses in the foreseeable future as the Company continues its research and development activities. As of December 31, 2013, the Company had cash of \$39.6 million and an accumulated deficit of \$99.6 million. The Company believes that its cash at December 31, 2013, together with the net cash proceeds of \$54.7 million received from its sale of Series C convertible preferred stock in May 2014 (see Note 14), and the funding it expects to receive under the license agreements with Daiichi Sankyo Company, Limited ("Daiichi Sankyo") and Baxter International, Inc. ("Baxter") (see Note 5), will be sufficient to fund planned expenditures and meet the Company's obligations through at least December 31, 2014. Since inception, the Company has funded its operations primarily through private placements of its convertible preferred stock, debt financings and license payments and, at times, has paid its vendors using its equity securities. The Company will need to raise additional funds in the future, however, there can be no assurance that such efforts will be successful or that, in the event that they are successful, the terms and conditions of such financing will be favorable. Any failure to obtain additional financing may have a material adverse effect upon the Company and could result in a substantial reduction in the scope of the Company's operations. If the Company is unable to raise additional funding to meet its working capital needs, it may be forced to delay or significantly reduce the scope of its research and development programs.

#### 2. Summary of Significant Accounting Policies

#### **Basis of Consolidation**

The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP"). The accompanying consolidated financial statements include the accounts of Coherus and its wholly owned subsidiaries as of December 31, 2013, Coherus Acquisition Corp. and Coherus Intermediate Corp. Unless otherwise specified, references to the Company are references to Coherus and its consolidated subsidiaries. All intercompany transactions and balances have been eliminated upon consolidation.

#### **Use of Estimates**

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. The Company bases its estimates on historical experience and other market-specific or other relevant assumptions that it believes are reasonable under the circumstances. The amounts of assets and liabilities reported in the Company's consolidated balance sheets and the amount of expenses and income reported for each of the periods presented are affected by estimates and assumptions, which are used for, but are not limited to, revenue recognition, determination of fair-value of common stock, convertible preferred stock

### **Coherus BioSciences, Inc.**

#### Notes to Consolidated Financial Statements (continued)

#### 2. Summary of Significant Accounting Policies (continued)

warrant liabilities, embedded derivative instruments, accounting for stock-based compensation, determining accruals for research and development costs and valuation of deferred tax assets. Actual results could differ from such estimates or assumptions.

#### **Concentration of Credit Risk**

The Company's financial instruments that are exposed to concentration of credit risk consist primarily of cash and cash equivalents. The Company maintains its cash in bank accounts which at times exceed federally insured limits. The Company also maintains restricted cash in money market funds that invest primarily in U.S. Treasury securities. The Company has not recognized any losses from credit risks on such accounts during any of the periods presented. The Company believes it is not exposed to significant credit risk on its cash and money market funds.

### **Customer Concentration**

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

	Year En Decembe	
	2012	2013
Daiichi Sankyo — related party	100%	74%
Baxter	—	26%

#### **Restricted Cash**

Restricted cash consists of cash held in a money market account with a bank, and which is collateral against the Company's corporate credit cards.

#### Fair Value of Financial Instruments

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

### **Property and Equipment**

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

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

#### **Impairment of Long Lived Assets**

The Company reviews long-lived assets, including property and equipment, for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be fully recoverable. An impairment loss would be recognized when the estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition is less than its carrying amount. Impairment, if any, is

### **Coherus BioSciences, Inc.**

#### Notes to Consolidated Financial Statements (continued)

#### 2. Summary of Significant Accounting Policies (continued)

measured as the amount by which the carrying amount of a long-lived asset exceeds its fair value. As of December 31, 2012 and 2013, there have been no such impairments.

#### **Convertible Preferred Stock**

The Company records all shares of convertible preferred stock at their respective fair values on the dates of issuance. In the event of a change of control of the Company, proceeds received from the sale of such shares will be distributed in accordance with the liquidation preferences set forth in the Company's Amended and Restated Certificate of Incorporation unless the holders of convertible preferred stock have converted their shares of convertible preferred stock into shares of common stock. Therefore, convertible preferred stock is classified outside of stockholders' deficit on the consolidated balance sheets as events triggering the liquidation preferences are not solely within the Company's control. The Company has elected not to adjust the carrying values of the convertible preferred stock to the liquidation preferences of such shares because of the uncertainty of whether or when such an event would occur.

#### **Convertible Preferred Stock Warrant Liability**

The Company classifies warrants exercisable for shares of the Company's Series A and Series B convertible preferred stock as derivative liabilities and adjusts their carrying value to fair value at the end of each reporting period. At the end of each reporting period, changes in the fair value of the convertible preferred stock warrant liability during the period are recorded as a component of other income (expense), net, in the consolidated statements of operations and comprehensive loss. The Company will continue to adjust the liability for changes in fair value until the earlier of the exercise or expiration of the warrants, at which time the liability would be reclassified to preferred stock.

#### **Embedded Derivative Liability**

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

#### **Accrued Research and Development Expenses**

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

#### **Revenue Recognition**

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

### **Coherus BioSciences, Inc.**

#### Notes to Consolidated Financial Statements (continued)

#### 2. Summary of Significant Accounting Policies (continued)

The Company enters into collaboration and license agreements for the development and commercialization of biosimilar products. The Company's performance obligations under the terms of these agreements may include (i) transfer of intellectual property rights (licenses), (ii) providing research and development services, (iii) the manufacture of drug materials for development purposes and (iv) participation on certain committees with the collaborators. Payments to the Company under these agreements may include nonrefundable upfront license fees, payments for research and development services, payments for the manufacture of drug materials, payments based upon the achievement of defined collaboration objectives and royalties on product sales. Under these agreements the Company may convey the right to sell products resulting from the collaborative efforts of the parties in specific geographic territories.

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

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

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

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

### Coherus BioSciences, Inc.

#### Notes to Consolidated Financial Statements (continued)

#### 2. Summary of Significant Accounting Policies (continued)

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

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

#### **Research and Development Expenses**

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

#### **Stock-Based Compensation**

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

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

The Company utilizes the Black-Scholes option-pricing model for estimating fair value of its stock options and restricted stock granted. Option valuation models, including the Black-Scholes option-pricing model, require

### **Coherus BioSciences, Inc.**

#### Notes to Consolidated Financial Statements (continued)

#### 2. Summary of Significant Accounting Policies (continued)

the input of highly subjective assumptions, and changes in the assumptions used can materially affect the grant-date fair value of an award. These assumptions include the risk-free rate of interest, expected dividend yield, expected volatility, the expected life of the award, and estimated forfeitures.

#### **Income Taxes**

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

The Company recognizes uncertain income tax positions at the largest amount that is more likely than not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained.

The Company's policy is to recognize interest and/or penalties related to income tax matters in income tax expense. The Company had accrued no amounts for interest and penalties in the Company's consolidated balance sheets at December 31, 2012 and 2013.

#### **Comprehensive Loss**

Comprehensive loss is comprised of two components: net loss and other comprehensive income (loss). Other comprehensive income (loss) refers to gains and losses that under U.S. GAAP are recorded as an element of stockholders' deficit, but are excluded from net loss. The Company did not record any transactions within other comprehensive income (loss) in the periods presented and, therefore, the net loss and comprehensive loss were the same for all periods presented.

#### Net Loss per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of shares of common stock outstanding for the period, without consideration for potential dilutive common shares. Since the Company was in a loss position for all periods presented, basic net loss per share is the same as diluted net loss per share as the inclusion of all potential dilutive common shares would have been anti-dilutive. Common shares subject to repurchase are excluded from the computation of weighted average shares as the continued vesting of such shares is contingent upon the holders' continued service to the Company. For the computation of net loss per share for the years ended 2012 and 2013, 3,585,685 and 1,272,470 shares subject to repurchase, respectively, were excluded from the computation of net loss per share, basic and diluted.

#### Unaudited Pro Forma Net Loss per Share

Unaudited pro forma basic and diluted net loss per share has been computed to give effect to the assumed conversion of all outstanding shares of the Company's convertible preferred stock and the cash exercise of the convertible preferred stock warrants upon the closing of the initial public offering ("IPO") as such warrants, if not exercised, will automatically be net exercised prior to the IPO. Also, the numerator in the pro forma basic and diluted net loss per share calculation has been adjusted to remove gains or losses resulting from the remeasurement of the convertible preferred stock warrant liability. The pro forma net loss per share does not include the shares expected to be sold and related proceeds to be received from the IPO. For purposes of pro

### **Coherus BioSciences, Inc.**

#### Notes to Consolidated Financial Statements (continued)

#### 2. Summary of Significant Accounting Policies (continued)

forma basic and diluted net loss per share, all shares of convertible preferred stock have been treated as though they had been converted to common stock on the earlier of January 1, 2013 or as of the date such shares were issued.

#### **Recent Accounting Pronouncements**

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2014-09, *Revenue from Contracts with Customers* ("ASU 2014-09"), which converges the FASB and the International Accounting Standards Board standards on revenue recognition. Areas of revenue recognition that will be affected include, but are not limited to, transfer of control, variable consideration, allocation of transfer pricing, licenses, time value of money, contract costs and disclosures. This guidance is effective for the fiscal years and interim reporting periods beginning after December 15, 2016, at which time the Company may adopt the new standard under the full retrospective method or the modified retrospective method. Early adoption is not permitted. The Company is currently evaluating the impact that the adoption of ASU 2014-09 will have on its consolidated financial statements and related disclosures.

In June 2014, the FASB issued ASU 2014-10, *Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation.* ASU 2014-10 simplifies the accounting guidance by removing all incremental financial reporting requirements for development stage entities. The amendments related to the elimination of the inception-to-date information and other disclosure requirement of Topic 915 should be applied retrospectively and are effective for annual reporting periods beginning after December 15, 2014 and interim periods therein. Early adoption is permitted. The Company early adopted ASU 2014-10 effective as of January 1, 2012. Adoption of this standard had no impact on the Company's financial position, results of operations or cash flows; however, the presentation of the financial statements has been changed to eliminate the disclosures that are no longer required.

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

#### 3. Fair Value Measurements

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

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

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

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

### **Coherus BioSciences, Inc.**

#### Notes to Consolidated Financial Statements (continued)

#### 3. Fair Value Measurements (continued)

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

In certain cases where there is limited activity or less transparency around inputs to valuation, securities are classified as Level 3. Level 3 liabilities consist of the convertible preferred stock warrant liability and embedded derivative instruments.

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

		Fair Value Measurements December 31, 2012		
	Total	Level 1	Level 2	Level 3
Assets:				
Restricted cash (money market funds)	<u>\$ 50</u>	\$ 50	\$	\$
Liabilities:				
Convertible preferred stock warrant liability	\$ 1,738	<u>\$                                    </u>	<u> </u>	\$ 1,738
			leasurements r 31, 2013	
	Total	Level 1	Level 2	Level 3
Assets:				
Restricted cash (money market funds)	<u>\$50</u>	\$ 50	\$	\$
Liabilities:				
Convertible preferred stock warrant liability	\$24,251	\$	<u>\$                                    </u>	\$24,251

There were no transfers between Level 1 and Level 2 during the periods presented.

The Company issued convertible notes in 2011 and 2013 (see Note 7). In connection with the convertible notes, the Company agreed to issue warrants to purchase shares of its preferred stock, the 2011 Warrants B and 2013 Warrants. The convertible notes also contained redemption features which were determined to be embedded derivatives requiring fair value accounting. The aggregate principal under the convertible notes issued in 2013 of \$10.0 million was less than the initial fair value of the warrants and embedded derivatives of \$13.6 million and \$4.1 million, respectively, therefore, the entire loan principal balance of \$10.0 million was offset by only a portion of the debt discount, as the debt could not be reduced to a carrying value amount which was less than zero. The difference of \$3.6 million and \$4.1 million associated with the convertible preferred stock warrant liability and embedded derivatives, respectively, was immediately charged to other income (expense), net, in the consolidated statements of operations and comprehensive loss (see Note 7 and Note 8 for further detail regarding the determination and valuation of the embedded derivatives and convertible preferred stock warrant liability, respectively).

### Coherus BioSciences, Inc.

#### Notes to Consolidated Financial Statements (continued)

#### 3. Fair Value Measurements (continued)

The fair values of the convertible preferred stock warrant liability and embedded derivatives were based on the following assumptions as of the issuance dates and as of December 31, 2013:

	July 2013 Issuance	August and September 2013 Issuance	December 31, 2013
Discount rate	30%	30%	30%
Weighted-average scenario probabilities:			
New equity financing	25%	65%	63%
New equity financing at lower valuation then previous financing	5%	5%	7%
Initial public offering	5%	5%	10%
Change of control	25%	5%	—
Maturity	40%	20%	20%

#### Preferred Stock Warrant Liability

The Company determined the fair value of the warrants issued by allocating the Company's equity value, using the Probability-Weighted Expected Return Method ("PWERM"). The Company's equity value was allocated among preferred stock, common stock, warrants and stock options expected to be outstanding at the liquidity events based on the rights and preferences of each class. The PWERM includes assumptions related to the fair value of the shares, the exercise price, expected volatility, expected term, risk-free interest rate and the expected dividend yield. The estimated expected volatility was based on the volatility of common stock of a group of comparable, publicly-traded companies. The estimated expected term was based on the estimated time to liquidity event. The risk-free interest rate was based on the U.S. Treasury yield for a term consistent with the estimated expected term. The significant unobservable input used in the fair value measurement of the convertible preferred stock warrant liability is the fair value of the underlying preferred stock at the valuation remeasurement date. Generally, increases (decreases) in the fair value of the underlying preferred stock would result in a directionally similar impact to the fair value measurement.

The following table sets forth a summary of the changes in the estimated fair value of the convertible preferred stock warrants (in thousands):

	Decen	nber 31,
	2012	2013
Balance, beginning of year	\$2,777	\$ 1,738
Warrants issued in connection with notes payable		9,950
Initial fair value of the warrants issued in excess of debt proceeds recognized in other income (expense), net		3,669
Warrants exercised	(400)	—
Change in fair value of convertible preferred stock warrant liability	(639)	8,894
Balance, end of year	\$1,738	\$24,251

#### **Embedded Derivatives in Convertible Notes**

The convertible notes issued in 2011 and 2013 had redemption features which were determined to be embedded derivatives requiring bifurcation and separate accounting. The fair value of the derivatives were determined based on an income approach that identified the cash flows using a "with-and-without" valuation

### Coherus BioSciences, Inc.

#### Notes to Consolidated Financial Statements (continued)

#### 3. Fair Value Measurements (continued)

methodology. The inputs used to determine the estimated fair value of the derivative instruments are based largely on the probability of an underlying event triggering the embedded derivative occurring and the timing of such event. The only derivative that had any significant value was the derivative liability corresponding to the redemption feature in the 2013 Notes associated with the option to receive a cash payment equal to 400% of outstanding principal plus accrued interest upon a change of control prior to a qualified licensing transaction ("QLT").

The Company periodically remeasured the derivative instrument to fair value as of each balance sheet date. In December 2013, following the receipt of the upfront license payment from Baxter license agreement (see Note 5), the Company achieved the QLT. As a result, upon a change of control, the redemption feature related to the holders' option to receive a cash payment in lieu of conversion into Series B convertible preferred stock was reduced from 400% to 100% of the outstanding principal, plus accrued interest. As such, the fair value of the derivative liability was reduced to zero at the time of the achievement of the QLT in December 2013.

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

	<u>December 31,</u> 2013
Balance, beginning of year	\$
Initial fair value of the embedded derivative issued in excess of debt proceeds recognized in other income	
(expense), net	4,096
Change in fair value of embedded derivative	(4,096)
Balance, end of year	\$

#### 4. Balance Sheet Components

#### **Prepaid Assets**

Prepaid assets are as follows (in thousands):

	Decem	ider 31,
	2012	2013
Prepaid clinical, material and manufacturing — related parties	\$9,058	\$3,177
Prepaid clinical, material and manufacturing	583	1,758
Prepaid other	342	753
Prepaid assets	\$9,983	\$5,688

Contemporaneous with the initial and subsequent closings of the Series B convertible preferred stock, the Company issued shares of Series B convertible preferred stock with a total fair value of \$3.5 million and \$12.0 million in January 2012 and December 2012, respectively, to various vendors in exchange for past and future services (see Note 9). To the extent the vendors would provide future services, the Company initially recorded a prepayment for the future services and a corresponding amount to Series B convertible preferred stock based on the fair value of the Series B convertible preferred stock on the dates such preferred shares were issued. The Company recognized the cost of the services as such services were provided as research and development expense based on invoiced amounts with a corresponding offset to prepaid assets. As of December 31, 2012 and 2013, the remaining balance of the prepayment related to the stock issuance was \$7.6 million and \$0, respectively, included in the above table as prepaid clinical, material and manufacturing — related parties.

### **Coherus BioSciences, Inc.**

### Notes to Consolidated Financial Statements (continued)

### 4. Balance Sheet Components (continued)

#### Property and Equipment, Net

Property and equipment are as follows (in thousands):

	Decer	nber 31,
	2012	2013
Machinery and equipment	\$1,535	\$2,051
Computer equipment and software	61	79
Furniture and fixtures	145	147
Leasehold improvements	90	91
Total property and equipment	1,831	2,368
Accumulated depreciation and amortization	(226)	(625)
Property and equipment, net	\$1,605	\$1,743

Depreciation and amortization expense was \$221,000 and \$404,000 for the years ended December 31, 2012 and 2013, respectively.

In June 2013, as part of a clinical manufacturing service agreement, the Company granted a first priority security interest to the Company's property and equipment located in Camarillo, California to Cook Pharmica LLC ("Cook"), a CMO.

During July 2013 and September 2013, the Company entered into the Bridge Loans (see Note 7), which were collateralized by a security interest in all of the Company's assets, tangible and intangible, subject to a prior security interest held by Cook on the Company's property and equipment located in Camarillo, California as discussed above.

### **Accrued and Other Liabilities**

Accrued and other liabilities are as follows (in thousands):

	December 31,	
	2012	2013
Accrued clinical and manufacturing — related parties	\$1,323	2013 \$2,792
Accrued compensation	462	1,549
Accrued professional and consulting fees	1,006	995
Accrued other	774	1,922
Other current liabilities	23	21
Accrued and other liabilities	\$3,588	\$7,279

December 21

### 5. Collaboration and License Agreements

The Company recognized revenue related to its collaboration and license agreements as follows (in thousands):

Daiichi Sankyo — related party \$1,8	December 31	
		, 2013
	,899 \$	2,025
Baxter	_	726
Total revenue \$1,8	,899 \$	2,751

### **Coherus BioSciences, Inc.**

#### Notes to Consolidated Financial Statements (continued)

#### 5. Collaboration and License Agreements (continued)

### Daiichi Sankyo

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

Upon execution of the agreement, Daiichi Sankyo paid a non-refundable, upfront license fee of \$10.0 million and purchased 4,780,000 shares of Series B convertible preferred stock at a price of \$4.1841 per share, or \$18.1 million in net cash proceeds. The Company concluded that there was no premium or discount associated with the purchase of the Series B convertible preferred stock since Daiichi Sankyo paid the same price paid by other investors at the close of the Series B convertible preferred stock offering which also occurred in January 2012. As such the Company recorded the \$18.1 million as a convertible preferred stock transaction separate from the license agreement. The agreement has an initial term of ten years and contains provisions allowing Daiichi Sankyo to renew the agreement for an additional three years with respect to particular countries. Daiichi Sankyo also has the right to terminate the agreement, in its entirety or on a country-by country basis, at any time if the development and/or commercialization is deemed to not be commercially viable, there are material safety, efficacy or patient tolerability issues that cannot be remedied or overcome, or during the opt-out window after the achievement of specified objectives in the agreement. In May 2012, Daiichi Sankyo opted out of the development and commercialization of etanercept in Taiwan and South Korea, and in August 2012, Daiichi Sankyo chose not to exercise their option with respect to the development and commercialization of etanercept and rituximab in China.

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

In June 2013, the Company and Daiichi entered into a Memorandum of Understanding No. 1 (the "MOU 1") in which both parties agreed to cooperate and share costs to conduct a global Phase 1 study of a biosimilar form of etanercept. This program was not originally contemplated in the license agreement. Under the MOU 1,

### Coherus BioSciences, Inc.

#### Notes to Consolidated Financial Statements (continued)

#### 5. Collaboration and License Agreements (continued)

the Company will gather all clinical data, format it into a case study report, and conduct the final analysis. The Company will transfer the clinical data and other regulatory approval application documents for the product and post marketing to Daiichi Sankyo within 90 days after such documents are finalized. Under the MOU 1, Daiichi's Sankyo's overall cost sharing responsibility include (i) 33% of the total budgeted cost and (ii) 100% of the cost of the comparator drug (Enbrel) used for the Japanese volunteers. The amounts received from Daiichi Sankyo under this cost sharing responsibility are recognized as a reduction in research and development expense as the Company engages in a research and development project jointly with Daiichi Sankyo, with both parties incurring costs while actively participating in development activities and both parties sharing costs and potential benefits of the arrangement. The Company accounted for the MOU 1 as a separate arrangement which was not deemed to be a material modification of the original license agreement with Daiichi Sankyo.

As of December 31, 2012, \$8.1 million of revenue was deferred under the agreement, of which \$2.0 million was included in current liabilities and \$6.1 million was included in non-current liabilities in the consolidated balance sheet. As of December 31, 2013, \$6.1 million of revenue was deferred under this agreement, of which \$2.0 million was included in current liabilities and \$4.1 million was included in non-current liabilities in the consolidated balance sheet. In addition, the Company recognized \$157,000 and \$1.3 million as a reduction of research and development expense related to the costs reimbursed by Daiichi Sankyo in the Company's statements of operations and comprehensive loss for the years ended December 31, 2012, and 2013, respectively.

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

#### Baxter

In August 2013, the Company entered into a license agreement with Baxter to develop and commercialize an etanercept biosimilar molecule, CHS-0214, worldwide, excluding the United States, Japan, Taiwan, South Korea, China and most of the Caribbean and South American nations. The agreement allowed for the development and commercialization of an alternative biosimilar to etanercept, and the expansion of the collaboration to include another product which lapsed in December 2013.

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

### Coherus BioSciences, Inc.

#### Notes to Consolidated Financial Statements (continued)

#### 5. Collaboration and License Agreements (continued)

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

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

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

The upfront payment of \$30.0 million and clinical development payments of up to \$96.0 million include \$56.0 million of contingent payments that are intended to cover development related expenses incurred by the Company, but potentially reimbursable, in part, to Baxter under certain limited circumstances. The Company concluded that the contingent payments that contain potentially reimbursable amounts to Baxter are not substantive milestones under the relevant accounting guidance, since the guidance does not allow the substantive milestone components of a payment to be bifurcated from non-substantive milestone components. The amounts that are contingent payments also contain a claw-back feature that, in the event that the Company will record the portion of the non-substantive contingent payment that contains the claw-back feature as a liability for the potential reimbursement of such funds to Baxter until the earlier of: (1) expiration or termination of the license agreement, which is ten years, or the determination of the non-substantive milestone payment that does not contain the claw-back feature will be recorded as deferred revenue and recognized as license revenue on a straight-line basis over the remaining estimated performance period of approximately three years. The Company determined that there is no other method that is more appropriate then the straight-line method of revenue recognition for this agreement given there is no discernable pattern of performance under the arrangement.

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

The upfront payment of \$30.0 million includes \$10.0 million designated as a contingent payment. Due to the potential for the Company to refund the 50% of the contingent payment to Baxter, \$5.0 million of the \$10.0 million payment was recorded as contingent liability to collaborator in the consolidated balance sheet. The remaining amount of \$5.0 million together with the \$20.0 million, or \$25.0 million, has been recorded as deferred revenue and is being amortized over the remaining estimated performance of period under the agreement using the straight line method.

### **Coherus BioSciences, Inc.**

#### Notes to Consolidated Financial Statements (continued)

#### 5. Collaboration and License Agreements (continued)

In December 2013, the Company received a payment of \$15.0 million resulting from the lapse of the opt-out period as a result of Baxter's decision not to opt out of the agreement. The payment includes \$5.0 million designated as a contingent payment. Due to the potential for the Company to refund 50% of that contingent payment to Baxter, \$2.5 million of the \$5.0 million payment was recorded as a contingent liability to collaborator in the consolidated balance sheet. The remaining amount of \$2.5 million together with the \$10.0 million, or \$12.5 million, has been recorded as deferred revenue and is being amortized over the remaining estimated performance of period under the agreement using the straight line method.

As of December 31, 2013, \$36.8 million of revenue was deferred under this agreement, of which \$12.3 million was included in current liabilities and \$24.5 million was included in non-current liabilities in the consolidated balance sheet. As of December 31, 2013, \$7.5 million, composed of \$5.0 million of the upfront fee and \$2.5 million of the December 2013 payment, was recorded as a contingent liability to collaborator in the consolidated balance sheet due to the potential refund to Baxter.

In February 2014, the Company and Baxter amended the license agreement to increase the non-substantive contingent payments for an additional \$5.3 million representing additional costs incurred by the Company which were not originally contemplated. The Company concluded that this amendment did not materially affect the underlying terms and conditions of the original agreement. Therefore, the Company will recognize the additional non-substantive contingent payment over the remaining performance period from the amendment date.

#### 6. Commitments and Contingencies

#### **Purchase Commitments**

The Company enters into contracts in the normal course of business with contract research organizations ("CRO") for preclinical studies and clinical trials and contract manufacturing organizations ("CMO") for the manufacture of clinical trial materials. As of December 31, 2013, the Company has commitments of \$4.1 million with CMOs for the manufacture of clinical trial material due within a year. The Company also has an agreement with Medpace, Inc. ("Medpace"), a CRO, which provides for a minimum fee commitment of \$35.0 million, in aggregate, for clinical trial services; however, the agreement is cancelable without cause upon 30 days prior notification by either party. As of December 31, 2013, \$5.7 million of the services related to this agreement have been performed.

#### **Facilities Leases**

The Company leases office spaces for its corporate headquarters in Redwood City, California and for laboratory facilities in Camarillo, California under operating lease agreements. Rent expense is recognized on a straight-line basis over the term of the lease and accordingly, the Company records the difference between cash rent payments and the recognition of rent expense as a deferred rent liability. The corporate headquarters lease expires in September 2016, and the laboratory lease expires in June 2017 with an option to extend for three years.

### **Coherus BioSciences, Inc.**

#### Notes to Consolidated Financial Statements (continued)

#### 6. Commitments and Contingencies (continued)

The future minimum lease payments for these facilities as of December 31, 2013 are as follows (in thousands):

Year ending December 31,	
2014	\$ 516
2015	550
2016	443
2017	46
Total minimum lease payments	46 \$1,555

Rent expense was \$371,000 and \$428,000 for the years ended December 31, 2012 and 2013, respectively.

#### **Guarantees and Indemnification**

The Company has indemnification agreements with two members of the board of directors and one member of the Company's Scientific Advisory Board for certain events or occurrences, subject to certain limits, while they are or were serving at the Company's request in such capacities. The term of each indemnification period lasts as long as these board members may be subject to any proceeding arising out of acts or omissions of such director in such capacity.

The maximum amount of potential future indemnification is unlimited; however, the Company currently holds director and officer liability insurance. This insurance allows the transfer of risk associated with the Company's exposure and may enable the Company to recover a portion of any future amounts paid. The Company believes that the fair value of these indemnification obligations is minimal. Accordingly, the Company has not recognized any liabilities relating to these obligations for any period presented.

#### 7. Debt Obligations

### **Convertible Notes Issued in 2011**

From July to December 2011, the Company entered into convertible note agreements (the "2011 Notes") with investors, which included multiple closings. In July 2011, the initial closing had an aggregate principal amount of \$3.8 million, and the subsequent closings occurred in August, October, November and December 2011 raising an aggregate principal amount of \$6.6 million. The initial closing of \$3.8 million consisted of \$3.5 million of cash received from the investors and \$260,000 of accrued employee compensation and/or bonuses payable by the Company that were converted into convertible notes for the balances owed to the individuals. The 2011 Notes bore interest of 8% per annum and had a maturity date of March 31, 2012. The outstanding principal and accrued interest on the 2011 Notes were convertible: (i) automatically upon a financing event in which the Company issued newly authorized shares of stock into that same stock at a conversion price equal to the price paid by the other investors in that financing event, (ii) upon a change of control or IPO, at the option of the note holder, into shares of Series A convertible preferred stock at a conversion price of \$0.75 per share or (iii) upon the maturity date, at the request of the majority note holders, if the financing event above had not occurred on or before the maturity date, into shares of Series A convertible preferred stock at a conversion price of \$0.75 per share. In connection with the issuance of the 2011 Notes, the Company issued warrants (the "2011 Warrants B") to purchase shares of its preferred stock at an exercise price of \$0.01 per share (see Note 8).

Upon issuance of the 2011 Notes, the Company recorded the fair value of the warrants of \$2.7 million as a debt discount and convertible preferred stock warrant liability (see Note 8). The Company also recorded a

#### **Coherus BioSciences, Inc.**

#### Notes to Consolidated Financial Statements (continued)

#### 7. Debt Obligations (continued)

beneficial conversion feature of \$5.4 million as a debt discount with a corresponding increase to additional paid-in capital. The debt discount was accreted using the effective interest method as additional interest expense over the term of the 2011 Notes.

In January 2012, as a result of the Series B convertible preferred stock financing event (see Note 9), the outstanding principal of \$10.4 million and accrued interest of \$236,000 related to the 2011 Notes automatically converted into 2,540,742 shares of Series B convertible preferred stock using a conversion price which represented the same issuance price of \$4.1841 per share paid by other Series B investors. Contemporaneously, the Company reacquired the beneficial conversion feature and recorded \$6.4 million related to the gain on the extinguishment of the 2011 Notes. In addition, the 2011 Warrants B became warrants to purchase 587,543 shares of Series B convertible preferred stock for \$0.01 per share.

During the year ended December 31, 2012, the Company recognized interest expense of \$1.5 million related to the accrued interest and amortization of debt discount, of which \$1.0 million related to beneficial conversion feature, \$433,000 related to debt discount amortization and \$53,000 related to interest on the outstanding debt.

#### **Convertible Notes Issued in 2013**

During July 2013 to September 2013, the Company entered into convertible note agreements (the "Bridge Loans") with various stockholders, employees and institutions for an aggregate principal amount of \$10.0 million. The Bridge Loans bore interest of 8% per annum and would mature on July 15, 2014. The principal and the accrued interest on the Bridge Loans were convertible: (i) automatically upon a future issuance of the Company's preferred or common stock into that same stock at a conversion price equal to the price paid by other investors in the financing event, (ii) at the option of the holder, upon a change of control, into shares of Series B convertible preferred stock at a conversion price equal to the lesser of \$4.1841 per share or the price per share paid in the IPO or (iv) upon the election of the holders, if the financing events stated above had not occurred on or before maturity date, into shares of Series B convertible preferred stock with a conversion price of \$4.1841 per share. In addition, upon a change of control, the holders were entitled to receive a cash payment equal to 400% of the outstanding principal, plus accrued interest, in lieu of conversion into Series B convertible preferred stock if the Company did not meet the QLT threshold. The QLT is deemed to have been achieved when (i) the Company has entered into a transaction with a third party to sell or offer to sell any product candidates of the Company that provides for aggregate cash payments of at least \$50.0 million payable within 12 months and (ii) the Company has received cash payments of at least \$25.0 million within 12 months and (ii) the Company has received cash payments of at least \$25.0 million within 12 months following the execution of the agreement due to any milestones. On December 9, 2013, the QLT was deemed to have been achieved.

In connection with the Bridge Loans, the Company also issued warrants to purchase shares of its convertible preferred stock at an exercise price of \$0.01 per share. The determination of the number of shares issuable pursuant to the 2013 warrants was determined based on 300% of the principal amount of the Bridge Loans divided by the conversion price (the "2013 Warrants") (see Note 8). In addition, at the issuance date of the notes, there was a beneficial conversion feature. The total aggregate Bridge Loans of \$10.0 million was less than the initial fair value of the warrants of \$13.6 million at the issuance date, therefore \$10.0 million was recognized as debt discount, and the difference of \$3.6 million was immediately charged to other income (expense), net in the consolidated statement of operations and comprehensive loss as the debt cannot be reduced to less than zero. No value was recorded initially for the beneficial conversion feature since the carrying value of the debt was zero. The debt discount of \$10.0 million is being accreted using the effective interest method as an additional interest expense over the term of the Bridge Loans.

The Bridge Loans redemption features were determined to be embedded derivatives requiring bifurcation and separate accounting. The fair value of the embedded derivative liability at issuance was determined to be

### **Coherus BioSciences, Inc.**

#### Notes to Consolidated Financial Statements (continued)

#### 7. Debt Obligations (continued)

\$4.1 million. As a result of the fair value of the warrant debt discount reducing the debt to zero at the time of the issuance as discussed above, the estimated fair value of the derivative liability of \$4.1 million was recognized within other income (expense), net, in the consolidated statement of operations and comprehensive loss and as a derivative liability on the consolidated balance sheet upon issuance. Changes in the fair value of the embedded derivative have also been recorded within other income (expense), net, in the consolidated statement of operations and comprehensive loss. The Company periodically remeasures the derivative liability to fair value.

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

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

The Bridge Loans were collateralized by a security interest in all assets, tangible and intangible, of the Company, subject to a prior security interest of Cook on the Company's property and equipment in Camarillo, California.

In May 2014, the Company completed an equity financing of Series C convertible preferred stock and, as a result, the Bridge Loans and related accrued interest automatically converted into shares of Series C convertible preferred stock at the Series C purchase price paid by other investors. In addition, as the warrants could be exercised for Series B convertible preferred stock any time after the QLT, in April and May 2014, the holders elected to exercise 100% of the outstanding warrants for 7,134,149 shares of Series B convertible preferred stock (see Note 14).

#### 8. Convertible Preferred Stock Warrants

The following table sets forth a summary of the convertible preferred stock warrants and the related estimated fair values as of December 31, 2012 and 2013 (in thousands, except share data):

December 31, 2012		December	31, 2013
Shares Underlying The Warrants	Estimated Fair Value	Shares Underlying The Warrants	Estimated Fair Value
106,560	\$ 198	106,560	\$ 170
491,943	1,540	491,943	1,122
		7,134,149	22,959
598,503	\$ 1,738	7,732,652	\$24,251
	Shares Underlying <u>The Warrants</u> 106,560 491,943 	Shares Underlying     Estimated       The Warrants     Fair Value       106,560     \$ 198       491,943     1,540	Shares Underlying The Warrants     Shares Underlying Fair Value       106,560     \$ 198       491,943     1,540       491,943     7,134,149

#### 2011 Warrants A

In January 2011, in conjunction with the issuance of the 2011 Notes, the Company issued warrants to purchase shares of its newly authorized shares of preferred stock upon a financing event ("2011 Warrants A"). In March 2011, as a result of the Series A convertible preferred stock financing event, the January 2011 convertible promissory notes and related accrued interest automatically converted into Series A convertible preferred stock and the 2011 Warrants A became exercisable warrants to purchase 106,560 shares of Series A convertible

### **Coherus BioSciences, Inc.**

#### Notes to Consolidated Financial Statements (continued)

#### 8. Convertible Preferred Stock Warrants (continued)

preferred stock with an exercise price of \$0.75 per share. The warrants will expire at the earlier of: (i) January 25, 2016, (ii) upon the closing of the Company's IPO, or (iii) upon the closing of the Company's change of control. The Company initially valued the 2011 Warrants A at \$53,000 using the Option Pricing Model ("OPM") that allocated total equity value to all the Company's equity securities in the capital structure at the time of issuance including potentially dilutive equity securities. These analyses generally used a backsolve approach that implies the total equity and common stock value from a round of preferred financing. None of the warrants have been exercised to date.

#### 2011 Warrants B

From July to December 2011, the Company issued the 2011 Warrants B with an exercise price of \$0.01 per share in conjunction with the issuance of the 2011 Notes (see Note 7). The warrants will expire at the earlier of: (i) seven years from the issuance dates, or (ii) upon the closing of the Company's change of control or IPO. If the warrant holders have not exercised the warrants prior to the closing of the change of control or IPO, the warrants will automatically be deemed to be net exercised in full immediately prior to the closing of the change of control or IPO. The 2011 Warrants B are exercisable upon the earlier of: (i) a financing event in which the Company issued newly authorized shares of stock, into that same stock at a conversion rate equal to the quotient obtained by dividing the sum of (a) 30% of the principal loan amount of the initial closing and (b) 20% of the principal loan amount of subsequent closing by the price paid by other investors in the financing event, or (ii) upon a change of control, an IPO, or maturity date, into Series A convertible preferred stock at the conversion rate equal to the quotient obtained by dividing the sum of (a) 30% of the principal loan amount of up principal loan amount of subsequent closing and (b) 20% of the principal loan amount of subsequent closing by \$0.75 per share.

The estimated fair value of the warrants at issuance was \$2.7 million based on probability-weighted present values of the warrants under the qualifying event scenarios with the follows assumptions:

	Next Financing Event in Which the Company Issued Newly Authorized Shares	Change of Control, IPO or
Issuance Date	of Preferred Stock	Maturity Date
July 21, 2011	35%	65%
August 31, 2011	50%	50%
October 31, 2011	75%	25%
November 29, 2011	85%	15%
December 21, 2011	90%	10%

In January 2012, as a result of the Series B convertible preferred stock financing event, the 2011 Warrants B became exercisable warrants to purchase 587,543 shares of Series B convertible preferred stock. In June 2012, warrants to purchase 95,600 of Series B preferred stock were exercised, resulting in cash proceeds of approximately \$1,000 and a reclassification of fair value of convertible preferred stock warrants to Series B preferred stock of \$400,000.

#### 2013 Warrants

From July to September 2013, the Company issued the 2013 Warrants with the exercise price of \$0.01 per share in conjunction with the issuance of the Bridge Loans (see Note 7). The warrants expire at the earlier of: (i) seven years from issuance dates, or (ii) upon the closing of the Company's change of control or IPO. If the warrant holders have not exercised the warrants prior to the closing of the change of control or IPO, the warrants will automatically be deemed to be net exercised in full immediately prior to the closing of the change of control or IPO.

### Coherus BioSciences, Inc.

#### Notes to Consolidated Financial Statements (continued)

#### 8. Convertible Preferred Stock Warrants (continued)

The determination of the number of shares pursuant to the 2013 Warrants was equal to 300% of the principal amount of the Bridge Loans divided by the conversion price, as defined. The 2013 Warrants were exercisable upon the earlier of: (i) a financing event in which the Company issued newly authorized shares of stock, into that same stock at a conversion price equal to the price paid by other investors in the financing event, (ii) an occurrence of a QLT, as defined under the Bridge Loans, into shares of Series B convertible preferred stock at a conversion price equal to \$4.1841 per share, (iii) election by the warrant holder to convert the underlying note upon a change of control, into shares of Series B convertible preferred stock at a conversion price equal to the lesser of (a) \$4.1841 per share, or (b) the price per share paid in the IPO, or (v) the maturity date if the financing event stated in (i) above has not occurred, into shares of Series B convertible preferred stock equal to the conversion price of \$4.1841 per share.

The estimated fair value of the 2013 Warrants at issuance was \$13.6 million based on probability-weighted values of the warrants under the qualifying event scenarios. For scenarios (i) and (ii), the cash flow method was used to value the present values of the warrants based on the warrant coverage, as adjusted for risk-adjusted discount rate of 30%. For scenarios (iii), (iv) and (v), the present values of the warrants were based on the fair value per share of the Series B convertible preferred stock using the PWERM. The Company weighed the scenarios based on management's estimate of the timing and probability of each qualifying event as of each of the issuance dates and then again at the end of each quarter for the mark to market adjustments. The Company recognized the fair value of the 2013 Warrants up to the total aggregate Bridge Loans of \$10.0 million as the debt cannot be reduced to less than zero. The remaining \$3.6 million of the total fair value of the 2013 Warrants was recognized immediately within other income (expense), net, in the consolidated statement of operations and comprehensive loss. In December 2013, following the receipt of the upfront license payment from the Baxter license agreement (see Note 5), the Company met the QLT criteria. As a result, the 2013 Warrants became exercisable to purchase 7,134,149 shares of Series B convertible preferred stock.

The 2011 Warrants A, 2011 Warrants B and 2013 Warrants are classified as convertible preferred stock warrant liabilities and are subject to remeasurement at each balance sheet date. The changes to the fair value of the warrants are recognized as a component of other income (expense), net, in the consolidated statements of operations and comprehensive loss. The net change in the fair value of the warrant liability was a decrease of \$0.6 million and an increase of \$0.9 million for the years ended December 31, 2012 and 2013, respectively.

#### 9. Convertible Preferred Stock

In January 2012, the Company issued 5,377,500 shares of Series B convertible preferred stock in an initial closing at a price of \$4.1841 per share for net cash proceeds of \$20.3 million. An additional 2,540,742 shares of Series B convertible preferred stock were issued at the same price per share in exchange for the conversion of \$10.6 million of the 2011 Notes B and related accrued interest (see Note 7). In June 2012, upon the exercise of 95,600 shares of Series B convertible preferred stock warrant liability was reclassified to the carrying value of the Series B convertible preferred stock. In December 2012, the Company issued 1,912,000 shares of Series B convertible preferred stock in a subsequent closing at a price of \$4.1841 per share for net cash proceeds of \$6.6 million.

Contemporaneously with the initial and subsequent closings of the Series B convertible preferred stock, the Company issued 836,500 and 2,876,365 shares of Series B convertible preferred stock in January 2012 and December 2012, respectively, to various vendors in exchange for past and future services. The shares issued in January 2012 and December 2012 was based on the \$4.1841 price per share which was the same price paid by the investors in the initial and subsequent closings for total value of \$3.5 million and \$12.0 million, respectively.

### Coherus BioSciences, Inc.

#### Notes to Consolidated Financial Statements (continued)

#### 9. Convertible Preferred Stock (continued)

To the extent the vendors had future services to be provided, the Company initially recorded a prepayment for the future services and a corresponding amount to Series B convertible preferred stock, as the shares were not subject to vesting or repurchase. The prepayments were amortized to research and development expense based on the invoiced amounts for such services as the services were performed.

Of the 2,876,365 shares of Series B convertible preferred stock issued in exchange for past and future services, pursuant to the terms of the agreement with Cook, 1,195,000 shares of Series B convertible preferred stock valued at \$5.0 million held by Cook were contingently subject to repurchase by the Company for cash based upon the occurrence of certain events, none of which occurred or were probable as of December 31, 2013. In February 2014, these shares were purchased by another party resulting in the termination of the Company's repurchase obligation.

As of December 31, 2012 and 2013, the outstanding convertible preferred stock was as follows (in thousands, except share data):

		Shares		
December 31, 2012	Shares Authorized	Issued and Outstanding	Carrying Value	Liquidation Preference
Series A	1,800,000	1,620,888	\$ 1,191	\$ 1,216
Series B	14,692,297	13,638,707	53,504	57,066
	16,492,297	15,259,595	\$54,695	\$ 58,282
		Shares		
	Shares	Issued and	Carrying	Liquidation
December 31, 2013	Authorized	Outstanding	Value	Preference
Series A	1 200 000	1,620,888	\$ 1,191	\$ 1,216
	1,800,000	1,020,000	φ 1,1 <i>5</i> 1	φ 1,210
Series B	26,290,997	13,638,707	53,504	57,066
Series B				

The rights, preferences and privileges of the convertible preferred stock are as follows:

### Conversion

Each share of Series A and B convertible preferred stock, at the option of the holder, is convertible into common stock at an initial conversion ratio of 1:1. This initial conversion ratio is subject to certain adjustments, from time to time, for dilution. Conversion of preferred stock into common stock is automatic at its then effective conversion rate immediately upon (i) the affirmative vote of at least fifty-five percent (55%) of the then outstanding Series B preferred stockholders, voting as a single, separate class or (ii) the closing of a firm commitment underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, covering the offer and sale of common stock by a nationally reputable underwriters in which the public offering price equals or exceeds \$9.00 per share (as adjusted for any stock dividends, stock splits or recapitalizations) and the aggregate net proceeds raised equals or exceeds \$40.0 million. In May 2014, the Company amended its Certificate of Incorporation contemporaneously with the issuance of Series C convertible preferred stock. As such, each share of Series A, Series B and Series C convertible preferred stock, at the option of the holder, is convertible into common stock at an initial conversion ratio of 1:1. This initial conversion ratio shall be subject to certain adjustments, from time to time, for dilution. Conversion of preferred stock into common stock is automatic at its then effective conversion rate immediately upon (i) the affirmative vote of (1) the holder of at least fifty-five percent (55%) of the then outstanding Series B convertible preferred stock, voting as a single, separate class and (2) the holders of at least fifty-five percent (55%) of the then

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### **Coherus BioSciences, Inc.**

#### Notes to Consolidated Financial Statements (continued)

#### 9. Convertible Preferred Stock (continued)

outstanding Series C convertible preferred stockholders, including at least two specified Series C preferred stockholders, voting as a single, separate class or (ii) the consummation of a firmly underwritten public offering pursuant to the Securities Act of 1933, as amended, provided, however, that (1) underwriters are of national reputation and (2) the aggregate gross proceeds to the Company are not less than \$45.0 million.

#### Voting

The holders of the Series A and B convertible preferred stock are entitled to voting rights equal to the number of shares of common stock into which each share of convertible preferred stock could be converted into at the record date for a vote or consent of stockholders, except as otherwise required by law. Except as discussed below, the holders of convertible preferred stock and common stock vote together and not as separate classes. In May 2014, the Company amended its Certificate of Incorporation contemporaneously with the issuance of Series C convertible preferred stock. The holders of the Series A, Series B and Series C convertible preferred stock are entitled to voting rights equal to the number of shares of common stock into which each share of convertible preferred stock could be converted into at the record date for a vote or consent of stockholders, except as otherwise required by law, and has voting rights and powers equal to the voting rights and powers of the common stockholders. The holder of preferred stock and the holder of common stock shall vote together and not as separate classes.

#### **Election of Directors**

The holders of Series A convertible preferred stock, Series B convertible preferred stock and common stock, voting separately as a single class, are each entitled to elect two members of the Company's Board of Directors. All remaining members of the Company's Board of Directors are elected by the holders of the common stock and convertible preferred stock voting together as a single class. In May 2014, the Company amended its Certificate of Incorporation contemporaneously with the issuance of Series C convertible preferred stock. The holders of Series A convertible preferred stock and Series B convertible preferred stock, voting separately as a single class are each entitled to elect two members of the Company's Board of Directors. The holders of Series C convertible preferred and common stock, voting separately as a single class are each entitled to elect one member of the Company's Board of Directors. All remaining members of the Company's Board of Directors are elected by the holders of the common stock and preferred stock holders, voting together as a single class on an as-if-converted to common stock basis.

#### Dividends

The holders of the Series B convertible preferred stock are entitled to receive dividends payable out of any funds or assets legally available, prior and in preference to any declaration or payment of any dividend on the Series A convertible preferred stock or common stock of the Company. After payment of the prior dividend right of the Series B convertible preferred stock, the holders of the Series A convertible preferred stock are entitled to receive dividends payable out of any funds or assets legally available, prior and in preference to any declaration or payment of any dividend on common stock of the Company. Such dividends are payable when, as and if declared by the Board of Directors, and are not cumulative. No dividends were declared through December 31, 2013. In May 2014, the Company amended its Certificate of Incorporation contemporaneously with the issuance of Series C convertible preferred stock. As such, the holder of Series C convertible preferred stock shall be entitled to receive dividends payable out of any funds or assets at the time legally available therefore, prior and in preference to any declaration or payment of any dividend on Series B convertible preferred stock. Series A convertible preferred or common stock.

### Coherus BioSciences, Inc.

#### Notes to Consolidated Financial Statements (continued)

#### 9. Convertible Preferred Stock (continued)

### Liquidation

In the event of any liquidation, dissolution or winding up of the Company, either voluntary or involuntary, the holders of Series B convertible preferred stock are entitled to receive, prior and in preference to any distribution of any of the assets or surplus funds of the Company to the holders of Series A convertible preferred stock or common stock, amounts per share equal to the original issue price (as adjusted for any stock dividends, combinations or splits), plus any declared but unpaid dividends on such shares. If upon the occurrence of such event, the assets and funds distributed among the holders of the Series B convertible preferred stock are insufficient to permit the payment to such holders of the full aforesaid preferential amounts, then, the entire assets and funds of the Company legally available for distribution are to be distributed with equal priority and pro rata among the holders of the Series B convertible preferred stock. After such payment has been made to the holders of Series B convertible preferred stock, the holders of Series A convertible preferred stock are entitled to receive, prior and in preference to any distribution of any of the assets or surplus funds of the Company to the holders of common stock, amounts per share equal to the original issue price (as adjusted for any stock dividends, combinations or splits), plus any declared but unpaid dividends on such shares. If upon the occurrence of such event, the assets and funds distributed among the holders of the Series A convertible preferred stock are insufficient to permit the payment to such holders of the full preferential amounts, then the entire assets and funds of the Company legally available for distribution to Series A convertible preferred stock holders are to be distributed with equal priority and pro rata among the holders of the Series A convertible preferred stock. After such payment has been made to the holders of Series A convertible preferred stock, no further payments shall be made to the holders of the preferred stock and any remaining assets of the Company shall be distributed with equal priority and pro rata among the holders of the Company's common stock. In May 2014, the Company amended its Certificate of Incorporation contemporaneously with the issuance of Series C convertible preferred stock. As such, the holders of Series C convertible preferred stock are entitled to receive, prior to and in preference to any distribution of any of the assets or surplus funds of the Company to the holders of Series B convertible preferred stock, Series A convertible preferred stock or common stock.

#### 10. Stock Option Plan and Stock-Based Compensation

#### **Restricted Common Stock ("Founders Shares")**

In October 2010 and January 2011, the Company issued 6,885,000 shares and 1,615,000 shares of restricted common stock, respectively, at \$0.005 per share to its founders under the Founders Shares agreements. Under the Founders Shares agreements, the Company has the right to repurchase the common stock which right lapses monthly in equal installments over four years. In order to vest, the holders are required to provide continued service to the Company. Upon vesting, the appropriate amounts are transferred from liabilities to additional paid in capital. If the holder of any unvested restricted common stock is terminated for any reason, the Company has the right to repurchase the unvested shares at the stockholder's original purchase price. As such, the shares subject to future vesting are not deemed outstanding for accounting purposes until the shares vest. In July 2012, one of the founders resigned from the Board of Directors. As such, 478,125 shares of common stock were repurchased by the Company for approximately \$2,000 in July 2012.

### **Coherus BioSciences, Inc.**

### Notes to Consolidated Financial Statements (continued)

#### 10. Stock Option Plan and Stock-Based Compensation (continued)

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

	Shares
Non-vested as of December 31, 2011	6,075,982
Vested	(2,012,172)
Repurchased by the Company	(478,125)
Non-vested as of December 31, 2012	3,585,685
Vested	(2,313,215)
Non-vested as of December 31, 2013	1,272,470

As of December 31, 2012 and 2013, the Company had 3,585,685 and 1,272,470 unvested shares of common stock which were subject to repurchase by the Company. As such, \$8,000 and \$7,000 were recorded as current and non-current other liabilities, respectively, in the accompanying consolidated balance sheet as of December 31, 2012. As of December 31, 2013, the total amount of \$5,000 was all recorded as accrued and other liabilities in the accompanying consolidated balance sheet. The unvested shares of common stock will continue to vest with the founders' continued service to the Company pursuant to the Founders Shares agreements.

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

The stock-based compensation expense recorded related to the Founders Shares was as follows (in thousands):

		Year Ended December 31,	
	2012	2013	
Research and development	\$232	\$ 227	
General and administrative	110	1,054	
	\$342	\$1,281	

The estimated weighted-average grant date fair value of restricted stock issued in 2010 and 2011 for both years was \$0.25 per share. No restricted common stock was granted in 2012 or 2013. The total unrecognized stock compensation expense as of December 31, 2013 of \$249,000 will be amortized as the shares vest over the remaining service period of 1.3 years.

#### 2010 Stock Plan

In 2010, the Company adopted the 2010 Stock Plan (the "Plan"). The Plan provides for the Company to grant shares and/or options to purchase shares of common stock to employees, directors, consultants, and other service providers at prices not less than the fair market value at the date of grant for incentive stock options and nonstatutory options. These options granted generally vest over four years, expire ten years from the date of grant, and are generally exercisable after vesting. Unvested options exercised are subject to the Company's repurchase right that lapses as the options vest. As of December 31, 2012 and 2013, no shares were subject to repurchase.

### **Coherus BioSciences, Inc.**

### Notes to Consolidated Financial Statements (continued)

#### 10. Stock Option Plan and Stock-Based Compensation (continued)

The following table sets forth the summary of option activities under the Plan:

		Option Outstanding		Option Outstanding	
	Shares Available for <u>Grant</u>	Number of Options	Weighte Averag Exercise I	ge	
Balances at December 31, 2011	25,000	1,625,000	\$ 0.	.215	
Authorized	2,535,224	—		—	
Granted	(1,019,022)	1,019,022	1.	.250	
Exercised	—	(37,188)	0.	.005	
Forfeited	47,812	(47,812)	0.	.005	
Balances at December 31, 2012	1,589,014	2,559,022	0.	.634	
Authorized	2,644,812	—		—	
Granted	(1,422,375)	1,422,375	1.	.250	
Granted — below fair value	(1,310,300)	1,310,300	0.	.850	
Exercised	—	(5,416)	1.	.250	
Forfeited	206,232	(206,232)	0.	.762	
Balances at December 31, 2013	1,707,383	5,080,049	\$ 0.	.856	

Additional information related to the status of options as of December 31, 2013 is summarized as follows:

	Number of Options	Weighted- Average Exercise Price	Weighted- Average Contractual <u>Terms (Years)</u>	Ir	ggregate ıtrinsic Value housands)
Options outstanding	5,080,049	\$ 0.856	8.84	\$	3,518
Options vested and expected to vest	5,006,116	\$ 0.855	9.17	\$	3,475
Options vested	1,933,981	\$ 0.692	8.30	\$	1,702
Options exercisable	1,971,482	\$ 0.679	8.27	\$	1,769

#### Valuation of Awards Granted to Employees

The Company estimated the fair value of each stock award on the date of grant using the Black-Scholes option-pricing model. The weighted average assumptions used to value options granted to employees under the Plan during the years ended December 31, 2012 and 2013 were as follows:

		Year Ended December 31,	
	2012	2013	
Expected term (years)	6.04	5.51	
Expected volatility	110%	108%	
Risk-free interest rate	0.93%	1.23%	
Expected dividend yield	0.0%	0.0%	

### Expected Term

The expected term represents the period for which the stock-based awards are expected to be outstanding and is based on the options' vesting term, contractual term and industry peers. The Company did not have sufficient historical information to develop reasonable expectations about future exercise patterns and post vesting employment termination behavior.

### **Coherus BioSciences, Inc.**

#### Notes to Consolidated Financial Statements (continued)

#### 10. Stock Option Plan and Stock-Based Compensation (continued)

#### Expected Volatility

The Company used an average historical stock price volatility of industry peers as representative of future stock price volatility since the Company does not have any trading history for its common stock.

#### Risk-Free Interest Rate

The Company based the risk-free interest rate by using an equivalent to the expected term based on the U.S. Treasury constant maturity rate as of the date of grant.

#### Expected Dividends

The Company has not paid and does not anticipate paying any dividends in the near future, and therefore used an expected dividend yield of zero in the valuation model.

The stock-based compensation expense recorded related to options granted to employees was as follows (in thousands):

	icu	Itur Enucu	
	Dece	mber 31,	
	2012	2013	
Research and development	\$ 30	\$431	
General and administrative	65	309	
	\$ 95	\$740	

Vear Ended

During the years ended December 31, 2012 and 2013, the total estimated fair value of the options vested was \$95,000 and \$0.7 million, respectively and the estimated weighted-average grant-date fair value of options granted was \$1.036 and \$1.129 per share, respectively. The aggregate intrinsic value of options exercised during the years ended December 31, 2012 and 2013 was \$46,000 and \$0, respectively.

As of December 31, 2013, total unrecognized stock-based compensation expenses related to unvested employee stock options was \$3.1 million. As of December 31, 2013, the remaining unrecognized compensation costs are expected to be recognized on a straight-line basis over a weighted-average period of approximately 3.00 years.

#### Nonemployees Stock-Based Compensation

The Company granted 125,000 stock options to purchase shares of common stock to nonemployees during the year ended December 31, 2013. The weighted-average exercise price of the options granted in 2013 was \$0.85 per share. The Company did not grant any stock options to purchase shares of common stock to nonemployees during the year ended December 31, 2012. For the years ended December 31, 2012 and 2013, the Company recorded stock-based compensation expense related to options granted to nonemployees of \$6,000 and \$24,000, respectively. The Company recorded stock-based compensation expense in research and development expense in the consolidated statements of operations and comprehensive loss. The Company remeasures the fair value of the unvested nonemployee options at each period using the Black-Scholes option-pricing model reflecting the same assumptions as applied to employee options in each of the reported years, other than the expected life, which is assumed to be the remaining contractual life of the options.

### 11. Income Taxes

The Company utilizes the liability method of accounting for deferred income taxes. Under this method, deferred tax liabilities and assets are recognized for the expected future tax consequences of temporary

### Coherus BioSciences, Inc.

#### Notes to Consolidated Financial Statements (continued)

#### 11. Income Taxes (continued)

differences between the carrying amounts and the tax basis of assets and liabilities. A valuation allowance is established against deferred tax assets because, based on the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. The Company's policy is to record interest and penalties on uncertain tax positions as income tax expense.

A reconciliation of the statutory U.S. federal rate to the Company's effective tax rate is as follows:

		Year Ended December 31,	
	2012	2013	
Percent of pre-tax income:			
U.S. federal statutory income tax rate	34.00%	34.00%	
State taxes, net of federal benefit	6.68	3.97	
Permanent items	5.65	(12.40)	
Research and development credit	_	4.53	
Other	(0.17)	—	
Change in valuation allowance	(46.16)	(30.10)	
Effective income tax rate	%	%	

Significant components of the Company's net deferred tax assets as of December 31, 2012 and 2013 consist of the following (in thousands):

	Dece	December 31,	
	2012	2013	
Deferred tax assets			
Net operating loss carryforwards	\$ 16,803	\$ 27,524	
Research and development credits	212	2,823	
Depreciation and amortization	132	26	
Other	205	3,121	
Gross deferred tax assets	17,352	33,494	
Less valuation allowance	(17,352)	(33,494)	
Net deferred tax assets	\$	\$	

The valuation allowance increased \$15.1 million and \$16.1 million during the years ended December 31, 2012 and 2013, respectively.

As of December 31, 2013, the Company had federal net operating loss carryforwards of approximately \$69.3 million, which will start to expire beginning in 2031, and various state net operating loss carryforwards of approximately \$69.1 million, which have various expiration dates beginning in 2031. Utilization of the net operating loss carryforwards and credits may be subject to a substantial annual limitation due to the ownership change limitations provided by Section 382 of the Internal Revenue Code of 1986, as amended, and similar state provisions. The annual limitation may result in the expiration of net operating losses and credits before utilization.

As of December 31, 2013, the Company had federal research and development credit carryforwards of approximately \$3.1 million, which will start to expire in 2031, and state research and development credit carryforwards of approximately \$0.7 million, which can be carried forward indefinitely.

### **Coherus BioSciences, Inc.**

#### Notes to Consolidated Financial Statements (continued)

#### 11. Income Taxes (continued)

In assessing the realizability of deferred tax assets, the Company considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which the temporary differences representing net future deductible amounts become deductible. Due to the Company's history of losses, and lack of other positive evidence, the Company has determined that it is more likely than not that its deferred tax assets will not be realized, and therefore, the deferred tax assets are fully offset by a valuation allowance at December 31, 2012 and 2013.

The Company files U.S, California, and other state income tax returns with varying statutes of limitations. The tax years from inception in 2010 forward remain open to examination due to the carryover of unused net operating losses and tax credits.

A reconciliation of the Company's unrecognized tax benefits for the years ended December 31, 2012 and 2013 is as follows (in thousands):

	Deter	December 51,	
	2012	2013	
Balance at beginning of year	\$14	\$ 73	
Additions based on tax positions related to current year	59	319	
Additions for tax positions of prior years	_	357	
Balance at end of year	\$73	\$749	

The entire amount of the unrecognized tax benefits would not impact the Company's effective tax rate if recognized. During the years ended December 31, 2012 and 2013, the Company did not recognize accrued interest and penalties related to unrecognized tax benefits. The Company does not anticipate that the amount of existing unrecognized tax benefits will significantly increase or decrease during the next 12 months.

#### 12. Net Loss and Unaudited Pro Forma Net Loss Per Share

The following outstanding dilutive potential shares have been excluded from the calculation of diluted net loss per share for the periods presented due to their anti-dilutive effect:

	Decemb	December 31,	
	2012	2013	
Stock options outstanding	2,559,022	5,080,049	
Convertible preferred stock	15,259,595	15,259,595	
Convertible preferred stock warrants	598,503	7,732,652	

In addition 3,585,685 and 1,272,470 shares as of December 31, 2012 and 2013, respectively, were excluded as such shares represented common stock which is vesting contingently upon the holders' continued service to the Company.

### **Coherus BioSciences, Inc.**

#### Notes to Consolidated Financial Statements (continued)

#### 12. Net Loss and Pro Forma Unaudited Net Loss Per Share (continued)

The following table sets forth the computation of the unaudited pro forma basic and diluted net loss per share (in thousands, except share and per share data):

	-	ear Ended cember 31, 2013
Numerator:		
Net loss	\$	(53,635)
Change in fair value of preferred stock warrant liability		12,563
Net loss used in computing pro forma net loss per share, basic and diluted	\$	(41,072)
Denominator:		
Weighted-average number of shares used in net loss per share, basic and diluted		5,554,477
Pro forma adjustments to reflect:		
Assumed conversion of convertible preferred stock	1	5,259,595
Assumed exercise of preferred stock warrants for cash		3,674,040
Weighted-average number of shares used in computing pro forma net loss per share, basic and diluted	2	4,488,112
Pro forma net loss per share, basic and diluted	\$	(1.68)

#### 13. Related Party Transactions

### **Notes Receivable from Founders**

In December 2011, the Company entered into unsecured promissory notes ("Notes Receivable") with the four founders of the Company. Of the four founders, three are members of the executive team of the Company. The aggregate amount of Notes Receivable was \$133,000 at the issuance date and the Notes Receivable bore interest at 0.2% per annum. The Company recorded imputed interest of 4% in relation to these notes based on published interest rates for comparable notes. The principal amount of the Notes Receivable, together with all accrued and unpaid interest, was due and payable upon the earlier of: (i) December 26, 2014, (ii) immediately prior to the first filing of a registration statement in connection with an IPO, (iii) immediately prior to the Notes Receivable becoming prohibited under the rules and regulation of the Securities and Exchange Commission, (iv) immediately prior to an acquisition of the Company, (v) the termination of the borrower's employment with the Company or (vi) the occurrence of an event of default.

As of December 31, 2012 and 2013, the Company had \$123,000 and \$107,000, respectively of Notes Receivable outstanding which were reflected as notes receivable from related parties in the Company's consolidated balance sheets. The interest income related to these Notes Receivable was immaterial for the years ended December 31, 2012 and 2013.

In September 2013, the Company forgave the Notes Receivable and all accrued interest of \$21,000 held by one of the holders of the notes.

In May 2014, the Company forgave the Notes Receivable of \$111,000 and the related accrued interest of approximately \$1,000, which will be reflected in the Company's statement of operations in the quarter ended June 30, 2014.

### **Coherus BioSciences, Inc.**

#### Notes to Consolidated Financial Statements (continued)

#### 13. Related Party Transactions (continued)

#### Daiichi Sankyo

The Company entered into a license agreement with Daiichi Sankyo (see Note 5), under which the Company issued 4,780,000 shares of Series B convertible preferred stock. As such, Daiichi Sankyo was deemed to be a related party by ownership of more than 10% of the Company's equity. Accordingly, related party transactions of \$1.9 million and \$2.0 million were reported as collaboration and license revenue — related party in the Company's consolidated statements of operations and comprehensive loss for the years ended December 31, 2012 and 2013, respectively. As of December 31, 2012, the Company had \$158,000 in receivables from a related party, \$8.1 million of revenue was deferred under this agreement, of which \$2.0 million was included in current liabilities in the consolidated balance sheet. As of December 31, 2013, \$6.1 million of revenue was deferred under this agreement, of which \$2.0 million was included in current liabilities and \$4.1 million was included in non-current liabilities in the consolidated balance sheet. In addition, the Company recognized \$158,000 and \$1.3 million as a reduction of research and development expense related to the costs reimbursed by Daiichi Sankyo in the Company's consolidated statements of operations and comprehensive loss for the years ended December 31, 2012, and 2013, respectively.

#### **Transactions Associated with Cook**

In January and December 2012, the Company issued a total of 3,585,000 shares of Series B convertible preferred stock to Cook as consideration for past and future services. As such, Cook was deemed to be a related party by ownership of more than 10% of the Company's equity. As of December 31, 2012, the Company had \$7.6 million in prepaid clinical, material and manufacturing — related party, \$1.7 million in accounts payable — related party, and \$1.3 million in accrued clinical and manufacturing — related party all reflected on the Company's consolidated balance sheet. As of December 31, 2013, the Company had \$3.0 million in prepaid clinical, material and manufacturing — related party and \$278,000 in receivables from a related party, (see Note 4), all reflected on the Company's consolidated balance sheet. For the years ended December 31, 2012 and 2013, the Company recognized \$15.8 million and \$6.1 million, respectively, of services rendered by Cook within research and development expense in the consolidated statements of operations and comprehensive loss. These Series B convertible preferred stock issued to Cook were valued based upon the price paid by investors in transactions which closed near the date of issuance.

#### **Transactions Associated with Medpace**

One member of the Board of Directors is also the chief executive officer of Medpace. As such, the Medpace was deemed to be a related party. As of December 31, 2012, the Company had \$1.5 million in prepaid clinical, material and manufacturing — related party, \$2,000 in accounts payable — related party, and \$5,000 in accrued clinical and manufacturing — related party, all reflected on the Company's consolidated balance sheet associated with Medpace. As of December 31, 2013, the Company had \$198,000 in prepaid clinical, material and manufacturing — related party, \$383,000 in accounts payable — related party, and \$2.8 million in accrued clinical and manufacturing — related party, all reflected on the Company's consolidated balance sheet associated with Medpace. For the years ended December 31, 2012 and 2013, the Company recognized \$1.0 million and \$4.7 million, respectively, for services rendered by Medpace within research and development expense in the consolidated statements of operations and comprehensive loss. Additionally, the Company also has an agreement with Medpace which provides for a minimum purchase commitment of \$35.0 million for clinical trial services to be provided over the term of the agreement; however, the agreement is cancelable without cause by either party upon 30 days prior written notification. As of December 31, 2013, \$5.7 million of the services related to this agreement has been performed.

### **Coherus BioSciences, Inc.**

#### Notes to Consolidated Financial Statements (continued)

#### 13. Related Party Transactions (continued)

#### **Recruiting Services**

One member of the Board of Directors was the chief executive officer of a company that provided recruiting services to the Company. As such, the recruiting services provided were deemed to be related party transactions. As of December 31, 2012, the Company had \$35,000 and \$16,000 of prepaid expenses and accounts payable, respectively, and there were no such amounts as of December 31, 2013, on the Company's consolidated balance sheets associated with these recruiting services. During the year ended December 31, 2012, the Company recognized \$163,000 and \$61,000 for services rendered by the recruiting company within research and development expense, and general and administrative expense, respectively, in the Company's consolidated statement of operations and comprehensive loss. During the year ended December 31, 2013, the Company recognized \$35,000 and \$18,000 for services rendered by the recruiting company within research and development expense, and general and administrative expense, respectively, in the Company's consolidated statement of operations and comprehensive loss.

#### **Convertible Notes—Related Parties**

From July to September 2011, the Company entered into the 2011 Notes with certain investors, including some members of the Board of Directors and their affiliated companies and some members of management, for a total aggregate amount of \$10.4 million (see Note 7) and issued the 2011 Warrants B to purchase shares of the Company's preferred stock at an exercise price of \$0.01 per share (see Note 8). As such, the \$9.3 million of the total aggregate amount of the 2011 Notes were considered related party transactions. In January 2012, as a result of the Series B convertible preferred stock financing event, the \$9.3 million of the 2011 Notes and accrued interest of \$193,000 were automatically converted into 2,263,939 shares of Series B convertible preferred stock at the issuance price of \$4.1841 per share, the amount paid by the other Series B investors, and the 2011 Warrant B became exercisable for warrants to purchase 509,988 shares of Series B convertible preferred stock. For the year ended December 31, 2012, the Company recognized \$1.1 million of interest expense incurred on the debt and amortization of the debt discount within interest expense on the Company's consolidated statement of operations and comprehensive loss.

In July to September 2013, the Company entered into Bridge Loans with certain investors, including existing stockholders, some members of the Board of Directors and their affiliated companies and some members of management for a total aggregate amount of \$10.0 million (see Note 7) and issued 2013 Warrants to purchase shares of the Company's preferred stock at an exercise price of \$0.01 per share (see Note 8). As such \$7.1 million of the total aggregate amount of the Bridge Loans were considered related party transactions. As of December 31, 2013, the carrying value of the related party Bridge Loans was \$3.1 million, net of debt discount. In December 2013, following the receipt of the upfront license payment from the Baxter license agreement, the Company met the qualified licensing transaction revenue threshold (see Note 8). As a result the 2013 Warrants associated with the related party transaction became exercisable to purchase 5,054,850 shares of Series B convertible preferred stock. For the year ended December 31, 2013, the Company recognized \$3.3 million of interest expense related to the debt and amortization of debt discount within interest expense in the Company's consolidated statement of operations and comprehensive loss.

#### 14. Subsequent Events

The Company evaluated subsequent events through August 4, 2014, the date at which the consolidated financial statements were available for issuance.

## **Coherus BioSciences, Inc.**

## Notes to Consolidated Financial Statements (continued)

#### 14. Subsequent Events (continued)

#### **Convertible Preferred Stock and Warrants**

In February 2014, the first priority security interest held by Cook to certain of the Company's property and equipment in Camarillo, California was released.

Pursuant to a stock purchase agreement with Cook, the Company issued shares that were subject to repurchase upon the achievement of certain events (see Note 9). In February 2014, the \$5.0 million of Series B preferred stock held by Cook was purchased by a future investor in the company resulting in the release of the repurchase feature related to such shares.

During April and May 2014, warrants to purchase 7,420,944 shares of Series B convertible preferred stock were exercised for \$74,000, which included the 7,134,149 shares of Series B convertible preferred stock warrants related to the Bridge Loans.

In May 2014, the Company completed a financing resulting in the issuance of 9,149,993 shares of Series C convertible preferred stock, for net cash proceeds of \$54.7 million. In conjunction with the Series C convertible preferred stock financing, the Bridge Loans and the related accrued interest were automatically converted into 1,763,848 shares of Series C convertible preferred stock at the price per share of such financing, and the collateralized security interest of the Company's assets, tangible and intangible, under the Bridge Loans was released. In addition, the Company issued 16,667 shares of Series C convertible preferred stock in exchange for consulting services.

# Acquisition

On February 12, 2014, the Company completed the acquisition of InteKrin Therapeutics, Inc. ("InteKrin"), a privately held, clinical-stage biopharmaceutical company focused on the development and commercialization of novel drugs for the treatment of immune diseases such as multiple sclerosis. The Company believes that InteKrin's product portfolio is complementary to the Company's systemic focus in anti-inflammatories with the anti-tumor necrosis factor (TNF) portfolio composed of etanercept and adalimumab biosimilars. InteKrin's primary product candidate, INT-131, is in the clinical stage. The Company will account for the acquisition as the purchase of a business. The total consideration for the acquisition of InteKrin was determined to be \$5.0 million and consisted of: (a) the issuance of 1,194,686 shares of Series B convertible preferred stock with an estimated fair value of \$2.7 million, (b) the assumption of InteKrin's convertible promissory note payable to investors of InteKrin, which was concurrently paid off by issuing 406,483 shares of the Company's Series B convertible preferred stock with an estimated fair value of \$1.0 million; (c) a cash payment of \$1,485, and (d) contingent consideration of \$1.3 million at the acquisition date. The fair value of Series B convertible preferred stock issued to InteKrin shareholders of \$2.29 per share was determined using the PWERM.

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

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

## **Coherus BioSciences, Inc.**

# Notes to Consolidated Financial Statements (continued)

### 14. Subsequent Events (continued)

# Amendment to the Certificate of Incorporation

In May 2014, the Company amended its Certificate of Incorporation with the following authorized shares: 57,000,000 shares of common stock, 36,207,039 shares of convertible preferred stock which have been designated as 1,727,448 shares of Series A convertible preferred stock, 23,479,591 shares of Series B convertible preferred stock, and 11,000,000 shares of Series C convertible preferred stock and other terms (see Note 9).

# License Agreement with Baxter

The Company received cash of \$25.3 million in March 2014, \$20.0 million in June 2014 and \$15.0 million in July 2014 upon the achievement of certain events pursuant to the Baxter license agreement. Of the total aggregate amount of \$60.3 million received from Baxter, \$20.2 million is contingently subject to reimbursement to Baxter.

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# **Coherus BioSciences, Inc.**

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	Condensed Co	nsolidated Statemer	nts of Operations	
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- Condensed Consolidated Statements of Comprehensive Loss
- Condensed Consolidated Statements of Cash Flows
- Notes to Unaudited Condensed Consolidated Financial Statements

# Coherus BioSciences, Inc. Condensed Consolidated Balance Sheets (in thousands, except share and per share data)

				Pro Forma Stockholders'
		cember 31, 2013 Note 2)	June 30, 2014 (unaudited)	Equity as of June 30, 2014 (unaudited)
Assets	,	1010 2)	(unautiteu)	(unautiteu)
Current assets:				
Cash and cash equivalents	\$	39,554	\$ 108,869	
Restricted cash		50	50	
Receivables from related parties		278	_	
Notes receivable from related parties		107	_	
Prepaid assets		5,688	5,789	
Total current assets		45,677	114,708	
Property and equipment, net		1,743	3,037	
Intangible assets		_	2,620	
Goodwill		_	943	
Other assets		27	875	
Total assets	\$	47,447	\$ 122,183	
Liabilities, Convertible Preferred Stock and Stockholders' (Deficit) Equity				
Current liabilities:				
Accounts pavable	\$	3,302	\$ 5,395	
Accounts payable — related parties	Ŷ	383	3,020	
Accrued and other liabilities		7,279	7,007	
Deferred revenue		14,283	25,132	
Convertible notes		1,111		
Convertible notes — related parties		3,092	_	
Contingent consideration			2,420	
Convertible preferred stock warrant liability		24,251	1,589	\$ —
Total current liabilities		53,701	44,563	
Deferred revenue, non-current		28,567	37,164	
Contingent liability to collaborator		7,500	25,150	
Contingent consideration, non-current		_	595	
Other liabilities, non-current		61	135	
Total liabilities		89,829	107,607	
Commitments and contingencies (Note 8)			,	
Series A convertible preferred stock, \$0.0001 par value:				
Shares authorized: 1,800,000 and 1,727,448 at December 31, 2013 and June 30, 2014 (unaudited), respectively				
Shares issued and outstanding: 1,620,888 at December 31, 2013 and June 30, 2014 (unaudited), no shares authorized, issued				
and outstanding, pro forma (unaudited)				
Liquidation preference: \$1,216 at December 31, 2013 and June 30, 2014 (unaudited)		1,191	1,191	_
Series B convertible preferred stock, \$0.0001 par value:				
Shares authorized: 26,290,997 and 23,479,591 at December 31, 2013 and June 30, 2014 (unaudited), respectively				
Shares issued and outstanding: 13,638,707 and 22,674,443 at December 31, 2013 and June 30, 2014 (unaudited), respectively,				
no shares authorized, issued and outstanding, pro forma (unaudited)				
Liquidation preference: \$57,066 and \$94,872 at December 31, 2013 and June 30, 2014 (unaudited), respectively		53,504	94,630	_
Series C convertible preferred stock, \$0.0001 par value:				
Shares authorized: no shares at December 31, 2013 and 11,000,000 at June 30, 2014 (unaudited)				
Shares issued and outstanding: no shares at December 31, 2013 and 10,930,508 at June 30, 2014 (unaudited), no shares				
authorized, issued and outstanding, pro forma (unaudited)			CE 400	
Liquidation preference: \$0 and \$65,583 at December 31, 2013 and June 30, 2014 (unaudited) Stockholders' (deficit) equity:			65,403	_
Common stock, \$0.0001 par value:				
Shares authorized: 46,598,700 and 57,000,000 at December 31, 2013 and June 30, 2014 (unaudited), respectively				
Shares issued and outstanding: 8,064,479 and 7,708,937 at December 31, 2013 and June 30, 2014 (unadited), respectively,				
44,168,793 shares issued and outstanding pro forma (unaudited)		1	1	4
Additional paid-in capital		2,514	3,151	166,965
Accumulated other comprehensive income		2,314	32	32
Accumulated deficit		(99,592)	(149,719)	(149,719)
Total Coherus stockholders' (deficit) equity		(97,077)	(146,535)	17.282
Noncontrolling interests		(37,077)	(140,555)	(113)
Total stockholders' (deficit) equity		(07.077)		\$ 17,169
	<u> </u>	(97,077)	(146,648)	э 17,109
Total liabilities, convertible preferred stock and stockholders' (deficit) equity	\$	47,447	\$ 122,183	

See accompanying notes to condensed consolidated financial statements.

# **Coherus BioSciences, Inc.**

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

( · · · · · · · · · · · · · · · · · · ·				
	Six Months Ended June 30,			
		2013	ne 50,	2014
	(unaudited)			
Revenue:				
Collaboration and license revenue—related party	\$	1,013	\$	1,013
Collaboration and license revenue				7,548
Total revenue		1,013		8,561
Operating expenses:				
Research and development (includes related party of \$7,668 and \$10,961 for the six months ended June 30, 2013				
and 2014, respectively)		17,123		32,861
General and administrative		2,613		7,399
Total operating expenses		19,736		40,260
Loss from operations	(	18,723)		(31,699)
Interest expense (includes related party of \$0 and \$2,687 for the six months ended June 30, 2013 and 2014,				
respectively)		—		(3,899)
Other income (expense), net		1,152		(14,642)
Net loss	(	17,571)		(50,240)
Net loss attributable to noncontrolling interests				113
Net loss attributable to Coherus	\$ (	17,571)	\$	(50,127)
Net loss per share attributable to Coherus, basic and diluted	\$	(3.55)	\$	(7.19)
Weighted-average number of shares used in computing net loss per share attributable to Coherus, basic and diluted	4,9	47,171	(	5,971,482
Pro forma net loss per share attributable to Coherus, basic and diluted			\$	(1.18)
Weighted-average number of shares used in computing pro forma net loss per share attributable to Coherus, basic				
and diluted			30	),145,504
See accompanying notes to condensed concolidated financial statements				

See accompanying notes to condensed consolidated financial statements.

# **Coherus BioSciences, Inc.**

# Condensed Consolidated Statements of Comprehensive Loss

# (in thousands)

		ths Ended e 30,
	2013	2014
	(unau	idited)
Net loss	\$(17,571)	\$(50,240)
Other comprehensive income:		
Foreign currency translation adjustments, net of tax	—	32
Comprehensive loss	(17,571)	(50,208)
Comprehensive loss attributable to noncontrolling interest	_	113
Comprehensive loss attributable to Coherus	\$(17,571)	\$(50,095)

See accompanying notes to condensed consolidated financial statements.

# **Coherus BioSciences, Inc.**

# **Condensed Consolidated Statements of Cash Flows**

(in thousands)

		hs Ended e 30,
	2013	2014
	(unau	dited)
Operating activities Net loss	¢(17 F71)	¢ (FO 240)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:	\$(17,571)	\$ (50,240)
Depreciation and amortization	195	247
Remeasurement of contingent consideration		1,705
Remeasurement of convertible preferred stock warrant liability	(1,153)	14,666
Preferred stock issued in exchange for services	7,393	14,000
Non-cash interest expense		3,897
Gain on extinguishment of 2013 Notes		(2,048)
Stock-based compensation expense	736	(2,048) 4,501
Changes in operating assets and liabilities:	730	4,501
Receivables from related parties	156	278
		107
Notes receivable from related parties	(2)	5
Prepaid assets Other current assets	1,445 37	
Other assets	57	(11)
	(278)	1,562
Accounts payable Accounts payable — related parties	(1,631)	2,637
Accrued and other liabilities	(1,031)	(299)
Deferred revenue	(1,013)	19,446
	624	19,440
Advance payments under license agreements with related party Contingent liability to collaborator		17,650
Other liabilities, non-current	(1)	315
Net cash (used in) provided by operating activities	(11,089)	14,528
Investing activities		2.224
Net cash acquired from acquisition of InteKrin Therapeutics, Inc.	(172)	2,334
Purchases of property and equipment	(172)	(1,553)
Net cash (used in) provided by investing activities	(172)	781
Financing activities		
Proceeds from issuance of convertible preferred stock, net of issuance cost		54,720
Proceeds from issuance of convertible preferred stock upon exercise of warrants	—	74
Proceeds from issuances of common stock upon exercise of stock options	—	19
Repurchase of restricted common stock	—	(2)
Payment of costs related to initial public offering		(837)
Net cash provided by financing activities	—	53,974
Effect of exchange rate changes in cash and cash equivalents		32
Net (decrease) increase in cash and cash equivalents	(11,261)	69,315
Cash and cash equivalents at beginning of period	14,548	39,554
Cash and cash equivalents at end of period	\$ 3,287	\$108,869

See accompanying notes to condensed consolidated financial statements.

## **Coherus BioSciences, Inc.**

#### Notes to Unaudited Condensed Consolidated Financial Statements

#### 1. Organization and Operations

#### **Description of the Business**

Coherus BioSciences, Inc. (the "Company" or "Coherus") was incorporated in the state of Delaware as BioGenerics, Inc. in September 2010 and changed its name to Coherus BioSciences, Inc. in April 2012. The Company is a late-stage clinical biologics platform company, focused on the global biosimilar market. The Company's headquarters and laboratory are located in Redwood City, California and in Camarillo, California, respectively. The Company operates in one segment.

#### Need to Raise Additional Capital

As of June 30, 2014, the Company had an accumulated deficit of \$150.0 million and cash and cash equivalents of \$108.9 million. The Company believes that its current available cash and cash equivalents together with the cash received from Baxter International, Inc. ("Baxter") of \$15.0 million in July 2014 (see Note 13), will be sufficient to fund its planned expenditures and meet the Company's obligations through at least September 30, 2015. However, if the anticipated operating results are not achieved in future periods, the planned expenditures may need to be reduced in order to extend the time period over which the then-available resources would be able to fund the operations. The Company may need to raise additional funds in the future, however there can be no assurance that such efforts will be successful or that, in the event that they are successful, the terms and conditions of such financing will be favorable.

### 2. Basis of Presentation and Summary of Significant Accounting Policies

#### **Unaudited Condensed Consolidated Financial Statements**

The accompanying condensed consolidated financial statements include the accounts of Coherus and its wholly owned subsidiaries as of June 30, 2014: Coherus Intermediate Corp, InteKrin Therapeutics, Inc. ("InteKrin"), and its 82.5% majority owned subsidiary of InteKrin Russia. The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP"), for interim financial information and pursuant to the Article 10 of Regulation S-X of the Securities Act of 1933, as amended (Securities Act). Accordingly, they do not include all of the information and notes required by U.S. GAAP for complete financial statements. These unaudited condensed consolidated financial statements include only normal and recurring adjustments that the Company believes are necessary to fairly state the financial position and the results of the Company's operations and cash flows. Interim-period results are not necessarily indicative of results of operations or cash flows for a full year or any subsequent interim period. The condensed consolidated balance sheet at December 31, 2013 has been derived from audited financial statements at that date, but does not include all disclosures required by U.S. GAAP for complete financial statements. Because all of the disclosures required by U.S. GAAP for complete financial statements are not included herein, these unaudited condensed consolidated financial statements and the notes accompanying them should be read in conjunction with our audited consolidated financial statements include elsewhere in this prospectus.

#### **Unaudited Pro Forma Presentation**

The unaudited pro forma stockholders' equity as of June 30, 2014 reflects the assumed conversion of all the outstanding shares of convertible preferred stock into shares of common stock, as if such shares were issued as common stock initially, the assumed exercise, for cash, of all outstanding warrants as of January 1, 2014, and the reclassification of the convertible preferred stock warrant liability into stockholders' equity.

Unaudited pro forma basic and diluted net loss per share attributable to Coherus has been computed using the weighted-average number of shares of common stock outstanding after giving effect to the assumed

## **Coherus BioSciences, Inc.**

#### Notes to Unaudited Condensed Consolidated Financial Statements (continued)

#### 2. Basis of Presentation and Summary of Significant Accounting Policies (continued)

conversion of all the outstanding shares of convertible preferred stock and the assumed cash exercise of the convertible preferred stock warrants upon the closing of the IPO. For purposes of pro forma basic and diluted net loss per share attributable to Coherus, all shares of convertible preferred stock have been treated as though they have been converted to common stock at the later of the issuance date or on January 1, 2014. Also, the numerator in the pro forma basic and diluted net loss per share attributable to Coherus calculation has been adjusted to remove gains or losses resulting from the remeasurement of the convertible preferred stock warrant liability related to warrants to purchase shares of convertible preferred stock. The pro forma net loss per share attributable to Coherus does not include the shares expected to be sold and related proceeds to be received from the IPO.

## **Foreign Currency**

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

#### **Deferred Offering Costs**

Deferred offering costs, which primarily consist of direct incremental legal and accounting fees relating to the IPO, are capitalized. The deferred offering costs will be offset against IPO proceeds upon the consummation of the offering. In the event the offering is terminated, deferred offering costs will be expensed. As of June 30, 2014, \$0.8 million of deferred offering costs were capitalized in other assets on the condensed consolidated balance sheet. No deferred offering costs were capitalized as of December 31, 2013.

#### **Derivative Liability**

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

# **Coherus BioSciences, Inc.**

#### Notes to Unaudited Condensed Consolidated Financial Statements (continued)

# 2. Basis of Presentation and Summary of Significant Accounting Policies (continued)

#### **Customer Concentration**

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

	SIX MUILUS	Linucu
	June 3	10,
	2013	2014
Daiichi Sankyo — related party	100%	12%
Baxter	_	88%

Six Months Ended

#### **Revenue Recognition**

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

The Company enters into collaboration and license agreements for the development and commercialization of biosimilar products. The Company's performance obligations under the terms of these agreements may include (i) transfer of intellectual property rights (licenses), (ii) providing research and development services, (iii) the manufacture of drug materials for development purposes and (iv) participation on certain committees with the collaborators. Payments to the Company under these agreements may include nonrefundable up front license fees, payments for research and development services, payments for the manufacture of drug materials, payments based upon the achievement of defined collaboration objectives and royalties on product sales. Under these agreements the Company may convey the right to sell products resulting from the collaborative efforts of the parties in specific geographic territories.

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

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

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

## **Coherus BioSciences, Inc.**

## Notes to Unaudited Condensed Consolidated Financial Statements (continued)

## 2. Basis of Presentation and Summary of Significant Accounting Policies (continued)

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

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

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

#### **Comprehensive Loss**

Comprehensive loss is composed of two components: net loss and other comprehensive income (loss). Other comprehensive income (loss) refers to gains and losses that under U.S. GAAP are recorded as an element of stockholders' equity (deficit), but are excluded from net loss. The Company's other comprehensive loss included foreign currency translation adjustments for the six months ended June 30, 2014.

# Net Loss per Share Attributable to Coherus

Basic net loss per share attributable to Coherus is calculated by dividing the net loss attributable to Coherus by the weighted-average number of shares of common stock outstanding for the period, without consideration for potential dilutive common shares. Since the Company was in a loss position for all periods presented, basic net loss per share attributable to Coherus is the same as diluted net loss per share attributable to Coherus as the inclusion of all potential dilutive common shares would have been anti-dilutive. Shares of common stock subject to repurchase are excluded from the calculation of weighted average shares as the vesting of such shares is contingent upon continued services being rendered by such holders. For the computation of net loss per share for the six months ended June 30, 2013 and 2014, 2,641,577 and 540,863 shares subject to repurchase, respectively, were excluded from the computation of net loss per share attributable to Coherus, basic and diluted.

# **Coherus BioSciences, Inc.**

## Notes to Unaudited Condensed Consolidated Financial Statements (continued)

#### 3. Fair Value Measurements

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

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

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

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

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

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

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

			leasurements r 31, 2013	
	Total	Level 1	Level 2	Level 3
issets:				
Restricted cash (money market funds)	<u>\$ 50</u>	<u>\$50</u>	<u>\$                                    </u>	<u>\$                                    </u>
iabilities:				
Convertible preferred stock warrant liability	\$24,251	<u>\$                                    </u>	<u>\$                                    </u>	\$24,251
			leasurements 0, 2014	
	Total	Level 1	Level 2	Level 3
issets:				
Certificate of deposit	\$ 900	\$ 900	\$ —	\$ —
Certificate of deposit denominated in Rubles	267	267	—	
Money market funds	31	31	—	
Restricted cash (money market funds)	50	50	—	
Total financial assets	\$1,248	\$ 1,248	\$	\$ —
iabilities:				
Convertible preferred stock warrant liability	\$1,589	\$ —	\$ —	\$1,589
Contingent consideration	3,015			3,015
Total financial liabilities	\$4,604	\$	\$	\$4,604

# **Coherus BioSciences, Inc.**

## Notes to Unaudited Condensed Consolidated Financial Statements (continued)

# 3. Fair Value Measurements (continued)

There were no transfers between Level 1 and Level 2 during the periods presented.

The fair value of the convertible preferred stock warrants was determined based on Level 3 inputs. The Company determined the fair value of the warrants by allocating the Company's equity value, using the Probability-Weighted Expected Return Method ("PWERM"). The Company's equity value was allocated among preferred stock, common stock, warrants and stock options expected to be outstanding at the liquidity events based on the rights and preferences of each class. The option-pricing model includes assumptions related to the fair value of the shares, the exercise price, expected volatility, expected term, risk-free interest rate, and the expected dividend yield. The estimated expected volatility was based on the volatility of common stock of a group of comparable, publicly-traded companies. The estimated expected term was based on the estimated time to liquidity event. The risk-free interest rate was based on the U.S. Treasury yield for a term consistent with the estimated expected term. The significant unobservable input used in the fair value measurement of the convertible preferred stock warrant liability is the fair value of the underlying preferred stock at the valuation remeasurement date. Generally, increases (decreases) in the fair value of the underlying preferred stock would result in a directionally similar impact to the fair value measurement.

The following table sets forth a summary of the changes in the estimated fair value of the convertible preferred stock warrants (in thousands):

Balance as of December 31, 2013	\$ 24,251
Warrants exercised	(37,328)
Change in fair value of convertible preferred stock warrant liability	14,666
Balance as of June 30, 2014	\$ 1,589

As part of the InteKrin acquisition, the Company recognized contingent consideration associated with payments to be made to the former InteKrin shareholders upon the achievement of certain events specified in the agreements (see Note 6). This fair value measurement is based on significant inputs not observable in the market and thus represents a Level 3 measurement within the fair value hierarchy. The Company valued the two contingent consideration scenarios (the Earn-Out Payment and the Compound Transaction Payment) using a probability-weighted discounted cash flow approach. A probability of reaching each contingent consideration threshold was estimated by Company's management. A probability-weighted value was determined by summing the probability of achieving each contingent payment threshold by the respective contingent payment. The expected cash flows were discounted at a rate of 60% selected to capture the risk of achieving contingent payment thresholds and earning contingent payment. This risk is comprised of InteKrin's continued development, a specific risk factor associated with meeting each contingent consideration threshold and related payout and counterparty risk associated with the payment of the contingent consideration.

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

Balance as of February 12, 2014 (acquisition date)	\$1,310
Change in fair value of contingent consideration	1,705
Balance as of June 30, 2014	\$3,015

# **Coherus BioSciences, Inc.**

# Notes to Unaudited Condensed Consolidated Financial Statements (continued)

# 4. Balance Sheet Components

# **Prepaid Assets**

Prepaid assets are as follows (in thousands):

	December 31, 2013	June 30, 2014
Prepaid clinical, material, manufacturing and other — related parties	\$ 3,177	<u>2014</u> \$ 392
Prepaid clinical, material and manufacturing	1,758	4,088
Prepaid other	753	1,309
Prepaid assets	\$ 5,688	\$5,789

# **Property and Equipment, Net**

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

	December 31, 2013	June 30, 2014
Machinery and equipment	\$ 2,051	<u>2014</u> \$3,093
Computer equipment and software	79	201
Furniture and fixtures	147	195
Leasehold improvements	91	102
Construction in progress		318
Total property and equipment	2,368	3,909
Accumulated depreciation and amortization	(625)	(872)
Property and equipment, net	\$ 1,743	\$3,037

Depreciation expense was \$195,000 and \$247,000 for the six months ended June 30, 2013 and 2014, respectively.

In February 2014, the first priority security interest held by Cook Pharmica LLC ("Cook"), a CMO, to certain of the Company's property and equipment in Camarillo, California was released.

# Accrued and Other Liabilities

Accrued and other liabilities are as follows (in thousands):

	December 31, 2013	June 30, 2014
Accrued clinical and manufacturing — related parties	\$ 2,792	<u>2014</u> \$2,223
Accrued compensation	1,549	956
Accrued professional and consulting fees	995	355
Accrued other	1,922	3,396
Other current liabilities	21	77
Accrued and other liabilities	\$ 7,279	\$7,007

# **Coherus BioSciences, Inc.**

#### Notes to Unaudited Condensed Consolidated Financial Statements (continued)

#### 5. Collaboration and License Agreements

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

		Six Months Ended June 30,	
	2013	2014	
Daiichi Sankyo — related party	\$ 1,013	\$ 1,013	
Baxter		7,548	
Total collaboration and license revenue	\$ 1,013	\$ 8,561	

#### Daiichi Sankyo

In January 2014, the Company and Daiichi Sankyo Company, Limited ("Daiichi Sankyo") entered into the Memorandum of Understanding No. 2 (the "MOU 2") in which both parties agreed to cooperate to conduct a global Phase 3 clinical trial in rheumatoid arthritis and that Daiichi Sankyo will be responsible for a minimum of 20% of the cost of the clinical trial. Also, both parties entered into a clinical supply agreement contemporaneously with the MOU 2 in which the Company will supply finished study drug and study comparator drug for Daiichi Sankyo's use in the Japanese portion of the product's clinical trial. Daiichi Sankyo shall reimburse these research and development costs in quarterly advance payments, which the Company has recorded as advance payments under the license agreement with related party in the condensed consolidated balance sheet as of June 30, 2014. The Company will recognize the advance payment as a reduction in the research and development expense when the research and development activity has been performed.

As of December 31, 2013, \$6.1 million of revenue was deferred under all arrangements with Daiichi Sankyo, of which \$2.0 million was included in current liabilities and \$4.1 million was included in non-current liabilities in the condensed consolidated balance sheet. As of June 30, 2014, \$5.1 million of revenue was deferred, of which \$2.0 million was included in current liabilities and \$3.1 million was included in non-current liabilities in the condensed consolidated balance sheet. In addition, the Company recognized \$0.5 million and \$2.4 million as a reduction of research and development expense related to the costs reimbursed by Daiichi Sankyo in the Company's condensed consolidated statements of operations for the six months ended June 30, 2013 and 2014, respectively.

#### Baxter

In February 2014, the Company and Baxter amended the license agreement to increase the non-substantive contingent milestone payments for an additional \$5.3 million. The Company concluded that this amendment did not materially affect the underlying terms and conditions of the original agreement.

In March 2014, the Company received a \$25.3 million contingent milestone payment which included the \$5.3 million referenced above. The Company recorded \$12.7 million as deferred revenue, which is being amortized over the remaining estimated performance period under the Baxter agreement. The remaining \$12.7 million was recorded as contingent liability to collaborator due to the potential refund of such amount to Baxter.

As of December 31, 2013, \$36.8 million of revenue was deferred under all arrangements with Baxter, of which \$12.3 million was included in current liabilities and \$24.5 million was included in non-current liabilities in the condensed consolidated balance sheet. As of December 31, 2013, \$7.5 million was recorded as contingent liability to collaborator in the condensed consolidated balance sheet due to the potential refund to Baxter.

As of June 30, 2014, \$56.9 million of revenue was deferred under all arrangements with Baxter, of which \$22.8 million was included in current liabilities and \$34.1 million was included in non-current liabilities in the

## Coherus BioSciences, Inc.

#### Notes to Unaudited Condensed Consolidated Financial Statements (continued)

#### 5. Collaboration and License Agreements (continued)

condensed consolidated balance sheet. As of June 30, 2014, \$25.2 million was recorded as contingent liability to collaborator due to the potential refund of such amount to Baxter in the future.

## 6. Acquisition of InteKrin Therapeutics, Inc.

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

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

The Company accounted for the InteKrin acquisition as the purchase of a business. The Company expensed the related acquisition costs, consisting primarily of legal expenses in the amount of \$134,000. These legal expenses are recorded in general and administrative expense in the condensed consolidated statement of operations for the six months ended June 30, 2014. The total consideration of \$5.0 million consists of: (a) issuance of 1,194,686 shares of Series B preferred stock with a fair value of \$2.7 million, (b) assumption of InteKrin's convertible promissory note payable to an InteKrin shareholder, which was concurrently paid off by issuing 406,483 shares of the Company's Series B convertible preferred stock with a fair value of \$1.0 million (c) cash payment of \$1,485, and (d) contingent consideration of \$1.3 million. The Company determined the fair value of the Series B convertible preferred stock of \$2.29 per share using the PWERM. The noncontrolling interest was not deemed to be significant at acquisition.

Pro forma results of operations for this acquisition have not been presented as such results are not material to the Company's results of operations for the six months ended June 30, 2013 and 2014.

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

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

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

## **Coherus BioSciences, Inc.**

#### Notes to Unaudited Condensed Consolidated Financial Statements (continued)

## 6. Acquisition of InteKrin Therapeutics, Inc. (continued)

#### Intangible Asset — IPR&D

The IPR&D consists of InteKrin's INT-131. The Company determined the fair value of the IPR&D based on the cost to recreate the asset to its current stage as the fair value is not determinable as result of the lack of financial projections for this asset due to its early development stage. By applying this method, management estimated that \$2.6 million of the acquisition consideration represents the fair value of the IPR&D. The IPR&D acquired through the InteKrin acquisition is treated as an indefinite-lived intangible asset and an annual impairment review will be performed by management. Once this product has been developed and commercialized, the useful life will be determined, and the carrying value of the finite-lived asset will be amortized prospectively over that estimated useful life. Alternatively, if this product is abandoned, the carrying value of the IPR&D will be charged to research and development expense.

#### **Contingent Consideration**

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

*Contingent Consideration* — *Earn-out Payment:* Upon completion of the first dosing of a human subject in the first Phase 2 clinical trial for InteKrin, InteKrin's stockholders can earn a minimal cash payment and 597,303 shares of the Company's Series B convertible preferred stock upon the successful achievement of this objective. The Company expects the first dosing to be completed in September 2014 and has assigned a 75% success probability to the achievement of this event. At the acquisition date, the fair value of the contingent consideration related to this earn-out payment was determined to be \$0.8 million.

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

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

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

## Goodwill

Goodwill resulting from this acquisition comprises the excess of the purchase price over the fair value of the underlying net assets acquired and primarily represents the strategic relationship acquired with InteKrin's investors. None of this goodwill will be deductible for tax purposes. Under the applicable accounting guidance, goodwill will not be amortized but will be tested for impairment on an annual basis or more frequently if certain indicators are present.

## **Coherus BioSciences, Inc.**

#### Notes to Unaudited Condensed Consolidated Financial Statements (continued)

#### 7. Debt Obligations

#### **Convertible Notes Issued in 2013**

During July 2013 to September 2013, the Company entered into convertible note agreements (the "Bridge Loans") with various stockholders, employees and institutions for an aggregate principal amount of \$10.0 million. The Bridge Loans accrued interest of 8% per annum and would mature on July 15, 2014. The principal and the accrued interest on the Bridge Loans were convertible: (i) automatically upon a qualified equity financing into shares of the series of capital stock issued in such financing at a conversion price equal to the price paid by other investors in the financing, (ii) at the option of the holder, upon a change of control of Coherus, into shares of Series B convertible preferred stock at a conversion price of \$4.1841 per share, (iii) automatically upon an IPO into shares of the holders, if none of the liquidity events stated above had occurred on or before maturity date, into shares of Series B convertible preferred stock at a conversion price of \$4.1841 per share.

In connection with the Bridge Loans, the Company also issued warrants to purchase shares of its convertible preferred stock at an exercise price of \$0.01 per share. The determination of the number of shares issuable pursuant to the 2013 warrants was determined based on 300% of the principal amount of the Bridge Loans divided by the conversion price. In addition, at the issuance date of the notes, there was a beneficial conversion feature. The total aggregate Bridge Loans of \$10.0 million was less than the initial fair value of the warrants of \$13.6 million at the issuance date. Therefore \$10.0 million was recognized as debt discount, and the difference of \$3.6 million was immediately charged to other income (expense), net in the consolidated statement of operations and comprehensive loss as the carrying value of the debt could not be reduced to less than zero. No value was recorded initially for the beneficial conversion feature since the carrying value of the debt discount of \$10.0 million was accreted using the effective interest method as an additional interest expense over the term of the Bridge Loans.

In May 2014, the Company completed an equity financing of Series C convertible preferred stock and, as a result, the Bridge Loans and related accrued interest of \$10.6 million automatically converted into 1,763,848 shares of Series C convertible preferred stock based on the price per share paid by other investors in the financing. In connection with the extinguishment of the Bridge Loans, the Company reacquired the beneficial conversion feature. The intrinsic value of the beneficial conversion feature at the date of the Bridge Loans extinguishment was \$3.9 million. This amount is reflected in additional paid in capital. The Company recorded a gain from the extinguishment of the debt in the amount of \$2.0 million which is reflected in other income (expense), net in the condensed consolidated statement of operations.

In addition, as the warrants could be exercised for Series B convertible preferred stock any time after achieving a qualified licensing threshold which was met on December 9, 2013 and before the Series C convertible preferred stock financing, in April and May 2014, all holders of these warrants elected to fully exercise warrants for 7,134,149 shares of Series B convertible preferred stock.

The Company recognized total interest expense of \$4.8 million during the year ended December 31, 2013 and \$3.9 million for the six months ended June 30, 2014 related to the accrued interest and amortization of the debt discount.

#### 8. Commitments and Contingencies

The Company enters into contracts in the normal course of business with contract research organizations for preclinical studies and clinical trials and contract manufacturing organizations ("CMOs") for the manufacture of clinical trial materials. As of June 30, 2014, the Company has a commitment of \$1.9 million with CMOs for the manufacture of clinical trial material due within a year. The Company has an agreement

## Coherus BioSciences, Inc.

#### Notes to Unaudited Condensed Consolidated Financial Statements (continued)

#### 8. Commitments and Contingencies (continued)

with Medpace, Inc. ("Medpace"), a CRO, which provides for a minimum fee commitment of \$35.0 million, in aggregate, for clinical trial services; however, the agreement is cancelable without cause by either party upon 30 days prior notification by either party. As of June 30, 2014, \$14.2 million of the services related to this agreement had been performed.

# 9. Common Stock Warrants and Preferred Stock Warrants

In March 2014, the Company issued warrants to purchase 922,309 shares of common stock with the exercise price of \$1.00 per share to two employees and one consultant for past services. The warrants are exercisable upon issuance and expire at the earlier of: (i) March 28, 2024, (ii) an IPO or (iii) the consummation of a liquidation event. If the holder has not exercised this warrant prior to the closing of a liquidation event or an IPO, these warrants shall automatically be net exercised. The Company valued the warrants at \$2.7 million using the Black-Scholes option-pricing model with the following assumptions: exercise price of \$1.00 per share, fair value of the common stock of \$3.44 per share, expected volatility of 93% and 96% for the employee and consultant warrants, respectively, expected terms of 5 and 10 years for the employee and consultant warrants, respectively, and dividend yield of zero. The grant date fair value per warrant share was \$2.97 for employees and \$3.25 for the consultant, resulting in warrant valuations of \$2.6 million and \$144,000 for the employees and consultant, respectively. Due to the immediate exercisability of the warrants upon issuance, the Company immediately recognized \$1.3 million and \$1.4 million of stock-based compensation in research and development expense and general and administrative expense, respectively, in the condensed consolidated statement of operations. None of the warrants were exercised as of June 30, 2014.

During April and May 2014, warrants to purchase 7,420,944 shares of Series B convertible preferred stock were exercised for \$74,000, which included the 7,134,149 shares of Series B convertible preferred stock warrants related to the Bridge Loans (see Note 7).

# 10. Stock-Based Compensation

#### **Founders Shares**

In October 2010 and January 2011, the Company issued 6,885,000 shares and 1,615,000 shares of common stock, respectively, at \$0.005 per share to its founders under the Founder Shares agreements. These Founders Shares agreements required continued rendering of service to the Company in order to vest in those shares. As such, the Company recognized stock-based compensation over the vesting term of four years based on the fair value of the common stock on the dates of issuance. In March 2014, the Company repurchased 400,000 shares of founders' common stock from three founders at \$0.005 per share. As of June 30, 2014, there were 540,863 shares subject to repurchase.

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

	Six Mont	Six Months Ended	
	June	June 30,	
	2013	2014	
Research and development	\$ 97	\$ 236	
General and administrative	257	2	
	\$ 354	\$ 238	

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The total unrecognized stock compensation expense as of June 30, 2014 of \$0.6 million will be amortized as the shares vest over the remaining service period of 0.8 years.

# **Coherus BioSciences, Inc.**

# Notes to Unaudited Condensed Consolidated Financial Statements (continued)

# 10. Stock-Based Compensation (continued)

# 2010 Stock Plan

The following table sets forth the summary of option activities under the 2010 Stock Plan (the "Plan") during the six months ended June 30, 2014:

		Options Outstanding	
	Shares Available for Grant	Number of Options	Weighted- Average Exercise Price
Balances at December 31, 2013	1,707,383	5,080,049	\$ 0.856
Authorized (unaudited)	3,500,000	—	
Granted — below fair value (unaudited)	(4,496,675)	4,496,675	1.098
Exercised (unaudited)	—	(44,458)	0.430
Forfeited (unaudited)	280,706	(280,706)	1.175
Balances at June 30, 2014 (unaudited)	991,414	9,251,560	\$ 0.966

The weighted average assumptions used to value options granted to employees under the Plan during the six months ended June 30, 2013 and 2014 were as follows:

		Six Months Ended June 30,	
	2013	2014	
Expected term (years)	5.51	6.5	
Expected volatility	109%	99%	
Risk-free interest rate	0.89%	2.07%	
Expected dividend yield	0.0%	0.0%	

The stock-based compensation expense recorded related to options granted to employees and nonemployees was as follows (in thousands):

		Six Months Ended June 30,	
	2013	2014	
Research and development	\$ 202	\$ 690	
General and administrative	180	877	
	\$ 382	\$ 1,567	

As of June 30, 2014, total unrecognized compensation expense related to unvested employee and non-employee stock options was \$17.0 million, which is expected to be recognized over the remaining weighted-average vesting period of approximately 3.49 years.

# **Coherus BioSciences, Inc.**

#### Notes to Unaudited Condensed Consolidated Financial Statements (continued)

#### 11. Net Loss and Pro Forma Net Loss Per Share Attributable to Coherus

The following outstanding dilutive potential shares have been excluded from the calculation of diluted net loss per share attributable to Coherus for the periods presented due to their anti-dilutive effect:

	June	June 30,	
	2013	2014	
Stock options outstanding	3,943,059	9,251,560	
Convertible preferred stock	15,259,595	35,225,839	
Convertible preferred stock warrants	598,503	311,708	
Common stock warrants	—	922,309	

In addition, 2,641,577 and 540,853 shares as of June 30, 2013 and 2014, respectively, were excluded as such shares represented restricted common stock which is vesting contingently upon the holders' continued service to the Company. Furthermore, 597,303 shares of Series B convertible preferred shares contingently issuable upon the successful achievement of an objective associated with contingent consideration payable to former InteKrin stockholders have also been excluded.

The following table sets forth the computation of the unaudited pro forma basic and diluted net loss per share attributable to Coherus (in thousands, except share and per share data):

		ix Months Ended ne 30, 2014
Numerator:		
Net loss attributable to Coherus	\$	(50,127)
Change in fair value of preferred stock warrant liability		14,666
Net loss used in computing pro forma net loss per share attributable to Coherus, basic and diluted	\$	(35,461)
Denominator:		
Weighted-average number of shares used in net loss per share attributable to Coherus, basic and diluted	(	6,971,482
Pro forma adjustments to reflect;		
Assumed conversion of convertible preferred stock	22	2,378,229
Assumed exercise of common and preferred stock warrants for cash		795,793
Weighted-average number of shares used in computing pro forma net loss per share attributable to Coherus, basic and		
diluted	30	0,145,504
Pro forma net loss per share attributable to Coherus, basic and diluted	\$	(1.18)

#### 12. Related Party Transactions

#### **Notes Receivable from Founders**

In December 2011, the Company entered into unsecured promissory notes ("Notes Receivable") agreement with the four founders of the Company. Of the four founders, three are members of the executive team of the Company. The aggregate amount of Notes Receivable was \$133,000 at the issuance date and the Notes Receivable bore interest at 0.2% per annum. The Company recorded an imputed interest of 4% in relation to these notes. The principal amount of the Notes Receivable, together with all accrued and unpaid interest, was due and payable upon the earlier of: (i) December 26, 2014, (ii) immediately prior to the first filing of a registration statement in connection with an IPO, (iii) immediately prior to the Notes Receivable becoming prohibited under the rules and regulation of the Securities and Exchange Commission, (iv) immediately prior to an acquisition of the Company, (v) the termination of the borrower's employment with the Company or (vi) the occurrence of an event of default.

## **Coherus BioSciences, Inc.**

#### Notes to Unaudited Condensed Consolidated Financial Statements (continued)

#### 12. Related Party Transactions (continued)

As of December 31, 2013, the Company had \$107,000 of Notes Receivable outstanding, which is reflected as notes receivable from related parties in the Company's consolidated balance sheets. The interest income related to these Notes Receivable was immaterial for the six months ended June 30, 2013 and 2014.

In May 2014, the Company forgave the outstanding balance of Notes Receivable of \$111,000 and the related accrued interest of approximately \$1,000, which is reflected in the Company's statement of operations for the six months ended June 30, 2014.

#### Daiichi Sankyo

The Company entered into a license agreement with Daiichi Sankyo, under which the Company issued 4,780,000 shares of Series B convertible preferred stock. As such, Daiichi Sankyo was deemed to be a related party by ownership of more than 10% of the Company's equity. Accordingly, related party transactions of \$1.0 million were reported as collaboration and license revenue–related party in the Company's statements of operations for each of the six months ended June 30, 2013 and 2014. As of December 31, 2013, \$6.1 million of revenue was deferred under this agreement, of which \$2.0 million was included in current liabilities in the consolidated balance sheet. As of June 30, 2014, the Company had \$5.1 million in deferred revenue under this agreement, of which \$2.0 million was included in current liabilities and \$3.1 million was included in non-current liabilities in the Company recognized \$0.5 million and \$2.4 million as a reduction of research and development expense related to the costs reimbursed by Daiichi Sankyo in the Company's condensed consolidated statements of operations for the six months ended June 30, 2013 and 2014, respectively.

#### **Transactions Associated with Cook**

In January and December 2012, the Company issued a total of 3,585,000 shares of Series B convertible preferred stock to Cook as consideration for past and future services. As such, Cook was deemed to be a related party by ownership of more than 10% of the Company's equity. As of December 31, 2013, the Company had \$3.0 million in prepaid assets (prepaid clinical, material and manufacturing–related parties) and \$278,000 in receivables from related parties, reflected on the Company's condensed consolidated balance sheet associated with Cook. During the second quarter of 2014, Cook divested a majority of its shares of the Company's Series B convertible preferred stock; therefore, as of June 30, 2014, Cook was no longer considered a related party. As a result, the condensed consolidated balance sheet as of June 30, 2014 no longer reflects these balances as related party amounts. For the six months ended June 30, 2013 and 2014, the Company recognized \$5.3 million and \$4.3 million of services rendered by Cook within research and development expense in the condensed consolidated statements of operations, respectively.

#### **Transactions Associated with Medpace Agreement**

One member of the Board of Directors is also the chief executive officer of Medpace. As such, Medpace was deemed to be a related party. As of December 31, 2013, the Company had \$198,000 in prepaid assets (prepaid clinical, material and manufacturing–related parties), \$383,000 in accounts payable–related parties, and \$2.8 million in accrued and other liabilities (accrued clinical and manufacturing–related parties), all reflected on the Company's condensed consolidated balance sheet associated with Medpace. As of June 30, 2014, the Company had \$292,000 in prepaid assets (prepaid clinical, material, manufacturing–related parties), \$2.9 million in accounts payable–related parties, and \$2.2 million in accrued and other liabilities (accrued parties), all reflected on the Company's condensed parties), all reflected on the Company's condensed consolidated balance sheet associated with Medpace. For the six months ended June 30, 2013 and 2014, the Company recognized \$2.8 million and \$8.8 million of services rendered by Medpace within research and development expense in the

#### Coherus BioSciences, Inc.

#### Notes to Unaudited Condensed Consolidated Financial Statements (continued)

# 12. Related Party Transactions (continued)

condensed consolidated statements of operations, respectively. The Company also has an agreement with Medpace which provides for a minimum fee commitment of \$35.0 million for clinical trial services which is further discussed in Note 8. As of June 30, 2014, \$14.2 million of the services related to this agreement has been performed.

#### **Recruiting Services**

One member of the Board of Directors was the chief executive officer of a company that provided recruiting services to the Company. As of June 30, 2014, the Company had \$99,000 in prepaid assets (prepaid clinical, material, manufacturing and other–related parties) and \$135,000 in accounts payable-related parties, reflected on the Company's condensed consolidated balance sheet. As of December 31, 2013, there were no such balances in the Company's consolidated balance sheet. During the six months ended June 30, 2013 and 2014, the Company recognized \$63,000 and \$257,000, respectively, for services rendered by the recruiting company recorded in research and development expense in the Company's condensed consolidated statements of operations.

#### **Convertible Notes — Related Parties**

In July to September 2013, the Company entered into Bridge Loans with certain investors, including existing stockholders, some members of the Board of Directors and their affiliated companies and some members of management, for a total aggregate amount of \$10.0 million and issued the 2013 Warrants to purchase shares of the Company's preferred stock at an exercise price of \$0.01 per share. As such, \$7.1 million of the total aggregate amount of the Bridge Loans were from related parties. As of December 31, 2013, the carrying value of the Bridge Loans was \$3.1 million, net of debt discount. In May 2014, the Company completed a preferred stock financing and contemporaneously the Bridge Loans and the related accrued interest were automatically converted into Series C preferred stock (see Note 7). For the six months ended June 30, 2013 and 2014, the Company recognized \$0 and \$2.7 million, respectively, of interest expense related to the debt and the amortization of the debt discount within interest expense in the Company's condensed consolidated statements of operations.

#### **InteKrin Acquisition**

In February 2014, the Company completed the acquisition of the InteKrin for total consideration of \$5.0 million (see Note 6). Mr. Dennis M. Lafear, the chief executive officer of the Company was the chairman of the board and acting president of InteKrin at the time of the acquisition. As such, the InteKrin acquisition was a related party transaction. Mr. Lanfear also owns 10% of the outstanding securities of InteKrin Russia.

#### 13. Subsequent Events

The Company evaluated subsequent events through September 15, 2014, the date at which the financial statements were available for issuance.

The Company received \$15.0 million in July 2014 and expects to receive \$10.0 million in September 2014 due to the achievement of certain events pursuant to the Baxter license agreement. Of the \$15.0 million received from Baxter in July 2014, \$2.5 million is contingently subject to reimbursement to Baxter.

In August 2014, the Company met the primary endpoint in a pivotal clinical pharmacokinetic ("PK") clinical study that compared similarity study of the Company's CHS-1420 product candidate to Humira<sup>®</sup> in healthy subjects. The parallel-group, single-dose study met the criteria for clinical PK similarity on all three required, prospectively defined, PK endpoints. Both agents were well tolerated and there were no differential safety findings observed between the two agents in this study.

# Shares



# **Common Stock**

# Prospectus

J.P. Morgan

Credit Suisse

**Cowen and Company** 

, 2014

# 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, the Financial Industry Regulatory Authority, or FINRA, filing fee and The NASDAQ Global Market, or NASDAQ, listing fee.

Item	Amou be pa	
SEC registration fee	\$	*
FINRA filing fee		*
NASDAQ 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	\$	*

\* To be completed 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.

Our amended and restated certificate of incorporation, attached as Exhibit 3.1, and our amended and restated bylaws, attached as Exhibit 3.3, provide for the indemnification provisions described above and elsewhere herein. We intend to enter 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 attached 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, 2011, which were not registered under the Securities Act.

- 1. In January 2011, we issued an aggregate of 1,615,000 shares of common stock to a service provider of the Company for aggregate cash consideration of \$8,075. These shares were subject to vesting restrictions which lapsed over time pursuant to the recipient's continued service to the Company. Such individual terminated services with the Company in March of 2013, at which time the Company repurchased 100,000 vested shares.
- 2. In January 2011, we issued an aggregate of \$159,840 in principal amount of unsecured convertible promissory notes and stock purchase warrants to purchase an aggregate of 106,560 shares of Series A convertible preferred stock at an exercise price of \$0.75 per share to five accredited investors. The warrants may be exercised at any time prior to their termination dates, which are five years from the date of issuance.
- 3. In March 2011, we issued an aggregate of 1,620,888 shares of our Series A convertible preferred stock at a price per share of \$0.75 for a combination of cash and conversion of \$160,699 in convertible debt, for an aggregate gross consideration of \$1.2 million, to 13 accredited investors.
- 4. From July 2011 through December 2011, in a series of closings, we issued an aggregate of \$10,394,477 in principal amount of unsecured convertible promissory notes and stock purchase warrants to purchase an aggregate of 587,543 shares of Series B convertible preferred stock at an exercise price of \$0.01 per share to 15 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 January 2012, we issued an aggregate of 8,754,742 shares of our Series B convertible preferred stock at a price per share of \$4.1841 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 836,500 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.
- 6. In April 2012, we issued an aggregate of 95,600 shares of our Series B convertible preferred stock at a price per share of \$0.01, for an aggregate gross consideration of \$956, pursuant to the exercise of outstanding stock purchase warrants to two accredited investors.

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- 7. In December 2012, we issued an aggregate of 4,788,365 shares of our Series B convertible preferred stock at a price per share of \$4.1841 for an aggregate gross consideration of \$20.0 million, to seven accredited investors. An aggregate of 2,876,365 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.
- 8. 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 7,134,149 shares of Series B convertible preferred stock at an exercise price of \$0.01 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.
- 9. In February 2014, we issued an aggregate of 420,106 shares of our Series B convertible preferred stock at a price per share of \$4.1841 for an aggregate gross consideration of \$1.8 million, to two accredited investors. An aggregate of 13,623 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.
- 10. In February 2014, we issued an aggregate of 143,400 shares of our Series B convertible preferred stock in consideration for services rendered to four service providers.
- 11. In February 2014, we issued an aggregate of 1,051,286 shares of our Series B convertible preferred stock to certain stockholders of InteKrin Therapeutics Inc., or InteKrin, in connection with our acquisition of InteKrin.
- 12. In April and May 2014, we issued an aggregate of 7,420,944 shares of our Series B convertible preferred stock at a price per share of \$0.01, for an aggregate gross consideration of \$74,209, pursuant to the exercise of outstanding stock purchase warrants to 19 accredited investors.
- 13. In May 2014, we issued an aggregate of 10,930,508 shares of our Series C convertible preferred stock at a price per share of \$6.00 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 16,667 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.
- 14. We granted stock options and stock awards to employees, directors and consultants under our 2010 Equity Incentive Plan, as amended, covering an aggregate of 9,748,372 shares of common stock, at a weighted-average exercise price of \$0.9713 per share. Of these, options covering an aggregate of 544,073 shares were canceled without being exercised.
- 15. We sold an aggregate of 87,062 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 sale and issuance of securities in the transactions described in paragraphs (1)-(13) by virtue of Section 4(a)(2) and/or Regulation D promulgated thereunder as transactions not involving any public offering. All of the purchasers of unregistered securities for which we relied on Section 4(a)(2) and/or Regulation D represented that they were accredited investors as defined under the Securities Act. We claimed such exemption on the basis that (a) the purchasers in each case represented that they intended to acquire the securities for investment only and not with a view to the distribution thereof and that they either received adequate information about the registrant or had access, through employment or other relationships, to such information and (b) appropriate legends were affixed to the stock certificates issued in such transactions.

We claimed exemption from registration under the Securities Act for the sales and issuances of securities in the transactions described in paragraphs (14)-(15) 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 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.

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 , 2014.

#### **COHERUS BIOSCIENCES, INC.**

By:

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 as his or her true and lawful attorneys-in-fact and agents, with full power of substitution, for him or her 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 attorney-in-fact and agent, with full power 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 that said attorney-in-fact and agent, or his substitute, 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.

Signature	Title	Date
Dennis M. Lanfear	Chairman, President and Chief Executive Officer (Principal Executive Officer)	, 2014
George G. Montgomery	Chief Financial Officer (Principal Financial Officer)	, 2014
Michael A. Nazak	Director of Finance (Principal Accounting Officer)	, 2014
James I. Healy, M.D., Ph.D.	Director	, 2014
V. Bryan Lawlis, Ph.D.	Director	, 2014
Christos Richards	Director	, 2014
Ali J. Satvat	Director	, 2014

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Signature	Title	Date
August J. Troendle, M.D.	Director	, 2014
Mats Wahlström	Director	, 2014
Mary T. Szela	Director	, 2014
	II-6	

Coherus BioSciences, Inc.

# Exhibit Index

Exhibit Number	Description
1.1*	Form of Underwriting Agreement.
3.1+	Fifth Restated Certificate of Incorporation, currently in effect.
3.2*	Form of Amended and Restated Certificate of Incorporation, to be in effect immediately prior to the consummation of this offering.
3.3+	Bylaws, currently in effect.
3.4*	Form of Amended and Restated Bylaws, to be in effect immediately prior to the consummation of this offering.
4.1	Reference is made to Exhibits 3.1 through 3.4.
4.2*	Form of Common Stock Certificate.
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.
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.
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.
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.
10.3†+	Distribution Agreement, effective December 26, 2012, by and between Orox Pharmaceuticals B.V. and Coherus BioSciences, Inc.
10.4++	Non-Exclusive License Agreement, effective July 10, 2013, by and between Genentech, Inc. and Coherus BioSciences, Inc.
10.5++	Commercial License Agreement, effective April 8, 2011, by and between Selexis SA and BioGenerics, Inc.
10.6†+	Commercial License Agreement, effective June 25, 2012, by and between Selexis SA and Coherus BioSciences, Inc.
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.
10.8(a)+	Office Lease, effective September 26, 2011, by and between CA-Towers at Shores Center Limited Partnership and BioGenerics, Inc.
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.
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.
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.
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 Pie Sciences. Inc.

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Exhibit <u>Number</u>	Description	
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.	
10.9(b)+	First Amendment to Lease, effective December 21, 2013, by and between Howard California Property Camarillo 5 and Coherus BioSciences, Inc.	
10.10(a)#+	BioGenerics, Inc. 2010 Equity Incentive Plan, as amended.	
10.10(b)#+	Form of Stock Option Grant Notice and Stock Option Agreement under the 2010 Equity Incentive Plan, as amended.	
10.11*#	Coherus BioSciences, Inc. 2014 Equity Incentive Award Plan and forms of agreement thereunder.	
10.12*#	Coherus BioSciences, Inc. 2014 Employee Stock Purchase Plan and forms of agreement thereunder.	
10.13*#	Form of Indemnification Agreement between Coherus BioSciences, Inc. and each of its directors, officers and certain employees.	
10.14#+	Separation Agreement, effective June 30, 2014, by and between Stephen C. Glover and Coherus BioSciences, Inc.	
23.1*	Consent of independent registered public accounting firm.	
23.2*	Consent of Latham & Watkins LLP (included in Exhibit 5.1).	
24.1*	Power of Attorney (included on the signature page).	
* To be filed by amendment.		

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 t with the SEC.

Indicates management contract or compensatory plan. #

Previously filed. +