

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

**FORM 10-K**

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

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

For the fiscal year ended December 31, 2018

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 001-36721

**Coherus BioSciences, Inc.**

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)

27-3615821  
(I.R.S. Employer  
Identification No.)

333 Twin Dolphin Drive, Suite 600  
Redwood City, California 94065  
(650) 649 - 3530

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

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

Title of Each Class

Name of Each Exchange on Which Registered

Common Stock, \$0.0001 par value per share

The Nasdaq Stock Market, Inc.

Securities Registered Pursuant to Section 12(g) of the Act: None

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period than the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit). Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

The aggregate market value of the registrant's common stock, held by non-affiliates of the registrant as of June 30, 2018 (which is the last business day of registrant's most recently completed second fiscal quarter) based upon the closing market price of such stock on the Nasdaq Global Market on that date, was approximately \$632.1 million. For purposes of this disclosure, shares of common stock held by each officer and director have been excluded in that such persons may be deemed to be "affiliates" as that term is defined under the Rules and Regulations of the Securities Exchange Act of 1934. This determination of affiliate status is not necessarily conclusive.

The number of shares of registrant's common stock issued and outstanding as of February 22, 2019 was 69,259,704.

**DOCUMENTS INCORPORATED BY REFERENCE**

Part III incorporates by reference certain information from the registrant's definitive proxy statement for the 2019 Annual Meeting of Stockholders.

COHERUS BIOSCIENCES, INC.  
ANNUAL REPORT ON FORM 10-K  
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## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements that involve risks and uncertainties. We make such forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that involve substantial risks and uncertainties concerning our business, operations and financial performance and condition, as well as our plans, objectives and expectations for our business operations and financial performance and condition. Any statements contained herein that are not statements of historical facts contained in this Annual Report on Form 10-K may be deemed to be forward-looking statements. In some cases, you can identify forward-looking statements by words such as “aim,” “anticipate,” “assume,” “attempt,” “believe,” “contemplate,” “continue,” “could,” “due,” “estimate,” “expect,” “goal,” “intend,” “may,” “objective,” “plan,” “predict,” “potential,” “seek,” “should,” “strive,” “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:

- whether we will be able to commercially launch and generate sales for UDENYCA™ (pegfilgrastim-cbqv) in the United States;
- whether we will be able to commercialize directly or through partners UDENYCA™ in Europe;
- our ability to continue to build the sales and marketing infrastructure for UDENYCA™;
- whether the results of our trials will be sufficient to support domestic or global regulatory approvals for CHS-1420 (our adalimumab (Humira®) biosimilar candidate), CHS-0214 (our etanercept (Enbrel®) biosimilar candidate) and CHS-131 (our therapeutic small molecule candidate);
- whether additional trials will be required to support domestic or global regulatory approvals for CHS-1420, CHS-0214 and CHS-131;
- whether we will be able to continue the preclinical development for CHS-2020 (our aflibercept (Eylea®) biosimilar candidate) and initiate the clinical development for CHS-3351 (our ranibizumab (Lucentis®) biosimilar candidate);
- our ability to obtain and maintain regulatory approval of any product candidates;
- our expectations regarding government and third-party payer coverage and reimbursement;
- our ability to manufacture our product candidates in conformity with regulatory requirements and to scale up manufacturing capacity of these products for commercial supply;
- our reliance on third-party contract manufacturers to supply our product candidates for us;
- 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 capital resources will be sufficient to fund our operations for at least the next 12 months;
- our ability to maintain and establish collaborations or obtain additional funding;
- the implementation of strategic plans for our business and product plans;
- the initiation, timing, progress and results of future preclinical and clinical studies and our research and development programs;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates;
- our expectations regarding the scope or enforceability of third party intellectual property rights, or the applicability of such rights to our product candidates; the cost, timing and outcomes of litigation involving our product candidates;
- our reliance on third-party contract research organizations to conduct clinical trials of our product candidates;
- the benefits of the use of our product candidates;
- the U.S. government’s policy mandating healthcare insurance coverage for pre-existing conditions will continue for the foreseeable future and will increase demand for high-quality biosimilars;
- the rate and degree of market acceptance of our current or any future product candidates;
- our ability to compete with companies currently producing the reference products, including Neulasta, Humira, Enbrel, Lucentis and Eylea;

- our financial performance;
- developments and projections relating to our competitors and our industry; and
- our expectation that NASH is estimated to become the leading cause of liver transplant in the United States by 2020 and that the U.S. prevalence of NASH is expected to reach 27 million by 2030.

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

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

**Item 1. Business****Overview**

We are a commercial-stage bioterapeutics company focused on the global biosimilar market. Biosimilars are a class of protein-based therapeutics with high similarity to approved originator products on the basis of various structural, physicochemical and biological properties, as well as in terms of safety and efficacy. 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.

On September 25, 2018, we received regulatory approval for the marketing of UDENYCA™ (pegfilgrastim-cbqv), a biosimilar to Neulasta, a long-acting granulocyte-colony stimulating factor, from the European Commission. On November 2, 2018, the U.S. Food and Drug Administration ("FDA") approved our biologics license application ("BLA") for UDENYCA™ as a biosimilar to Neulasta. We initiated U.S. sales of UDENYCA™ in January 2019.

Our clinical-stage pipeline includes the following product candidates:

- 1) Immunology, anti-tumor necrosis factor ("Anti-TNF") biosimilar candidates, CHS-1420 for adalimumab (Humira®) and CHS-0214 for etanercept (Enbrel®), which have both completed Phase 3 clinical programs;
- 2) Ophthalmology biosimilar candidates, CHS-3351 for ranibizumab (Lucentis®), which is in Good Manufacturing Practice ("GMP") production stage and CHS-2020 for aflibercept (Eylea®), which is in preclinical development; and
- 3) Small molecule therapeutic candidate, CHS-131, a novel, selective modulator of peroxisome proliferator-activated receptor-g ("PPAR-g"), which could be for non-alcoholic steatohepatitis ("NASH") and other metabolic conditions, and which completed a Phase 2b proof-of-concept trial in 2016 in relapsing remitting multiple sclerosis ("MS"), and completed a Phase 2b proof-of-concept trial in Type 2 diabetes mellitus in September 2009.

**Oncology Biosimilar**

UDENYCA™ stimulates production of granulocytes (a type of white blood cell) in order to promote the body's ability to fight infections. We completed two pivotal pharmacokinetic ("PK") and pharmacodynamic ("PD") studies for UDENYCA™ in the U.S. comparing UDENYCA™ to Neulasta, for which we reported topline results in October 2015 and in July 2016. Both studies met their primary PD endpoints of absolute neutrophil count ("ANC"). In terms of PK parameters, the first study also met bioequivalence for  $C_{max}$ , but the Area Under the Curve ("AUC") portion of the PK results did not meet bioequivalence due to the presence of a low, anomalous PK profile in the first treatment period Neulasta group and a relatively small sample size for the observed biological variability. We initiated the second follow-on PK/PD study in February 2016, which met all its primary clinical PK/PD endpoints. In January 2016, we completed an immunogenicity study in healthy volunteers. In August 2016, we submitted a BLA for UDENYCA™ to the FDA under Section 351(k) of the Public Health Service Act ("351(k) BLA"), which enables an applicant to pursue approval of a product candidate as a biosimilar. We received a complete response letter ("CRL") regarding this BLA from the FDA in June 2017. We resubmitted the BLA in May 2018, and the FDA approved the BLA for UDENYCA™ in November 2018. In October 2016, we filed a Marketing Authorization Application ("MAA") with the European Medicines Agency ("EMA"), which was approved by the European Commission ("EC") in September 2018. We initiated U.S. sales of UDENYCA™ in January 2019.

**Anti-TNF Biosimilars**

Our first anti-TNF product candidate, CHS-1420, is an adalimumab (Humira) biosimilar candidate. We completed a Phase 3 study in psoriasis patients with top line 12-week data released in August 2016, followed by positive confirmatory results at 24-weeks in January 2017, all to support a planned filing of a marketing application in the United States. If approved, we anticipate we would be able to launch CHS-1420 in the U.S. on or after December 15, 2023, in accordance with settlement and license agreements with AbbVie Inc. ("AbbVie") that grant Coherus global, non-exclusive license rights under AbbVie's intellectual property to commercialize CHS-1420.

Our second anti-TNF product candidate, CHS-0214, is an etanercept (Enbrel) biosimilar candidate. We have global rights to CHS-0214, excluding certain Caribbean and Latin American countries, except for Brazil where we retain rights to CHS-0214. We have completed two Phase 3 clinical trials with CHS-0214 in rheumatoid arthritis and psoriasis, which met their primary clinical endpoints in November 2015 and January 2016, respectively.

## Ophthalmology Biosimilars

Our preclinical stage pipeline consists of CHS-3351, a ranibizumab (Lucentis) biosimilar product candidate, and CHS-2020, an aflibercept (Eylea) biosimilar candidate. We are executing GMP manufacturing to support clinical studies in humans for CHS-3351. We are conducting certain preclinical activities for CHS-2020, such as process development and biosimilarity exercises.

## Overview of the Market Opportunity for Biosimilars

According to Evaluate Pharma, total global annual revenues from adalimumab, etanercept and pegfilgrastim-based originator products exceeded \$32 billion in 2018. We intend to pursue a branded strategy to address the potential commercial opportunity, emphasizing a high level of similarity of our biosimilar products to the originators, while offering significantly more value to the United States healthcare system.

The global market opportunity for biosimilars is large and growing because of several factors. First, many of the top-grossing biologic drugs in the world faced, or are facing the expiry of their patent protection within the next five years. 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. Further, in the United States, the largest market globally, we believe that government policy mandating healthcare insurance coverage of treatments for pre-existing conditions will continue for the foreseeable future and will increase demand for high-quality biosimilars.

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. With the approval of UDENYCA™, we believe we have demonstrated our core capabilities and expertise in product development. We have also assembled a distinguished scientific advisory board of leading scientists who are acknowledged experts in their respective fields.

Our business model places our internal team at the center of a coordinated development effort in which our senior team of experts focuses on the highly-specialized, strategic and technical aspects of biosimilar development. For other aspects of our operations that require greater scale or more capital-intensive investments, we have established a network of relationships with highly-competent external organizations and strategic partnerships that we believe will provide the competitive scale required to address the global biosimilar market opportunity. For example, in December 2015, we entered into a strategic manufacturing agreement with KBI Biopharma, Inc. (“KBI Biopharma”) for long-term commercial manufacturing of UDENYCA™. In December 2017, we issued and sold an aggregate of 776,104 shares of common stock to KBI Biopharma, in a private placement transaction for gross consideration of \$6.8 million. In November 2018, we extended our partnership with KBI until December 31, 2023. In addition, our dynamic organization allows us to respond to the rapidly evolving biosimilar landscape.

## Our Strategy

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

- **Maximizing the commercial opportunity of UDENYCA™, our first commercial-stage biosimilar drug in the United States.** We believe our commercial team possesses a deep understanding of the buy-and-bill, oncology biologics marketplace. With UDENYCA™, we believe we are able to effectively provide value and choice without compromise to patients, physicians, group purchasing organizations (“GPOs”), and payers seeking to use pegfilgrastim at lower prices. Originator biologic drug price increases represent a significant burden to the U.S. healthcare system and we believe high-quality, high-value biosimilars such as UDENYCA™ can help lower that burden. With UDENYCA™ approved in Europe, we are also open to partnering the product in Europe.
- **Advancing our lead programs through clinical development to secure approvals in major markets.** We have developed a late-stage clinical pipeline consisting of two product candidates, CHS-1420 and CHS-0214, for which we plan to submit 351(k) BLAs in the United States. We attempt to adapt our clinical trials to meet the regulatory requirements of multiple jurisdictions globally, such that one set of pivotal clinical trials may be sufficient for approval in all jurisdictions.
- **Continuing 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 candidate portfolio, we have identified two potential product candidates, CHS-3351, a ranibizumab (Lucentis) biosimilar product candidate, and CHS-2020, an aflibercept (Eylea) biosimilar candidate, that have met our stringent selection criteria and which have entered early development. We will continue to evaluate other potential product candidates to further expand our pipeline.

- **Leveraging 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.
- **Maximizing the value of our portfolio and pipeline by retaining commercial rights to our biosimilar candidates in the U.S.** We intend to retain U.S. rights to our biosimilar products and product candidates, while opportunistically licensing rights in other geographic areas in exchange for upfront, cost sharing, milestone and royalty payments depending on legal and other developments.
- **Attracting and retaining 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. We believe that our level of technical expertise is 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 IQVIA Institute for Human Data Science, the 2017 U.S. biologics market represented over \$120 billion in sales, with virtually the entire market composed of branded originator products. Patent expirations for many commercially successful branded biologic products will provide an unprecedented opportunity for cost containment through the introduction of biosimilars. Through 2023, and potentially beyond, 26 major branded biologic products, all with worldwide annual sales in excess of \$1 billion each, face loss of patent exclusivity in at least one major pharmaceutical market. These products achieved over \$100 billion in aggregate worldwide sales in 2018. We believe this wave of patent expirations will create significant opportunities in the coming years. The following originator products (all of which are “blockbuster” biologics) are facing loss of patent exclusivity in at least one major market through 2023:

Actemra	Herceptin	Neulasta	Simponi
Advate	Humira	Norditropin SimpleXx	Stelara
Avastin	Kadcyla	NovoMix 30	Tysabri
Botox	Kogenate	NovoRapid	Victoza
Enbrel	Lantus	Orencia	Xolair
Eylea	Levemir	Remicade	
Forteo	Lucentis	Rituxan	

Escalating healthcare costs and healthcare reform have been major drivers for the advancement of the biosimilar market. Governments and insurers are in search of mechanisms to contain costs and expand patient access without sacrificing quality of care. Further, governments and commercial payers are using an increasing and disproportionate amount of healthcare spending on biologic therapeutics. IQVIA Institute for Human Data Science reported in 2018 that spend related to biologic medicines increased by 56% in the last five years in the U.S. Compounding the issue is the fact that biologic therapeutic costs are escalating at an increasingly unsustainable rate. Consequently, we believe there is tremendous cost pressure to bring high-quality, lower-priced biologic therapeutics to market. We further believe our products target payer segments having among the highest rates of spending and anticipated spending growth, including inflammation and cancer.

We expect the biosimilar marketplace to have several distinct characteristics as it develops. We believe that the market adoption and penetration rates for biosimilars in the U.S. will primarily be determined by three key factors: (1) biosimilar product quality, as demonstrated by the development program in alignment with the 351(k) pathway, (2) supply reliability, including the ability to meet market demand rapidly and consistently and (3) delivering incremental value to payers, providers and patients. We believe there will be strong market adoption and penetration for UDENYCA™ and, if approved, our biosimilar pipeline candidates due to the quality of our products our U.S.-based supply chain and our value offering to payers, providers and patients. We believe that there will be substantially fewer biosimilar competitors relative to the competition experienced in the generic drug space, pricing stability, and favorable market dynamics due to the large level of capital investment and technical expertise required to develop, obtain approval for, and commercialize biosimilars.

### The Challenge of Biosimilar Product Development

Proteins consist of one or more long chains of amino acids 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, called posttranslational modifications, that can occur following synthesis that create inherent variability. Chief among these is the glycosylation, or the attachment of sugars to 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, as it is the case for small-molecule therapeutic generics, regulators have issued guidelines that require demonstration of high degree of analytical similarity and no clinically meaningful differences.

## **Our Approach**

### ***Five Key Steps to Biosimilar Drug Development***

We focus our efforts around 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.

#### *Step 1: Cell Line Development and Manufacturing*

The amino acid sequence of the candidate biosimilar molecule must precisely match that of the originator. 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 that produce protein that most closely matches the posttranslational modifications of the originator, since such product quality characteristics impact PK, and/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 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 structural and physicochemical similarity between our biosimilar candidate and the originator product. We also evaluate functional similarity by determining biologic activity of our biosimilar candidate and the originator product using a battery of sensitive *in vitro* pharmacology assays that assess known, likely and plausible mechanisms of action for all approved indications of the originator product. 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*

In addition to the assessment of analytical similarity, we may compare our biosimilar product candidate to the originator product in relevant animal models.



#### *Steps 4 and 5: Clinical Studies*

Once biosimilarity has been established in the first three steps, the goal of the clinical program is to demonstrate that there are no clinically meaningful differences between the biosimilar product candidate and the originator product in terms of safety, purity, and potency of the product. The FDA expects a biosimilar product sponsor to conduct comparative human PK and PD studies (if there is a relevant PD measure) and a clinical immunogenicity assessment. In certain cases, such as where there is a high correlation between PD and PK profiles and clinical effectiveness, the results from these studies alone may provide adequate clinical data to support approval. If there is any residual uncertainty about whether clinically meaningful differences may exist between the biosimilar product candidate and the originator product based on any of the above required testing, a comparative Phase 3 or confirmatory clinical study will be necessary.

#### *Step 4: Pivotal Phase 1 Human Pharmacokinetic and Pharmacodynamic Study and Clinical Immunogenicity Assessment*

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 and immunogenicity similarity. The U.S. and European regulatory agencies have established requirements for bioequivalence with respect to three prospectively defined parameters as follows:

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

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

In addition to the demonstration of PK biosimilarity (similar levels of exposure to the biologic at different time points), these studies should also measure, when possible, PD biosimilarity (similar exposure-response to the biologic) to assess whether there are any potential clinically meaningful differences between the two products. Potential PD biomarkers are specific to each reference product and should demonstrate characteristics of the product's target effects. For each PD biomarker, it is important to consider:

- 1) its time of onset relative to dosing;
- 2) its dynamic range over the exposure range;
- 3) its sensitivity to differences between the biosimilar product candidate and the originator product;
- 4) its relevance to the mechanism of action of the drug; and
- 5) the analytical validity of the assay.

The goal of the clinical immunogenicity assessment is to evaluate potential differences between the biosimilar product candidate and the originator product in the incidence and severity of the human immune response. Immune responses may impact both efficacy and safety by altering PK, inducing anaphylaxis, or by generating neutralizing antibodies ("NAb") that neutralize the protein product, thereby hindering its efficacy.

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

If the above clinical comparisons, including PK and PD comparisons and immunogenicity studies, do not sufficiently rule out the possibility of clinically meaningful differences between the products, then a comparative clinical study will be required to support approval. This may be a single Phase 3 or a smaller 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 originator product and biosimilar product candidate 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 originator and has a similar safety profile as the originator product with no clinically meaningful differences. We also work with the regulatory agencies to ensure that a successful trial in a particular indication will lead to extrapolation and approval of all indications that the originator product has unless one or more indications are prohibited for regulatory exclusivity reasons. 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 biosimilar product candidates:

Candidate	Originator Product	Status	Coherus Commercial Rights
UDENYCA™	pegfilgrastim (Neulasta)	• Approved in the E.U. and U.S.	Worldwide, ex-Latin America (except Brazil and Argentina)
CHS-1420	adalimumab (Humira)	• Completed Phase 3 clinical study in psoriasis in 2016 • Completed PK bioequivalence bridging studies with Phase 3 drug material in 2017	Worldwide, ex-Latin America (except Brazil)
CHS-0214	etanercept (Enbrel)	• Phase 3 clinical trials in psoriasis and in rheumatoid arthritis met primary efficacy endpoints in 2015 and 2016, respectively • Completed two bridging Phase 1 studies and completed a relative bioavailability data study of CHS-0214 at two different concentrations in 2016	Worldwide, ex-Latin America (except Brazil) <sup>1</sup>
CHS-3351	ranibizumab (Lucentis)	• GMP manufacturing to support clinical studies in humans	Worldwide, ex-Latin America (except Brazil)
CHS-2020	aflibercept (Eylea)	• Preclinical stage	Worldwide, ex-Latin America (except Brazil)

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

### Oncology Biosimilar Product Opportunity

#### UDENYCA™ (pegfilgrastim-cbqv)

Granulocyte colony-stimulating factor (“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. Neulasta revenues in the U.S. were approximately \$3.9 billion in 2018.

#### Product Overview

Neulasta, the reference product for UDENYCA™, 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 UDENYCA™ 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 UDENYCA™. The biological effect of UDENYCA™ on neutrophils was assessed by measuring the proliferation of NFS-60 cells that are commercially available hematopoietic cells (blood cells that give rise to other blood cells) of neutrophilic lineage expressing G-CSF receptors and have been used extensively for testing G-CSF products. The biological activity of UDENYCA™ (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. We determined that UDENYCA™ stimulated the proliferation of the NFS-60 cells in a manner consistent with that observed with Neulasta.

Neulasta is approved in the U.S. 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.

## Current Development Status and Data

The EC granted marketing authorization to UDENYCA™ in September 2018 and the FDA approved UDENYCA™ in November 2018.

### Step 1: Cell Line Development and Manufacturing

We confirmed that the amino acid sequence of UDENYCA™ is identical to the originator molecule. UDENYCA™ is manufactured in *E. coli* and PEGylation occurs as a subsequent step in the manufacturing process. For PEGylation of UDENYCA™, we used the equivalent polyethylene glycol (“PEG”), molecule as Neulasta and established that chemistry and site of attachment of the PEG molecule was the same. In December 2015, we entered into a strategic manufacturing agreement with KBI Biopharma for long-term commercial manufacturing of UDENYCA™.

### Step 2: Analytical Characterization and In Vitro Comparability

Filgrastim produced from *E. coli* is not glycosylated. We performed extensive analytical characterization of UDENYCA™ and have determined its basic and higher-order structures are similar to Neulasta. We studied the *in vitro* activity of UDENYCA™ in an assay measuring the proliferation of the murine myeloid leukemia cell line, NFS-60. UDENYCA™ 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 UDENYCA™, 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 UDENYCA™ 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 (“ANC”), and total white blood cell count were observed at all dose levels of UDENYCA™. Clinical chemistry findings and mild to moderate splenic enlargement in the UDENYCA™-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 UDENYCA™ or other toxic effects, in order to compare these attributes observed for UDENYCA™ with those we observed for Neulasta. We administered either UDENYCA™ or Neulasta at dose levels of 0.075, 0.25 and 0.75 mg/kg once weekly for 4 weeks. We found that UDENYCA™ 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 UDENYCA™ and Neulasta in terms of potentially harmful antibody responses or other toxicities, or in terms of PK and PD.

### Steps 4 and 5: Clinical Studies

All clinical studies were conducted in healthy subjects, with mutual consensus with the FDA and EMA, for the following reasons:

- 1) the mode of action of pegfilgrastim, to increase circulating neutrophils, is identical in healthy subjects and patients receiving chemotherapy;
- 2) healthy subjects are the more sensitive study population to evaluate similarity or differences in PK, PD, and immunogenicity compared to potentially immunocompromised cancer patients; and
- 3) the most common side effects of pegfilgrastim (bone pain and headache) is the same in healthy subjects and cancer patients and are self-limiting and short-lived.

The pharmacodynamic effect of pegfilgrastim, to increase circulating neutrophils, is in fact representative of the drug’s efficacy. Therefore, the demonstration of biosimilarity in PK, PD, and immunogenicity was sufficient to demonstrate no clinically meaningful differences between UDENYCA™ and Neulasta and FDA did not require us to conduct a Phase 3 clinical study in support of the 351(k) BLA.

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

In March 2015, after receiving written feedback from the FDA on our development plan for UDENYCA™, we initiated a pivotal Phase 1 PK/PD study for UDENYCA™ under the 351(k) (biosimilar) pathway in the U.S., which was completed in October 2015. This study met its primary PD endpoints for ANC (“absolute neutrophil counts”). The primary PD endpoints consisted of area under the ANC–time curve calculated from time 0 to the last measured time point (ANC AUC<sub>0–last</sub> and ANC AUC<sub>0–960</sub>) and peak neutrophil count (ANC<sub>max</sub>). In terms of PK parameters, the study also met bioequivalence for C<sub>max</sub>. However, the AUC portion of the PK results did not

meet bioequivalence due to a relatively small sample size for the observed biological variability in the overall study population and the presence of a low, anomalous PK profile in the first treatment period Neulasta group.

We then initiated our pivotal PK/PD and confirmatory safety and efficacy study in the first quarter of 2016 and successfully completed that study in July 2016. This study was considered by us and FDA as our confirmatory efficacy study due to the increase in sample size and other clinical trial design features. This second study met all of its endpoints for PK,  $C_{max}$  and AUC, and for PD, absolute neutrophil count ( $ANC_{max}$  and  $ANC_{AUC}$ ). For both PK and PD endpoints, the 90% confidence intervals for the geometric mean ratio (“GMR”) were well contained within the pre-specified margins of 80% to 125%. This randomized, single-blind, three-sequence, three-period crossover study in healthy subjects assessed PK, PD, and safety (including immunogenicity) of a 6 mg subcutaneous (SC) injection of UDENYCA™ compared to 6 mg SC dose of Neulasta. A total of 122 healthy volunteer subjects were randomized to one of three treatment sequences, each with three treatments (Neulasta/Neulasta/ UDENYCA™ or UDENYCA™/Neulasta/Neulasta or Neulasta/ UDENYCA™/Neulasta). Subject inclusion criteria, procedures and study design, as well as other measures, reflected modifications addressing findings in the previous PK/PD studies, successfully decreasing subject variability and eliminating the extreme subject outliers previously observed.

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

Between November 2012 and March 2013, we conducted our first-in-man 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 UDENYCA™ compared to Neulasta in 78 healthy human subjects. The UDENYCA™ drug product used for this study was not representative of the commercial drug product used in later studies. This Phase 1 study did not establish bioequivalence necessary to support a 351(k) BLA development pathway. In October 2014, we met with the FDA to discuss our development plan for UDENYCA™ and proceeded with the studies described above in step 4 and below in step 5. In the 351(k) BLA, this study was included in the integrated safety analysis.

In May 2015, we initiated an immunogenicity study in healthy volunteers, which was completed in January 2016. Each subject received two sequential doses of UDENYCA™ or two sequential doses of Neulasta. Predefined success criteria for the study included the co-endpoints, NAb and anti-drug antibodies (“ADA”). The primary endpoints were predefined and reviewed by the FDA. The study met both of its co-primary endpoints with the assays used at the time. There were no treatment-emergent NAb detected in any subject in either treatment group.

We submitted the 351(k) BLA in August 2016, which was accepted for filing by the FDA in October 2016. We received a CRL regarding this BLA from the FDA in June 2017. The CRL included a request from FDA for the reanalysis of immunogenicity samples from the study started in May 2015 using revised and validated immunogenicity assays. The revised assays were designed to better understand the impact of ADA on PK parameters and the differences in antibodies to the PEG or G-CSF components of pegfilgrastim. The reanalysis demonstrated that there were no treatment-emergent NAb in either treatment group and the majority of ADA generated in both the UDENYCA™ and Neulasta treatment groups were antibodies to the PEG component. Furthermore, there were no clinically meaningful differences between UDENYCA™ and Neulasta in the ADA to the G-CSF component. The CRL also requested certain additional manufacturing related process information, which we provided. We resubmitted the 351(k) BLA for UDENYCA™ in May 2018 and the FDA approved UDENYCA™ in November 2018.

### **Immunology (Anti-TNF) Product Opportunity**

Tumor necrosis factor (“TNF”) belongs to a family of soluble protein mediators (“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.

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

##### *Product Overview*

Humira, which is the reference product (“originator”) for CHS-1420, is a monoclonal antibody that can bind to a substance in the body known as tumor necrosis factor (“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 has also been demonstrated that Humira can bind to receptors on white blood cells, which may lessen the ability of the body's immune system to fight infection.

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;
- hidradenitis suppurativa;
- uveitis;
- ulcerative colitis; and
- plaque psoriasis.

Humira has been approved by the Japanese Pharmaceutical and Medical Devices Agency ("PMDA") for the treatment of the following indications only when conventional therapies are not sufficiently effective:

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

Worldwide sales of Humira are projected to exceed \$20 billion in 2019, with about \$15 billion in the U.S., which is the primary region 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 2019, sales of Humira and Enbrel worldwide are projected to exceed \$26 billion. Our settlement and license agreements with AbbVie grant Coherus global, non-exclusive rights under AbbVie's intellectual property to commercialize CHS-1420.

#### *Current Development Status and Data*

We have successfully advanced CHS-1420 through steps 1 through 5 of our approach to biosimilar drug development. In August 2014, we completed a pivotal Phase 1 PK/PD study comparing CHS-1420 to Humira in healthy volunteers. This Phase 1 PK study met the primary endpoint and demonstrated bioequivalence for all prospectively defined endpoints and was conducted under an IND application in the U.S. We reached concurrence with regulatory authorities in the U.S. and Europe on the design of a harmonized global Phase 3 program to support registration in these territories. In August 2015, we initiated a Phase 3 clinical trial in psoriasis and announced positive 12-week data from that trial in August 2016, followed by confirmatory positive 24-week results in January 2017 to support the planned filing of a marketing application in the U.S. and the E.U. in 2019 or beyond. We completed a Phase 1 PK bridging study comparing our Phase 3 material to U.S. manufactured Humira in March 2017. In January 2017, we initiated a PK study bridging to E.U. manufactured Humira and a PK study comparing U.S. Humira to E.U. Humira. If approved, we believe we will be able to extrapolate the data from our trial in psoriasis to gain approval for CHS-1420 in all the indications included in the label for Humira.

#### *Step 1: Cell Line Development and Manufacturing*

As with all our molecules, we matched the amino acid sequence of CHS-1420 to the originator molecule (adalimumab) prior to development and demonstrated it to be identical. We established Master Cell Banks ("MCBs"), and Working Cell Banks ("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 characterized CHS-1420 and Humira using a multi-dimensional analytical study, demonstrating a high degree of similarity between CHS-1420 and Humira. 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 demonstrated CHS-1420 to be highly similar to Humira through *in vitro* receptor binding studies, specifically in its ability to inhibit TNF- $\alpha$  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 healthy adult volunteers. This is a single dose, double-blind parallel group study designed to demonstrate bioequivalence between CHS-1420 and Humira. A secondary objective was to assess the safety and tolerability of CHS-1420 in this population. The study has been successfully completed and met the primary endpoint and demonstrated bioequivalence with respect to the three prospectively defined PK endpoints. CHS-1420 and Humira were both well tolerated in this single-dose study in healthy adult volunteers.

We completed a Phase 1 PK bridging study comparing our Phase 3 material to U.S. manufactured Humira in March 2017.

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

In August 2015, we initiated a Phase 3 clinical trial in psoriasis that enrolled 545 subjects. This is a confirmatory, randomized, double-blind, active-control, parallel-group, three-part study in patients with active, moderate to severe, chronic plaque psoriasis. This trial met its primary endpoint demonstrating similarity between CHS-1420 and Humira with respect to percentage of subjects achieving the PASI-75 scores at 12 weeks. Both CHS-1420 and Humira were similarly well tolerated with similar safety profiles. In part two of this trial, from week 16 to week 24, half the subjects randomized to Humira crossed-over to CHS-1420, modeling a chronic patient's transition to a biosimilar. In January 2017, we reported that maintenance of PASI-75 was similar across the three subsequent treatment groups: CHS-1420 followed by CHS-1420, Humira followed by CHS-1420, and Humira followed by Humira. CHS-1420 and Humira were similarly well tolerated in all groups during part two of the trial. In part three of the trial, all subjects will receive CHS-1420 for an additional 24 weeks. This trial would be considered the primary confirmatory safety and efficacy trial to support a registration filing.

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

#### *Product Overview*

Enbrel, the reference product for CHS-0214, is a complex fusion protein that combines the protein for tumor necrosis factor receptor 2 ("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 ("TNF- $\alpha$ " and "TNF- $\beta$ ," respectively), and inhibits TNF- $\alpha$  and TNF- $\beta$  from binding to cell surface proteins that recognize them. Autoimmune diseases are caused by an overactive immune response. Enbrel treats these diseases by inhibiting TNF- $\alpha$ , 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 EMA and the FDA for the treatment of the following indications:

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

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

- rheumatoid arthritis; and
- juvenile idiopathic arthritis.

In 2019, sales of Enbrel are projected to exceed approximately \$6.7 billion worldwide, of which \$4.5 billion are expected to be generated in the U.S. We developed CHS-0214 for U.S., Europe and Japan. We have licensed CHS-0214 to Orox for certain Caribbean and Latin American countries.

The expiration of certain originator patents pertaining to Enbrel in major markets offers us a potential near-term opportunity to introduce a biosimilar competitor in these markets. Specifically, we believe we are not precluded by the originator's patents from introducing an Enbrel biosimilar candidate in Europe or Japan. We intend to evaluate commercial partners to compete in these markets.

#### *Current Development Status and Data*

We have successfully advanced CHS-0214 through steps 1 through 5 of our approach to biosimilar drug development. Our pivotal Phase 1 human PK/PD study was conducted in the U.S. We evaluated CHS-0214 in two randomized Phase 3 clinical trials in patients with psoriasis and in patients with rheumatoid arthritis, both of which met their primary endpoints in November 2015 and January 2016, respectively. Although we could file a European marketing application for CHS-0214, we intend to prioritize approval and commercialization in the U.S. as we believe it is a more economically attractive market. If approved, we believe we will be able to extrapolate the data from our trials in rheumatoid arthritis and psoriasis to gain approval for CHS-0214 in all the indications included in the label for Enbrel.

##### *Step 1: Cell Line Development and Manufacturing*

We have identified the amino acid sequence of CHS-0214 and confirmed that it is identical to the reference product, Enbrel. We established MCBs and WCBs, and produced toxicology materials in the third quarter of 2012 and Phase 1 study materials at a U.S. contract manufacturing organization ("CMO"). We then transferred the manufacturing process to a European CMO for Phase 3 clinical trial supply and to another European CMO for 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 ("ADCC"), and complement-dependent cytotoxicity ("CDC")), we have shown CHS-0214 to have highly similar pharmacological activity to Enbrel. ADCC and CDC refer to biological mechanisms of immune system defense, which facilitate the body's ability to use its immune system to target and destroy a given target cell. Comparing the effects of CHS-0214 and Enbrel on these mechanisms provides us a basis for determining how similar CHS-0214 is to Enbrel in terms of pharmacological activity.

##### *Step 3: In Vivo Animal Comparability*

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

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

We announced the Phase 1 PK similarity study 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 U.S. to the E.U., we conducted an additional Phase 1 PK similarity study comparing CHS-0214 to one lot of Enbrel manufactured in Europe, which met its primary endpoint in April 2015. The design of this study was a single-dose, cross-over study similar to the one described above.

In 2016, we initiated a Phase 1 PK bioequivalence study comparing E.U. Enbrel to CHS-0214 produced under a new process and also initiated a Phase 1 PK comparability study comparing CHS-0214 produced under a new process and CHS-0214 under a former process and used in the two Phase 3 trials. We completed these two studies in October 2016. The Phase 1 PK bioequivalence study achieved the primary PK bioequivalence endpoint. The Phase 1 PK comparability study provided additional relative bioavailability data for CHS-0214.

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

We announced the dosing of the first patient in a Phase 3 rheumatoid arthritis clinical trial in June 2014, and subsequently initiated a separate Phase 3 clinical trial in psoriasis in July 2014. The design of each Phase 3 clinical trial incorporated guidance from regulatory agencies regarding key study parameters.

The Phase 3 clinical trial in rheumatoid arthritis was designed as a double blind, multi-center, parallel group study in which patients with DMARD (disease-modifying antirheumatic drug)-refractory active rheumatoid arthritis were put on a stable dose of methotrexate. This trial enrolled 647 subjects who were randomized 1:1 to CHS-0214 50 mg or Enbrel 50 mg, administered subcutaneously weekly over a period of 24 weeks. Following the initial 24-week double-blind period, all patients were moved to a CHS-0214 treatment for a period of 6 months. In January 2016, the trial met its primary end-point of the proportion of subjects achieving ACR20 (20% improvement according to the American College of Rheumatology criteria) at 24 weeks, which was within the pre-specified margins for demonstrating equivalence of CHS-0214 compared to Enbrel. There were no clinically meaningful differences in the safety and immunogenicity profiles of the two products.

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

In July 2015, we initiated an open-label, safety extension study (“OLSES”) evaluating the longer-term safety and durability of response of subjects who completed 48 weeks in the confirmatory safety and efficacy Phase 3 trials of CHS-0214 in patients with rheumatoid arthritis and psoriasis. We enrolled 359 subjects in this study, which completed treatment in October 2017. The maintenance of ACR20 response or 50% improvement in the PASI response was achieved in patients with rheumatoid arthritis or psoriasis, respectively, and results of secondary and other efficacy assessments demonstrated maintenance of clinical response over time. The safety data of this study were consistent with the known Enbrel literature. In addition, no new safety signals were identified with up to an additional 109 weeks of treatment with CHS-0214.

### **Ophthalmology Product Opportunity**

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

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

According to Evaluate Pharma, Lucentis achieved approximately \$3.6 billion in worldwide sales in 2018, and is expected to decrease to approximately \$3.1 billion in 2020, when the composition of matter patent on ranibizumab expires in the U.S. We selected Lucentis as the biosimilar development target for our biosimilar, CHS-3351, to leverage the analytics deployed on bevacizumab and because we could address a concentrated market where we believe we can focus resources and establish a therapeutic franchise.

Lucentis has been approved by the FDA for the treatment of the following indications:



- Neovascular (wet) age-related macular degeneration;
- Macular edema following retinal vein occlusion;
- Diabetic macular edema;
- Diabetic retinopathy; and
- Myopic choroidal neovascularization.

*Current Development Status and Data*

*Step 1: Cell Line Development and Manufacturing*

We have identified the amino acid sequence of CHS-3351 and confirmed that it is identical to the reference product, Lucentis. We have established a MCB as well as a WCB. We completed certain GMP manufacturing efforts in support of clinical studies in humans. We are currently transferring the manufacturing process of CHS-3351 bulk drug substance to a new CMO in the U.S. for production of material to supply preclinical studies and clinical trials.

**CHS-2020 (Our Aflibercept (Eylea) Biosimilar Candidate)**

Eylea, the reference product for CHS-2020, is a complex fusion protein that combines the vascular endothelial growth factor (VEGF)-binding portions from the extracellular domains of human VEGF receptors 1 and 2, that are fused to the Fc portion of the human IgG1 immunoglobulin and binds to circulating VEGFs.

According to Evaluate Pharma, Eylea achieved approximately \$7.0 billion in worldwide sales in 2018, and is expected to remain stable at that level until 2023, when it loses market exclusivity in the U.S. We selected Eylea as a biosimilar development target because we could address a concentrated market where we believe we can focus resources and establish a therapeutic franchise.

Eylea has been approved by the FDA for the treatment of the following indications:

- Neovascular (wet) age-related macular degeneration;
- Macular edema following retinal vein occlusion; and
- Diabetic retinopathy.

*Current Development Status and Data*

*Step 1: Cell Line Development and Manufacturing*

We have identified the amino acid sequence of CHS-2020 and confirmed that it is identical to the protein in the reference product, Eylea. We are currently in preclinical development.

**Early-Stage Biosimilar Pipeline**

We are continuously performing product opportunity reviews of additional biosimilar pipeline candidates in conjunction with our scientific advisory board.

## Small Molecule Therapeutic Candidate in Development

CHS-131 is a potential novel, first-in-class, well-tolerated, once-daily oral drug candidate under development for non-alcoholic steatohepatitis (“NASH”) and other metabolic conditions. CHS-131 is a selective ligand for peroxisome proliferator-activator receptor gamma (“PPAR $\gamma$ ”) which is part of a family of nuclear receptors that are expressed in a broad range of tissues and regulate multiple metabolic processes. PPAR $\gamma$  plays a central role in regulating storage and metabolism of dietary fats, and is a relevant target in conditions with loss of normal adipocyte function, hypoadiponectinemia and insulin resistance. The activation of PPAR $\gamma$  drives adiponectin expression and insulin sensitization, addressing a core issue that underpins the NASH disease process. PPAR $\gamma$  is a clinically validated target in NASH by pioglitazone, which is recognized in the American Association for the Study of Liver Diseases (“AASLD”) guidelines.

CHS-131 has a novel chemical scaffold, unrelated to thiazolidinediones. CHS-131 has demonstrated an improved safety profile from thiazolidinediones in preclinical and clinical testing, and has been administered to over 600 human subjects in multiple clinical studies.

In June 2016, we reported positive Phase 2b efficacy data on CHS-131 in relapsing remitting multiple sclerosis (“MS”). This six-month study demonstrated significant reduction in contrast-enhancing lesions meeting its primary endpoint. CHS-131 was generally well-tolerated and without evidence of immune suppression or the side-effects commonly seen in other oral MS therapies.

Results of a positive Phase 2b study of CHS-131 in Type 2 diabetes mellitus were published in 2014. This six month randomized, double-blind, placebo controlled study of four doses (0.5 mg, 1 mg, 2 mg, 3 mg) of CHS-131 in comparison to 45 mg of pioglitazone in 367 subjects on a background of sulfonylurea or sulfonylurea plus metformin, demonstrated a steep dose response for efficacy as measured by changes in HbA1c. The 2-mg dose demonstrated near-maximal efficacy, which was not statistically different from the efficacy of 45 mg of pioglitazone.

NASH is a highly prevalent serious condition with no approved therapies. It is part of the spectrum of non-alcoholic fatty liver disease (“NAFLD”) and is characterized by hepatic fat deposition with inflammation, accumulating fibrosis, and ultimately liver cirrhosis. NASH-related cirrhosis is currently a leading cause of chronic liver disease and is associated with hepatocellular cancer. It is estimated to become the leading cause of liver transplant in the United States by 2020. The U.S. prevalence of NASH is expected to reach 27 million by 2030.

## Sales and Marketing

Our strategy is to retain commercial rights to our biosimilar products in the U.S. For UDENYCA™, the sales call points in the U.S. 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.

For our other biosimilar and small molecule drug candidates (CHS-1420, CHS-0214, CHS-3351, CHS-2020 and CHS-131), we seek to license rights regionally or globally to commercially proficient partners.

## Manufacturing

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

## Competition

The development and commercialization of protein-based therapeutics is highly competitive. While we believe that our biologics platform, knowledge, experience and scientific resources provide us with competitive advantages, we face potential competition from many different sources. Such competition includes larger and better-funded pharmaceutical, generic pharmaceutical, specialty pharmaceutical and biotechnology companies, as well as originator companies and any other firms developing the biosimilars that would compete with the product candidates in our pipeline and other novel products with similar indications.

UDENYCA™ faces competition from Amgen (which holds rights to Neulasta, the reference product of UDENYCA™), and Mylan N.V. (“Mylan”), and may face competition from Sandoz International GmbH (“Sandoz”), Apotex Inc. (“Apotex”) and Pfizer Inc. (“Pfizer”).

CHS-1420 may face competition from AbbVie (the holder of rights to Humira, the reference product of CHS-1420), Amgen (which has a biosimilar to Humira (Amjevita™) approved in the U.S. and (Amgevita™ / Solymbic™) approved in the E.U.), Sandoz, (which has a biosimilar to Humira (Hyrimoz™) approved in the E.U.), Samsung Bioepis (which has a biosimilar to Humira (Imraldi™)

approved in the E.U.), Pfizer, Mylan, Momenta Pharmaceuticals, Inc. (“Momenta”), Fujifilm Kyowa Kirin Biologics Co., Ltd (“Fujifilm”), Fresenius Kabi (“Fresenius”), and Boehringer Ingelheim GmbH (“Boehringer Ingelheim”) (which has a biosimilar to Humira (Cyltezo™) approved in the U.S. and E.U.).

CHS-0214 may compete with products developed by Pfizer, (which holds ex-North America rights to Enbrel, the reference product of CHS-0214), Sandoz (which has a biosimilar to Enbrel (Erelzi™) approved in the U.S. and in the E.U.), Samsung Bioepis Co Ltd. (“Samsung Bioepis”), which has an approved biosimilar to Enbrel (Benepali™) in the E.U., Lupin Limited (“Lupin”), and LG Chem, Ltd. (“LG”).

CHS-3351 may face competition from Genentech USA, Inc. (the holder of rights to Lucentis, the reference product of CHS-3351), as well as Pfenex Inc., Samsung Bioepis, Xbrane Biopharma AB (in collaboration with STADA Arzneimittel AG) and Bioeq IP AG (in collaboration with Formycon AG), companies that have each disclosed development plans for a Lucentis biosimilar candidate.

CHS-2020 may face competition from Regeneron Pharmaceuticals, Inc. (the holder of rights to Eylea, the reference product of CHS-2020), as well as Momenta Pharmaceuticals, Inc. and Santo Holding GmbH (in collaboration with Formycon AG), companies that have each disclosed development plans for an Eylea biosimilar candidate.

We expect any products that we develop and commercialize directly or with partners to compete on the basis of, among other things, efficacy, safety, price and the availability of reimbursement from government and other third-party payers. 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 Company, Limited (“Daiichi Sankyo”) for the development and commercialization of certain biosimilar products in certain territories (the “Daiichi Sankyo 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. Daiichi Sankyo had 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 had 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. Under the Daiichi Sankyo Agreement, we received an upfront payment in cash of \$10.0 million and \$20.0 million in the form of an equity investment and multiple payments under the memoranda of understanding.

In May 2012, Daiichi Sankyo terminated its licensed rights, solely as to CHS-0214, our etanercept biosimilar candidate, 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. In July 2017, Daiichi Sankyo announced its decision, which we accepted, to discontinue development of CHS-0214 in Japan and to conclude the parties’ global open-label safety extension study in rheumatoid arthritis. As a result, we regained the rights to develop and commercialize CHS-0214 in Japan. In August 2017, we entered into a letter of agreement with Daiichi Sankyo to terminate the Daiichi Sankyo Agreement, including any and all memoranda of understanding and other agreements executed between the parties relating to CHS-0214.

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

We entered into a license agreement in August 2013 and two subsequent amendments thereto with Baxalta Incorporated, Baxalta US Inc., and Baxalta GmbH, collectively Baxalta (then Baxter International, Inc., part of Shire plc (“Shire”), as of June 2016), to develop and commercialize an etanercept biosimilar molecule, CHS-0214, worldwide, excluding the U.S., Japan, Taiwan, South Korea, China and most of the Caribbean and South American nations (as amended, the “Baxalta Agreement”). On September 26, 2016, Shire issued a termination notice of the Baxalta Agreement, in its entirety as part of its strategic portfolio review after its acquisition of Baxalta. Under the Baxalta Agreement, we received an upfront payment of \$30.0 million and were eligible to receive up to \$335.3 million in contingent payments, of which we actually received \$215.3 million. Upon the termination of the Baxalta Agreement, we regained from Shire all development and commercial rights previously licensed under the Baxalta Agreement.

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

In December 2012, we entered into a distribution agreement with Orox Pharmaceuticals B.V. (“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. Each 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 Agreements with Selexis SA***

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

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

### ***Settlement and License Agreements with AbbVie, Inc.***

On January 24, 2019, we entered into three settlement and license agreements with AbbVie, that grant Coherus global, royalty-bearing, non-exclusive license rights under AbbVie’s intellectual property to commercialize CHS-1420, our proposed adalimumab (Humira) biosimilar. The global settlements resolve all pending disputes between the parties related to our adalimumab biosimilar. Under the U.S. settlement, our license period in the U.S. commences on December 15, 2023.

### **Intellectual Property**

Our commercial success depends in part on our ability to avoid infringing the proprietary rights of third parties. Additionally, our commercial success may depend on 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 U.S., the patent term is generally 20 years from the earliest date of filing a non-provisional patent application in the applicable country. In the U.S., a patent’s term may, in certain cases, be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office in examining and granting a patent or may be shortened if a patent is terminally disclaimed over a commonly owned patent or a patent naming a common inventor and having an earlier expiration date.

In the normal course of business, we pursue patent protection for inventions related to our product candidates. We own a patent portfolio of 22 patent families related to our biosimilar product candidates, each of which includes United States patent applications and/or issued patents, and some include foreign counterparts to certain of the U.S. patents and patent applications. Our patent portfolio includes issued or pending claims directed to: formulations for CHS-1420 and CHS-0214; methods of manufacturing biological proteins, including CHS-1420 and CHS-0214; and drug products and devices, including their methods of use and methods of manufacture.

In a merger completed February 12, 2014, we acquired InteKrin Therapeutics Inc. (“InteKrin”) and its small molecule PPAR-g modulator, CHS-131, which is being developed for the treatment of NASH.

InteKrin has an exclusive license from Amgen to a portfolio of four patent families related to CHS-131, each of which includes U.S. patents, that we own applications and/or issued patents, and some include foreign counterparts to certain of the U.S. patents and patent applications. The licensed patent portfolio includes issued or pending claims directed to PPAR-g modulating molecules and therapeutic product compositions that are expected to expire in 2020 and 2021, as well as certain salt forms and polymorphic forms directed to PPAR-g modulating molecules that are expected to expire in 2024. Additionally, we and our subsidiary InteKrin own a portfolio of ten patent families related to CHS-131, each of which includes U.S. patent applications and/or issued patents, and some include foreign counterparts to certain of the U.S. patents and patent applications. This patent portfolio includes issued or pending claims directed to PPAR-g agonist pharmaceutical compositions, and methods of treating disorders including diabetes, multiple sclerosis, non-alcoholic fatty liver disease or lipodystrophy, blood cancers, bone disorders, Huntington’s disease, and progressive supranuclear palsy.

Upon the first FDA approval for a CHS-131 product, we intend to seek Hatch-Waxman patent term extension of CHS-131 related patents, that we own or license. Any such extension cannot be longer than five years and the total patent term, including the extension period, must not exceed fourteen years following FDA approval.

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 U.S. 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 U.S. 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 U.S. by the FDA as biological products (“biologics”), except for CHS-131, which is regulated as a drug product candidate. The FDA subjects drugs and biologics to extensive pre- and post-market regulation pursuant to the Federal Food, Drug and Cosmetic Act (“FFDCA”) and its implementing regulations, and in the case of biologics, the FFDCA and the Public Health Service Act (“PHSA”) and their implementing regulations. In addition, we are subject to other federal and state statutes and regulations. These laws 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 drugs and 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 or NDAs, 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 process required by the FDA before a new biologic or drug may be marketed in the U.S. is long, expensive and inherently uncertain. Biologic and drug development in the U.S. typically involves the completion of preclinical laboratory and animal tests in accordance with good laboratory practices (“GLP”), the submission to the FDA of an investigational new drug (“IND”) application, which must become effective before clinical testing may commence, the performance of adequate and well-controlled clinical trials to establish the safety and effectiveness of the biologic or drug for each indication for which FDA approval is sought in compliance with good clinical practice (“GCP”) requirements, the submission to the FDA of an original BLA under Section 351(a) of the PHSA (“original BLA”) or an NDA, as appropriate, satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug or biologic is produced, and FDA approval and review of the original BLA or NDA. Developing the data to satisfy FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease.

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

An IND must become effective before U.S. 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 GCP requirements, which are designed 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.

Human clinical trials for novel drugs and biologics, such as our product candidate CHS-131, are typically conducted in three sequential phases that may overlap or be combined.

- Phase 1—The product candidate is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and elimination. In the case of some therapeutic candidates for severe or life-threatening diseases, such as cancer, especially when the product candidate may be inherently too toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.
- Phase 2—Clinical trials are performed on a limited patient population intended to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.
- Phase 3—Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical study sites. These studies are intended to establish the overall risk-benefit ratio of the product and provide an adequate basis for product labeling.

Post-approval trials, sometimes referred to as “Phase 4” clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, FDA may mandate the performance of such “Phase 4” clinical trials.

The FDA may order the temporary or permanent discontinuation of a clinical trial at any time or impose other sanctions if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The study protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board (“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.

Concurrent with clinical trials, sponsors usually complete additional animal safety studies, develop additional information about the chemistry and physical characteristics of the product candidate and finalize a process for manufacturing commercial quantities of the product candidate in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and the manufacturer must develop methods for testing the quality, purity and potency of the product candidate. To help reduce the risk of the introduction of adventitious agents with use of biological products, the PHS emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other criteria, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final biological product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the biological product candidate does not undergo unacceptable deterioration over its shelf life. Additionally, for both NDA and BLA products, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its proposed shelf-life.

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, detailed information regarding the investigational product is submitted to the FDA in the form of a BLA or NDA requesting approval to market the product for one or more indications. The BLA or NDA must include all relevant data available from pertinent preclinical and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. Data can come from company-sponsored clinical studies intended to test the safety and effectiveness of a use of the product, or from a number of alternative sources, including studies initiated by investigators. Under the Prescription Drug User Fee Act ("PDUFA") as amended, each original BLA or NDA must be accompanied by a significant user fee. Fee waivers or reductions are available in certain circumstances, such as where a waiver is necessary to protect the public health, where the fee would present a significant barrier to innovation, or where the applicant is a small business submitting its first human therapeutic application for review.

Within 60 days following submission of the application, the FDA reviews an original BLA or NDA submitted to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any original BLA or NDA that it deems incomplete or not properly reviewable at the time of submission, and may request additional information. In this event, the original BLA or NDA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the original BLA or NDA. The FDA reviews the original BLA to determine, among other things, whether the proposed product is safe, pure and potent for its intended use, and has an acceptable purity profile, and in the case of an NDA, whether the product is safe and effective for its intended use, and in each case, whether the product is being manufactured in accordance with cGMP. The FDA may refer applications for novel products or products that 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 and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

During the product approval process, the FDA also will determine whether a risk evaluation and mitigation strategy ("REMS") is necessary to assure the safe use of the product. If the FDA concludes a REMS plan is needed, the sponsor of the original BLA or NDA must submit a proposed REMS plan. The FDA will not approve an original BLA or NDA without a REMS plan, if required. In determining whether a REMS plan is necessary, the FDA must consider the size of the population likely to use the drug or biologic, the seriousness of the disease or condition to be treated, the expected benefit of the drug or biologic, the duration of treatment, the seriousness of known or potential adverse events, and whether the drug or biologic is a new molecular entity. A REMS plan may be required to include various elements, such as a medication guide or patient package insert, a communication plan to educate health care providers of the risks, limitations on who may prescribe or dispense the drug or biologic, or other measures that the FDA deems necessary to assure the safe use of the drug or biologic. In addition, the REMS plan must include a timetable to assess the strategy at 18 months, three years, and seven years after the strategy's approval.

The FDA will not approve the application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an original BLA or NDA, the FDA will typically inspect one or more clinical sites to assure compliance with cGMP. After the FDA evaluates an original BLA or NDA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A complete response letter indicates that the review cycle of the application is complete and the application is not ready for approval. A complete response letter may require additional clinical data and/or an additional pivotal Phase 3 trial or trials, and/or other significant, expensive and time-consuming requirements related to clinical trials, preclinical trials or manufacturing. Even if such additional information is submitted, the FDA may ultimately decide that the original BLA or NDA does not satisfy the criteria for approval.

Even if a product receives regulatory approval, the approval may be significantly limited to specific indications and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a risk management plan, or otherwise limit the scope of any approval. In addition, the FDA may require post marketing clinical trials, sometimes referred to as “Phase 4” clinical trials, designed to further assess a biological product’s safety and effectiveness, and testing and surveillance programs to monitor the safety of approved products that have been commercialized.

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

The Biologics Price Competition and Innovation Act of 2009 (“BPCIA”), amended the PHS Act and created an abbreviated approval pathway for biological products shown to be highly similar to a FDA-licensed reference biological product. The BPCIA attempts to minimize duplicative testing and thereby lower development costs and increase patient access to affordable treatments. Thus, under the biosimilar approval pathway, an application for licensure of a biosimilar product pursuant to a Section 351(k) BLA 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 PK and PD 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 is defined to mean that the proposed 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, biosimilar may also be determined to be “interchangeable” with the reference 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 U.S. 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 original 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 Amendment of 2017 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 an original BLA for licensure as a new biological product under section 351(a) of the PHSA.

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. In certain circumstances, a regulatory exclusivity period can extend beyond the life of a patent and thus block Section 351(k) BLA applications from being approved on or after the patent expiration date. In addition, the FDA may under certain circumstances extend the exclusivity period for the reference product by an additional six months if the FDA requests, and the manufacturer undertakes, studies on the effect of its product in children, a so-called pediatric extension.

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

#### *Advertising and Promotion*

Once an NDA, original BLA, or 351(k) BLA is approved, a product will be subject to continuing post-approval regulatory requirements, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. For instance, the FDA closely regulates the post-approval marketing and promotion of biologics, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet. Failure to comply with these regulations can result in significant penalties, including the issuance of warning letters directing a company to correct deviations from FDA standards, a requirement that future advertising and promotional materials be pre-cleared by the FDA and federal and state civil and criminal investigations and prosecutions.

Biologics and drugs 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 marketing application or supplement to the approved marketing application before the change can be implemented. A 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 supplements as it does in reviewing original application. There are also continuing annual program user fee requirements for marketed products.

#### *Adverse Event Reporting and GMP Compliance*

Adverse event reporting and submission of periodic reports are required following FDA approval of a marketing application. The FDA also may require post-market testing, including Phase 4 testing, a 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 cGMPs after approval. 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***

We are 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 transparency 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 (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 payer, including commercial insurers.

Additionally, federal civil and criminal false claims laws, including the civil False Claims Act, prohibit 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.

The federal Civil Monetary Penalties Law prohibits, among other things, the offering or transferring of remuneration to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary’s selection of a particular supplier of Medicare or Medicaid payable items or services. Noncompliance with such beneficiary inducement provision of the federal Civil Monetary Penalties Law can result in civil money penalties for each wrongful act, assessment of three times the amount claimed for each item or service and exclusion from the federal healthcare programs.

Federal and state government price reporting laws require manufacturers to calculate and report complex pricing metrics to government programs. Such reported prices may be used in the calculation of reimbursement and/or discounts on marketed products. Participation in these programs and compliance with the applicable requirements subject manufacturers to potentially significant discounts on products, increased infrastructure costs, and potentially limit the ability to offer certain marketplace discounts.

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 \$165,786 per year (or up to an aggregate of \$1.105 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. 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 federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) created new federal criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payers, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

We may also be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology and Clinical Health Act (“HITECH”) and their respective implementing regulations, imposes specified requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA’s privacy and security standards directly applicable to “business associates,” defined as independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney’s fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, thus complicating compliance efforts.

Some states require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and require manufacturers to report information related to payments and other transfers of value to healthcare providers and institutions as well as marketing expenditures and pricing information.

The shifting commercial compliance environment and the need to build and maintain robust systems to comply with different compliance and/or reporting requirements in multiple jurisdictions increase the possibility that a healthcare company may violate one or more of the requirements. If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, 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 U.S., 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 EMA and a decision issued by the European Commission. However, substitution of a biosimilar for the originator is a decision that is made at the local (national) level on a country-by-country basis. Additionally, a number of European countries do not permit the automatic substitution of biosimilars for the originator product. Other regions, including Canada, Japan and Korea, also have their own legislation outlining a regulatory pathway for the approval of biosimilars. In some cases, other countries have either adopted European guidance (Singapore and Malaysia) or are following guidance issued by the World Health Organization (Cuba and Brazil). While there is overlap in the regulatory requirements across regions, there are also still some areas of non-overlap.

We are also subject to privacy laws in the jurisdictions in which we are established or in which we sell or market our products or run clinical trials. For example, in Europe we are subject to Regulation (EU) 2016/679 (General Data Protection Regulation or GDPR) in relation to our collection, control, processing and other use of personal data (i.e., data relating to an identifiable living individual).

We process personal data in relation to participants in our clinical trials in the European Economic Area (“EEA”), including the health and medical information of these participants. The GDPR is directly applicable in each E.U. Member State, however, it provides that E.U. Member States may introduce further conditions, including limitations which could limit our ability to collect, use and share personal data (including health and medical information), or could cause our compliance costs to increase, ultimately having an adverse impact on our business. The GDPR imposes onerous accountability obligations requiring data controllers and processors to maintain a record of their data processing and implement policies as part of its mandated privacy governance framework. It also requires data controllers to be transparent and disclose to data subjects (in a concise, intelligible and easily accessible form) how their personal information is to be used, imposes limitations on retention of personal data; defines for the first time pseudonymized (i.e., key-coded) data; introduces mandatory data breach notification requirements; and sets higher standards for data controllers to demonstrate that they have obtained valid consent for certain data processing activities. We are also subject to E.U. rules with respect to cross-border transfers of personal data out of the E.U. and EEA. Where we transfer personal data out of the E.U. or EEA, we do so in compliance with the relevant E.U. data export requirements from time to time. We are subject to the supervision of local data protection authorities in those E.U. jurisdictions where we are established or otherwise subject to the GDPR. Fines for certain breaches of the GDPR are significant: up to the greater of EUR 20 million or 4% of total global annual turnover. In addition to the foregoing, a breach of the GDPR could result in regulatory investigations, reputational damage, orders to cease and desist certain activities, changes in the use of our data, enforcement notices, as well as potential civil claims including class action type litigation where individuals suffer harm.

### ***Pharmaceutical Coverage, Pricing and Reimbursement***

In the U.S. 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 payers, including government health administrative authorities, managed care providers, private health insurers and other organizations. Third-party payers 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 payer 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.

The Centers for Medicare & Medicaid Services (“CMS”) adopted, effective January 1, 2018, a Medicare Part B rule on biosimilar payment and coding, which requires that each biosimilar to the same reference product be issued a unique Q-code for Medicare reimbursement purposes and that the payment amount for a billing code that describes a biosimilar is based on the average sales price (“ASP”) specific to each biosimilar.

### ***Healthcare Reform***

In March 2010, then President Barack Obama signed the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively known as the Affordable Care Act, which substantially changed the way healthcare is financed by both governmental and private insurers in the U.S., and significantly affected the pharmaceutical industry. The Affordable Care Act contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement adjustments and fraud and abuse changes. Additionally, the Affordable Care Act subjects biologic products to potential competition by lower-cost biosimilars; increases the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1%; imposes a non-deductible annual fee on pharmaceutical manufacturers or importers who sell “branded prescription drugs” to specified federal government programs; and 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.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, and we expect there will be additional challenges and amendments to the Affordable Care Act in the future. For example, on December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, or Texas District Court Judge, ruled that the entire Affordable Care Act is invalid based primarily on the fact that the Tax Cuts and Jobs Act of 2017 repealed the tax-based shared responsibility payment imposed by the Affordable Care Act, on certain individuals who fail to maintain qualifying health coverage for all or part of a year, which is commonly referred to as the “individual mandate”. While the Texas District Court Judge, as well as the current presidential administration and CMS, have stated that this ruling will have no immediate effect, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the Affordable Care Act will impact the law.

Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted, including aggregate reductions of Medicare payments to providers of 2% per fiscal year and reduced payments to several types of Medicare providers.

Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. Individual states in the U.S. have also become increasingly active in implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

## **Employees**

As of December 31, 2018, we had 232 employees. Within our workforce, 87 employees are engaged in research and development, 105 in sales, commercial analytics, market access and marketing, and 40 in business development, finance, legal, human resources, facilities, information technology and general management and administration.

## **Additional Information**

We view our operations and measure our business as one reportable segment operating primarily in the U.S. See Note 2 to our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K for additional information. Additional information required by this item is incorporated herein by reference to Part I, Item 1A “Risk Factors” and Part II, Item 6 “Selected Financial Data.”

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

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

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

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

## **Item 1A. Risk Factors**

*Investing in the common stock of a biotherapeutics company is a highly speculative undertaking and involves a substantial degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information in this Annual Report on Form 10-K, including our financial statements and related notes thereto. If any of the following risks are realized, our business, financial condition, results of operations and prospects could be materially and adversely affected. As a result, the trading price of our common stock could decline and you could lose part or all of your investment. The risks described below are not the only*

risks facing the Company. Risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition, liquidity, and results of operations and/or prospects.

## **Risks Related to Our Financial Condition and Capital Requirements**

***We have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future.***

We have incurred net losses in each year since our inception in September 2010, including net losses of \$209.4 million, \$238.3 million and \$127.8 million for the years ended December 31, 2018, 2017 and 2016, respectively. As of December 31, 2018, we had an accumulated deficit of \$984.8 million. The losses and accumulated deficit were primarily due to the substantial investments we made to identify and develop our product candidates, including conducting, among other things, analytical characterization, process development and manufacturing, formulation and clinical studies, and providing general and administrative support for these operations.

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 completed Phase 3 or other BLA-enabling development with all our lead products, UDENYCA™ (pegfilgrastim-cbqv), CHS-1420 (our adalimumab (Humira) biosimilar candidate) and CHS-0214 (our etanercept (Enbrel) biosimilar candidate). Our BLA for UDENYCA™ was accepted for review by the FDA in October 2016, and we received a CRL from the FDA in June 2017. We resubmitted our BLA for UDENYCA™ on May 3, 2018 and the FDA accepted our resubmission on May 14, 2018. Our MAA for UDENYCA™ was accepted for review by the EMA in November 2016, and on September 25, 2018, the European Commission (“EC”) approved the MAA of UDENYCA™. On November 2, 2018, the FDA approved UDENYCA™ as a biosimilar to Neulasta to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. It may be several months before we submit an application for market approval with the relevant regulatory agencies for CHS-1420 and CHS-0214. We have not yet initiated clinical trials for CHS-3351 (our ranibizumab (Lucentis) biosimilar) or for CHS- 2020 (our aflibercept (Eylea) biosimilar). 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 payers, 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 not become profitable.

We expect to continue to incur significant expenses and sustained operating losses for the foreseeable future. Our expenses will increase substantially if and as we:

- establish a sales, marketing and distribution infrastructure to commercialize UDENYCA™ or any of our product candidates for which we may obtain marketing approval;
- continue our nonclinical and clinical development of our product candidates;
- initiate additional nonclinical, clinical or other studies for our product candidates;
- expand the scope of our current clinical studies for our product candidates;
- advance our programs into more expensive clinical studies;
- 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;
- seek to identify, assess, acquire and/or develop other biosimilar product candidates or products that may be complementary to our products;
- make upfront, milestone, royalty or other payments under any license agreements;
- seek to create, maintain, protect and expand our intellectual property portfolio;

- engage legal counsel and technical experts to help us evaluate and avoid infringing any valid and enforceable intellectual property rights of third parties;
- engage in litigation including patent litigation and IPR proceedings with originator companies or others that may hold patents;
- seek to attract and retain skilled personnel;
- create additional infrastructure to support our operations as a public company and our product development and planned future commercialization efforts; and
- experience any delays or encounter issues with any of the above, including but not limited to failed studies, conflicting results, safety issues, manufacturing delays, litigation or regulatory challenges that may require longer follow-up of existing studies, additional major studies or additional supportive studies or analyses in order to pursue marketing approval.

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

***We are heavily dependent on the ability to raise 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 and commercialization efforts or other operations.***

As of December 31, 2018, our cash and cash equivalents were \$72.4 million. We expect that our existing cash and cash equivalents, together with the \$75 million credit agreement executed in January 2019 will be sufficient to fund our current operations for at least the next 12 months. We have financed our operations primarily through the sale of equity securities, convertible notes, and credit facilities, as well as through our license agreements with Baxalta Incorporated, Baxalta US Inc., and Baxalta GmbH (collectively “Baxalta”, now subsidiaries of Shire plc), and Daiichi Sankyo Company, Limited (“Daiichi Sankyo”) (referenced in more detail below).

However, 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:

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

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

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

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

We have incurred substantial losses during our operating history and 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 rolling three-year period), such corporation’s ability to use its pre-change net operating loss carryforwards (“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 (some of which changes 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 may 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.

Additionally, the Tax Cuts and Jobs Act of 2017 (the “Tax Act”), which was signed into law on December 22, 2017, changed the rules governing the use of U.S. federal NOLs, including by imposing a reduction to the maximum deduction allowed for NOLs generated in tax years beginning after December 31, 2017. In addition, NOL carryforwards arising in tax years ending after December 31, 2017 can be carried forward indefinitely, but carryback is generally prohibited. Such limitations may significantly impact our ability to use NOL carryforwards generated after December 31, 2017, as well as the timing of any such use, and could adversely affect our future cash flows.

**Risks Related to Launch and Commercialization of UDENYCA™ and our Other Product Candidates**

***We have a limited operating history in an emerging regulatory environment on which to assess our business. We will not generate any revenue from product sales until 2019 and may never be profitable.***

We are a biotherapeutics company with a limited operating history in an emerging regulatory environment of biosimilar products. Although we have received upfront payments, milestone and other contingent payments and/or funding for development from some of our collaboration and license agreements, UDENYCA™ (pegfilgrastim-cbqv) is our only product approved for commercialization in the United States (“U.S.”) and European Union (“E.U.”), and we have no products approved in any other territories. The U.S. Food and Drug Administration (“FDA”) approved UDENYCA™ on November 2, 2018, as a biosimilar to Amgen’s Neulasta®, to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. The European Commission (“EC”), through the European Medicines Agency (“EMA”), approved UDENYCA™ on September 25, 2018 for substantially the same indication as approved by the FDA.

On January 3, 2019, we initiated the sale of UDENYCA™ in in the U.S.

Our ability to generate meaningful revenue and achieve profitability depends on our ability, alone or with strategic collaboration partners, to successfully market and sell UDENYCA™, and to complete the development of, and obtain the regulatory and marketing approvals necessary to commercialize, one or more of our other product pipeline candidates, which include:

- CHS-1420 (our adalimumab (Humira) biosimilar candidate);
- CHS-0214 (our etanercept (Enbrel) biosimilar candidate);
- CHS-3351 (our ranibizumab (Lucentis) biosimilar)
- CHS-2020 (our aflibercept (Eylea) biosimilar); and
- CHS-131 (a small molecule for nonalcoholic steatohepatitis (“NASH”) and multiple sclerosis).

We cannot predict when we will begin generating meaningful revenue from product sales, as this depends heavily on our success in many areas, including but not limited to:

- launching and commercializing UDENYCA™ either directly or with collaboration partners or distributors;
- healthcare providers, payers, and patients adopting our product candidates once approved and launched;



- obtaining additional regulatory and marketing approvals for product candidates for which we complete clinical studies;
- obtaining adequate third-party coverage and reimbursements for our products;
- obtaining market acceptance of our product candidates as viable treatment options;
- completing nonclinical and clinical development of our product candidates;
- developing and testing of our product formulations;
- attracting, hiring and retaining qualified personnel;
- 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;
- addressing any competing technological and market developments;
- identifying, assessing and developing (or acquiring/in-licensing) new product candidates;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how; and
- defending against any litigation including patent or trade secret infringement lawsuits, that may be filed against us, or achieving successful outcomes in Inter Partes Review (“IPR”) petitions that we have filed, or may in the future file, against third parties.

Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs to commercialize any such product. Our expenses could increase beyond our expectations if we are required by the FDA, 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 additional 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 payers) 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 additional regulatory approval for our products, our business may suffer. Additionally, if we are not able to generate revenue from the sale of any approved products, we may never become profitable.

***Our ability to generate revenue relies substantially on the successful launch and commercialization of UDENYCA™, which is currently our only commercial product offering.***

Our ability to generate revenue will be primarily dependent on the sale of UDENYCA™ to healthcare providers, and we expect that the sales of UDENYCA™ will account for substantially all of our revenue for the foreseeable future. While we are in various stages of research and development with other biosimilar and pharmaceutical products, there can be no assurance that we will be able to successfully develop and commercialize any new product candidates. In order to substantially increase our revenue, we will need to educate community oncology clinics and hospitals, group purchasing organizations (“GPOs”), wholesalers, and insurance payers about UDENYCA™. We had limited contact with these entities to date because UDENYCA™ was not approved by regulatory authorities until late 2018. If we are unable to contract and increase prescriptions of UDENYCA™ with our customers, expand payer coverage and reimbursement, or successfully develop and commercialize new products or services, our revenue and our ability to achieve and sustain profitability would be impaired.

***We hired new marketing and sales team members to launch and market UDENYCA™. If we fail to develop, organize, and execute an effective marketing and sales strategy, as well as retain a significant number our sales and marketing team members, we may fail to generate meaningful sales or achieve expected commercial results.***

In 2018, we substantially increased the size of our marketing and sales team to help us launch and sell UDENYCA™. While we believe our sales and marketing team is comprised of individuals with proven industry experience, technical expertise, and supporting distribution capabilities to commercialize UDENYCA™, we will have no experience selling or marketing UDENYCA™. To successfully launch and increase our marketing efforts for UDENYCA™ we will need to develop, grow, and retain our sales and marketing team members, as well as increase our brand recognition, value proposition, and commercial outreach efforts, either on our own or with others. Doing so may be expensive, difficult, time consuming, and require active learning and adaptation. Any failure or delay in the development, cohesion, or execution of our sales and marketing efforts or supply and distribution capabilities may adversely impact sales of UDENYCA™. Further, given our lack of prior experience in marketing and selling biosimilar 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 UDENYCA™ or we may incur excess costs as a result of hiring more sales representatives than necessary. With respect to certain geographical markets, such as the E.U., 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.

***The commercial success of UDENYCA™, or any future product candidate, will depend upon the degree of market acceptance and adoption by healthcare providers, patients, third-party payers and others in the medical community.***

Even with the requisite approvals from the FDA and comparable foreign regulatory authorities, the commercial success of UDENYCA™, or any of our future product candidates, if approved, will depend in part on the medical community, patients and third-party payers 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 payers and others in the medical community. The degree of market acceptance of any of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

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

Market acceptance of UDENYCA™, and our other future product candidates, if approved, 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 payers 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 payers and others in the medical community, we will not be able to generate sufficient revenue to become or remain profitable.

***The third-party coverage and reimbursement status of UDENYCA™ (or our other product candidates, if approved) 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 UDENYCA™, or any 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 payers are essential for most patients to be able to afford expensive treatments such as ours. Sales will depend substantially, both domestically and abroad, on the extent to which the costs of our products 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 payers. If coverage and reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize UDENYCA™ or any of our product candidates, if approved. 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 U.S., third-party payers, including private and governmental payers 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 payers and other governmental payers develop their coverage and reimbursement policies for drugs and biologics. It is difficult to predict what third-party payers will decide with respect to the coverage and reimbursement for any newly approved product. In addition, in the U.S., no uniform policy of coverage and reimbursement for biologics exists among third-party payers. Therefore, coverage and reimbursement for biologics can differ significantly from payer to payer. 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 payer separately, with no assurance that coverage and adequate reimbursement will be obtained. For example, CMS issued a proposed Medicare Part B rule in the third quarter of 2015 on biosimilar payment and coding, which requires that multiple biosimilars to the same reference product be grouped and issued the same J-code for Medicare reimbursement purposes and that the payment amount for a billing code that describes a biosimilar is based on the ASP of all biosimilar products that reference a common biological product's license application. However, on November 2, 2017, CMS adopted a final policy to no longer group biological products with a common reference product into the same billing code, which became effective January 1, 2018.

Effective January 2018, CMS assigned a product specific Q-Code to UDENYCA™, which is necessary to allow UDENYCA™ to have its own reimbursement rate and average selling price with Medicare or other third-party payers. However, reimbursement is not guaranteed and rates may vary based on product life cycle, site of care, type of payer, coverage decisions, and provider contracts. Furthermore, while third-party payers may adopt the Q-Code assigned by CMS for UDENYCA™, there remains uncertainty as to whether such payers will ultimately cover and pay providers for the administration and use of the product with each patient. If UDENYCA™, or any of our future product candidates, are not covered or adequately reimbursed by third-party payers, including Medicare, then the cost of the relevant product may be absorbed by healthcare providers or charged to patients. If this is the case, our expectations of the pricing we expect to achieve for such product and the related potential revenue, may be significantly diminished.

Outside the U.S., 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 U.S., the reimbursement for our products may be reduced compared with the U.S. and may be insufficient to generate commercially reasonable revenue and profits.

Increasing efforts by governmental and third-party payers in the U.S. 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 UDENYCA™ or any of 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 UDENYCA™ and any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes.

***UDENYCA™ and our other product candidates, even if approved, 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 U.S. 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 ("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, original BLA, 351(k) BLA or MAA. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

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

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

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

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

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

***Changes in funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.***

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

### **Risks Related to Competitive Activity**

***UDENYCA™, or our other biosimilar product candidates if approved, will face significant competition from the reference products and from other biosimilar products or 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 operate in 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 multinational pharmaceutical and biotechnology companies that enjoy significant competitive advantages, such as substantially greater financial, research and development, manufacturing, personnel, marketing resources, and the benefits of mergers and acquisitions.

Specifically, some of the pharmaceutical and biotechnology companies we expect to compete with include: Apotex, Sandoz, Amgen, Pfizer, Boehringer Ingelheim GmbH ("Boehringer Ingelheim"), Teva Pharmaceutical Industries, Ltd. ("Teva"), and Samsung Bioepis, Ltd. ("Samsung Bioepis"), (a Merck/Biogen/Samsung biosimilar venture), Mylan N.V. ("Mylan"), and Cinfa Biotech S.L. ("Cinfa"), as well as other smaller companies. We are currently aware that such competitors are engaged in the development and commercialization of biosimilar product candidates to pegfilgrastim (Neulasta), adalimumab (Humira) and etanercept (Enbrel).

We understand that Mylan and Biocon Ltd., Mylan's partner, received approval for a Neulasta biosimilar candidate (Fulphila (pegfilgrastim-jmdb)) in the U.S. in June 2018. In July and September 2018, the Committee for Medicinal Products for Human Use ("CHMP") of the EMA provided positive opinions on four Neulasta biosimilar candidates from Intas Pharmaceuticals LTD. ("Intas"), Mylan and its partner Biocon, Sandoz and Cinfa. We understand that Sandoz and Apotex have each submitted a Neulasta biosimilar product candidate for market approval in the U.S. and that Sandoz received a Complete Response Letter from the FDA at the end of June 2016.

Similarly, Pfizer, Boehringer Ingelheim, Amgen, Sandoz and Samsung Bioepis are examples of companies engaged in development of biosimilar product candidates for adalimumab (Humira). We understand Pfizer completed its Phase 3 program in 2017 and that Sandoz filed its application for regulatory approval with the FDA in November 2017. Boehringer Ingelheim's Humira biosimilar (Cyltezo, adalimumab-admb) was approved in the U.S. in August 2017 and in the E.U. in October 2017, and that Samsung Bioepis' Humira biosimilar was approved in the E.U. in August 2017. In addition, in September 2016, the FDA approved Amgen's adalimumab biosimilar (Amjevita, adalimumab-atto) for multiple inflammatory diseases.

On January 16, 2016, the EC approved Samsung Bioepis' etanercept biosimilar (Benepali) for the treatment of rheumatoid arthritis, psoriatic arthritis, axial spondyloarthritis (ankylosing spondylitis and non-radiographic axial spondyloarthritis) and plaque psoriasis. In June and August 2016, the EC and FDA, respectively, approved Sandoz' etanercept biosimilar (Erelzi, etanercept-szsz) for multiple inflammatory diseases.

These companies also have greater brand recognition and more experience in conducting preclinical testing and clinical trials of product candidates, obtaining FDA and other regulatory approvals of products and marketing and commercializing products once approved.

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

- settling, or refusing to settle, patent lawsuits with biosimilar companies, resulting in such patents remaining an obstacle for biosimilar approval;
- 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 U.S. 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, payers, 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 payer 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 U.S. 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.

For example, 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 Constitution of the U.S. The FDA rejected Abbott Laboratories' petition on September 23, 2016. In addition, on April 21, 2017 Apotex Inc. and its subsidiary Apobiologix submitted a Citizen Petition to the FDA asking the agency to require any biosimilar applicant seeking to submit a 351(k) BLA referencing Neulasta® to conduct comparative clinical efficacy studies, including PK, PD, and immunogenicity studies, in at least one intended patient population. The FDA dismissed this Citizen Petition in October 2017.

***UDENYCA™ and our other 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.***

Successful competitors in the biosimilar market have the ability to effectively compete on price with healthcare providers, and through payers and their third-party administrators, who exert downward pricing pressure on our price offerings. It is possible our biosimilar competitors' compliance with price discounting demands in exchange for market share or volume requirements could exceed our capacity to respond in kind and reduce market prices beyond our expectations. Such practices may limit our ability to increase market share and may also impact profitability.

***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.***

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.

***If other biosimilars of pegfilgrastim (Neulasta), adalimumab (Humira), etanercept (Enbrel), ranibizumab (Lucentis) or aflibercept (Eylea) are approved and successfully commercialized before UDENYCA™ or our product candidates for these originator products (CHS-1420, CHS-0214, CHS-3351 or CHS-2020, respectively), our business would suffer.***

We expect other companies to seek approval to manufacture and market biosimilar versions of Neulasta, Humira, Enbrel, Lucentis or Eylea. If other biosimilars of Neulasta, Humira, Enbrel, Lucentis or Eylea are approved and successfully commercialized before UDENYCA™, CHS-1420, CHS-0214, CHS-3351 or CHS-2020, respectively, we may never achieve meaningful market share for these products, our revenue would be reduced and, as a result, our business, prospects and financial condition could suffer. For instance, Mylan received FDA approval for its pegfilgrastim biosimilar in June 2018, and in July 2018, Mylan initiated the commercialization in the U.S. of this biosimilar. Furthermore, in July 2018, the Committee for Medicinal Products for Human Use ("CHMP") of the EMA has adopted positive opinions for the marketing authorization of UDENYCA™ and a pegfilgrastim biosimilar candidate from Intas and in September 2018, the CHMP has adopted positive opinions for three additional pegfilgrastim biosimilar candidates from Sandoz, Mylan and Cinfa.

***If an improved version of an originator product, such as Neulasta, Humira, Enbrel, Lucentis or Eylea, 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 submitted to 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, sales of the reference originator product 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.

***Although UDENYCA™ is approved by the FDA and the EMA, we may be delayed in selling UDENYCA™ due to direct or indirect legal challenges by our competitors or the government.***

Although UDENYCA™ received marketing approval in the U.S. and the E.U., we may also be subject to direct legal challenges from Amgen, the manufacturer of Neulasta®, or other current or future manufacturers of pegfilgrastim biosimilars, such as Mylan N.V., and we could be delayed or prevented from launching UDENYCA™ as a result of court orders or as a result of the time necessary to resolve such challenges.

Similarly, we may be subject to indirect legal challenges in the U.S. as a result of new executive orders from the President of the U.S. or the amendment or reversal of various laws by the U.S. Congress that govern or impact the approval of biosimilars, including the Patient Protection and Affordable Care Act (“PPACA”) and the BPCIA, which in aggregate may cause a delay in the commercial launch of Udenyca™.

#### **Risks Related to Our Ability to Hire and Retain Highly Qualified Personnel**

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

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

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

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

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

As of December 31, 2018, we had 232 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.

#### **Risks Related to Reliance on Third-Party Vendors**

***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, good clinical practices (“GCP”), and Good Laboratory Practices (“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 GCPs, the data generated in our nonclinical and clinical studies may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional nonclinical and clinical studies before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical studies comply with GCP regulations. In addition, our clinical studies must be conducted with product generated under cGMP regulations. Failure to comply by any of the participating parties or ourselves with these regulations may require us to repeat clinical studies, which would delay the regulatory approval process. Moreover, our business may be implicated if our CRO or any other participating parties violate federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

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

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

***We rely on third parties, and in some cases a single third party, to manufacture nonclinical, clinical and commercial drug 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 as well as to establish commercial supplies of our product candidates. 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 U.S. Our failure or the failure of our third party manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates or any other product candidates or products that we may develop. Any failure or refusal to supply the components for our product candidates that we may develop could delay, prevent or impair our clinical development or commercialization efforts. If our contract manufacturers were to breach or terminate their manufacturing arrangements with us, the development or commercialization of the affected products or product candidates could be delayed, which could have an adverse effect on our business. Any change in our manufacturers could be costly because the commercial terms of any new arrangement could be less favorable and because the expenses relating to the transfer of necessary technology and processes could be significant.

If any of our product candidates are approved, in order to produce the quantities necessary to meet anticipated market demand, any contract manufacturer that we engage may need to increase manufacturing capacity. If we are unable to build and stock our product

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

***We are dependent on Orox for the commercialization of our biosimilar product candidates in certain markets and we intend to seek additional commercialization partners for major markets, and the failure to commercialize in those markets could have a material adverse effect on our business and operating results.***

Our exclusive licensee, Orox, is responsible for commercialization of certain of our products and product candidates, including UDENYCA™, CHS-1420 and CHS-0214, in certain Caribbean and Latin American countries (excluding Brazil, and in the case of UDENYCA™, also excluding Argentina). We intend to seek commercialization partners for all products in Europe and other jurisdictions outside the U.S. (excluding certain Caribbean and Latin American countries). Our license with Orox, or other future license or collaboration agreements, may not be successful. Factors that may affect the success of our licenses and collaborations include, but are not limited to, the following:

- our existing and potential licensees and collaboration partners may fail to exercise commercially reasonable efforts to market and sell our products in their respective licensed jurisdictions or they may be ineffective in doing so;
- our existing and potential licensees and collaboration partners may incur financial, legal or other difficulties that force them to limit or reduce their participation in our joint projects;
- our existing and potential licensees and collaboration partners may terminate their licenses or collaborations with us, which could make it difficult for us to attract new partners and/or adversely affect perception of us in the business and financial communities; and
- our existing and potential licensees and collaboration partners may choose to pursue alternative, higher priority programs, which could affect their commitment to us.

Moreover, any disputes with our licensees and collaboration partners will substantially divert the attention of our senior management from other business activities and will require us to incur substantial costs associated with litigation or arbitration proceedings. If we cannot maintain successful license and collaboration arrangements, our business, financial condition and operating results may be adversely affected.

***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.

***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 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, in 2012, we entered into a collaboration agreement with Daiichi Sankyo for the development and commercialization of CHS-0214 in Japan. In addition, in 2013, we entered into a collaboration agreement with Baxalta (now part of Shire plc) for the development and commercialization of CHS-0214 in Europe, Brazil and other jurisdictions outside the U.S. In June 2016 and July 2017, we regained development and commercial rights for CHS-0214 from Shire plc for Europe, Canada, Brazil, the Middle East and other territories and Daiichi Sankyo in Japan as a result of the termination of the Daiichi Sankyo Agreement due to Daiichi Sankyo's decision to discontinue the development 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 2012.

In the future, we may also find it necessary to form alliances or joint ventures with major pharmaceutical companies to jointly develop and/or commercialize specific biosimilar product candidates. In such alliances, we would expect our collaboration partners to provide substantial capabilities in clinical development, manufacturing, regulatory affairs, sales and marketing. We may not be successful in entering into any such alliances. Even if we do succeed in securing such alliances, we may not be able to maintain them if, for example, development or approval of a product candidate is delayed or sales of an approved product are disappointing. If we are unable to secure or maintain such alliances, we may not have the capabilities necessary to continue or complete development of our product candidates and bring them to market, which may have an adverse effect on our business.

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

### **Risks Related to Manufacturing and Supply Chain**

***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 costlier manufacturing alternatives.

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

For UDENYCA™ and each of our lead product candidates, CHS-1420 and CHS-0214, we currently engage a distinct vendor or service provider for each of the principal activities supporting our manufacture and development of these lead products, such as manufacture of the biological substance present in each of the products, manufacture of the final filled and finished presentation of these products, as well as laboratory testing, formulation development and clinical testing of these products. For example, in December 2015, we entered into a strategic manufacturing agreement with KBI Biopharma, Inc. for long-term commercial manufacturing of UDENYCA™. Because we currently have not engaged back up suppliers or vendors for these single-sourced services, and although we believe that there are alternate sources that could fulfill these activities, we cannot assure you that identifying and establishing relationships with alternate suppliers and vendors would not result in significant delay in the development of our product candidates. Additionally, we may not be able to enter into arrangements with alternative service providers on commercially reasonable terms or at all. A delay in the development of our product candidates, or having to enter into a new agreement with a different third party on less favorable terms than we have with our current suppliers, could have a material adverse impact on our business.

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

All entities involved in the preparation of therapeutics for clinical studies or commercial sale, including our existing contract manufacturers for our product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in 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, NDA or MAA on a timely basis and must adhere to GLP and cGMP regulations enforced by the FDA and other regulatory agencies through their facilities inspection program. Some of our contract manufacturers may have never produced a commercially approved pharmaceutical product and therefore have not obtained the requisite regulatory authority approvals to do so. The facilities and quality systems of some or all of our collaboration partners and third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates or any of our other potential products. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. For example, a FDA inspection in the fourth quarter of 2016 of KBI Biopharma, our contract manufacturer for UDENYCA™ bulk drug substance, resulted in various form 483 observations. KBI Biopharma submitted corrective actions to the FDA. The FDA completed its review and has stated that the inspection is now closed. Although we oversee the contract manufacturers, we cannot control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements. If these facilities do not pass a pre-approval plant inspection, regulatory approval of the products may not be granted or may be substantially delayed until any violations are corrected to the satisfaction of the regulatory authority, if ever.

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

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

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

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

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

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

The inherent variability in protein structure from one production lot to another is a fundamental consideration with respect to establishing biosimilarity to an originator product to support regulatory approval requirements. For example, the glycosylation of the protein, meaning the manner in which sugar molecules are attached to the protein backbone of a therapeutic protein when it is produced

in a living cell, is critical to therapeutic efficacy, half-life (how long the drug stays in the body), efficacy and even safety of the therapeutic and is therefore a key consideration for biosimilarity. Defining and understanding the variability of an originator molecule in order to match its glycosylation profile requires significant skill in cell biology, protein purification and analytical protein chemistry. Furthermore, manufacturing proteins with reliable and consistent glycosylation profiles at scale is challenging and highly dependent on the skill of the cell biologist and process scientist.

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

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

## **Risks Related to Adverse Events**

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

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

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

***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. 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 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 USPTO and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. As the pharmaceutical industry expands and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

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

Third parties may assert that we are employing their proprietary technology without authorization. We are aware of third-party patents or patent applications with claims, for example, to compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. While we have conducted freedom to operate analyses with respect to UDENYCA™ and our lead product candidates, CHS-1420 and CHS-0214, as well as our pipeline candidates, 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 U.S. and abroad that is relevant or necessary to the commercialization of our product candidates. Moreover, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents covering our product candidates. With respect to products we are evaluating for inclusion in our future biosimilar product pipeline, our freedom to operate analyses, including our research on the timing of potentially relevant patent expirations, are ongoing.

There may also be patent applications that have been filed but not published and if such applications issue as patents, they could be asserted against us. For example, in most cases, a patent filed today would not become known to industry participants for at least 18 months given patent rules applicable in most jurisdictions, which do not require publication of patent applications until 18 months after filing. Moreover, some U.S. patents may issue without any prior publication in cases where the patent applicant does not also make a foreign filing. We may also face claims from non-practicing entities that have no relevant product revenue and against whom our own patent portfolio may have no deterrent effect. In addition, coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our product candidates, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid and/or unenforceable, and we may not be able to do this. Proving that a patent is invalid or unenforceable is difficult. For example, in the U.S., 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.

On May 10, 2017, Amgen Inc. and Amgen Manufacturing Inc. filed an action against us in the U.S. District Court for the District of Delaware alleging infringement of one or more claims of Amgen's US patent 8,273,707 (the "'707 patent") under 35 U.S.C. § 271. The complaint seeks injunctive relief, monetary damages and attorney fees. On December 7, 2017, the U.S. Magistrate Judge issued under seal a Report and Recommendation to the District Court recommending that the District Court grant, with prejudice, the Company's pending motion to dismiss Amgen's complaint for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6). On March 26, 2018, Judge Stark of the District Court adopted the U.S. Magistrate Judge's Report and Recommendation to grant the motion of the Company pursuant to Federal Rule of Civil Procedure 12(b)(6) to dismiss with prejudice the patent infringement complaint alleging infringement of the '707 patent on the grounds that such complaint failed to state a claim upon which relief may be granted. In May 2018, Amgen filed a Notice of Appeal in the U.S. Court of Appeals for the Federal Circuit. Amgen and Coherus have filed briefs in this matter and decision on the appeal is expected from the Federal Circuit in 2019.

On January 24, 2019, we entered into settlement and license agreements with AbbVie, that grant us global, royalty-bearing, non-exclusive license rights under AbbVie's intellectual property to commercialize CHS-1420, our proposed adalimumab (Humira) biosimilar. The global settlements resolve all pending disputes between the parties related to CHS-1420. Under the U.S. settlement, our license period in the U.S. commences on December 15, 2023.

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

On August 4, 2017, we filed a petition for IPR against U.S. patent 8,163,522 (the "'522 patent"). The '522 patent, controlled by Amgen, is generally directed to a method for making etanercept, the pharmaceutically active component of Enbrel. On September 6, 2017, we filed a petition for IPR against U.S. patent 8,063,182, (the "'182 patent"). The '182 patent, controlled by Amgen, is generally directed to the etanercept protein, the pharmaceutically active component of Enbrel. The PTAB denied institution on both petitions on March 9, 2018. As of September 30, 2018, we have determined that these matters are closed and there will be no further action related to the petitions for IPR on either the '522 patent or the '182 patent.

IPR filings, including our IPR filings, are a matter of public record and can be viewed at the USPTO PTAB website.

Third parties may submit applications for patent term extensions in the U.S. 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.

We do not know whether any of our pending patent applications 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.



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

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

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

Examples of submarine patents include Brockhaus, *et al.*, U.S. patents 8,063,182 and 8,163,522 (controlled by Amgen), which are directed to the fusion protein in Enbrel. If these patents are not successfully challenged (such as in IPRs or in district court litigation), and licenses to them are not available to us, they will preclude our ability to introduce an etanercept (Enbrel) biosimilar product candidate in the U.S. market until at least 2029.

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

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

We cannot guarantee that any of our patent searches or analyses, including but not limited to the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete and thorough, nor can we be certain that we have identified each and every patent and pending application in the U.S. 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 U.S. 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.

***We may be involved in lawsuits or IPR proceedings to protect or enforce our patents, which could be expensive, time consuming and unsuccessful.***

We may discover that competitors are infringing our issued patents. Expensive and time-consuming litigation may be required to abate such infringement. For example, we recently filed a complaint against Amgen alleging that Amgen’s Humira biosimilar infringes certain of our patents. Proceedings, such as the Amgen complaint, to enforce our patent rights, 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. If we or one of our collaboration partners 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 U.S., defendant counterclaims alleging invalidity and/or unenforceability are

commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including but not limited to lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could include an allegation that someone involved in the prosecution of the patent withheld relevant or material information related to the patentability of the invention from the USPTO or made a misleading statement during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable.

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

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

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

We employ individuals, retain independent contractors and consultants and members on our board of directors or scientific advisory board who were previously employed at universities or other pharmaceutical companies, including our competitors or potential competitors. For example, our Chief Executive Officer, Dennis M. Lanfear, and our Chief Technical Officer, Peter K. Watler, Ph.D., are former employees of Amgen. Mr. Lanfear and Dr. Watler were employed at Amgen during periods when Amgen's operations included the development and commercialization of Neupogen, Neulasta and Enbrel. Our former Chief Medical Officer, Barbara K. Finck, M.D., is a former employee of Immunex Corporation ("Immunex"), the company that initially developed 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. Senior members of our commercial team who will be responsible for any launch of our Neulasta biosimilar formerly held positions at Amgen. 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, we may be subject to claims that we or our employees or consultants have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. 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.

On March 3, 2017, Amgen Inc. and Amgen USA Inc. (collectively "Amgen") filed an action against us, KBI Biopharma Inc., our employee Howard S. Weiser and Does 1-20 in the Superior Court of the State of California, County of Ventura. The complaint alleges that we engaged in unfair competition and improperly solicited and hired certain former Amgen employees in order to acquire and access trade secrets and other confidential information belonging to Amgen. On June 1, 2017, Amgen filed a Second Amended Complaint, which alleges as to Coherus (i) unfair competition under California Business and Professions Code Section 17200 et seq., (ii) misappropriation of trade secrets, (iii) aiding and abetting breach of duty of loyalty and (iv) tortious interference with contract. As to defendant Weiser, the Second Amended Complaint alleges (i) unfair competition under California Business and Professions Code Section 17200 et seq., (ii) misappropriation of trade secrets, (iii) breach of contract, (iv) violation of Penal Code Section 502 and (v) breach of duty of loyalty. KBI Biopharma Inc. is not named as defendant in the Second Amended Complaint. The Second Amended Complaint seeks injunctive relief and monetary damages. Although Amgen has indicated it intends to seek a preliminary injunction, no motion has been filed yet. In December 2018, the court set a trial date of April 22, 2019.

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

In addition, changes to U.S. patent laws 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 U.S. 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 U.S. transitioned to a “first-to-file” system for deciding which party should be granted a patent when two or more patent applications claiming the same invention are filed by different parties. A third party that files a patent application in the USPTO before we do, could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. The change to “first-to-file” from “first-to-invent” is one of the changes to the patent laws of the U.S. resulting from the Leahy-Smith America Invents Act (the “Leahy-Smith Act”), signed into law on September 16, 2011. Among some of the other significant changes to the patent laws are changes that limit where a patentee may file a patent infringement suit and provide opportunities for third parties to challenge any issued patent in the USPTO. It is not yet clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

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

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

While our business is based primarily on the timing of our biosimilar product launches to occur after the expiration of relevant patents and on avoiding infringing valid and enforceable rights of third parties, we have filed a number of patent applications seeking patents that cover various proprietary elements of our product candidates when we have believed securing such patents may afford a competitive advantage. Our patent portfolio includes pending patent applications and issued patents, in the U.S. and globally, covering etanercept and adalimumab products and methods of making them. We cannot guarantee that our proprietary technologies will avoid infringement of third party patents. Moreover, because competitors may be able to develop their own proprietary technologies, it is uncertain whether any of our issued patents or pending patent applications directed to etanercept and adalimumab would cover the etanercept and adalimumab products of any competitors. The product and patent landscape is highly uncertain and we cannot predict whether our patent filings will afford us a competitive advantage against third parties or if our etanercept and adalimumab products will avoid infringement of third party patents.

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

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

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

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

Filing, prosecuting, defending and enforcing patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the U.S. can be less extensive than those in the U.S. 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 U.S. Further, licensing partners may choose not to file patent applications in certain jurisdictions in which we may obtain commercial rights, thereby precluding the possibility of later obtaining patent protection in these countries. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S. or importing products made using our inventions into the U.S. 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 U.S. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Governments of foreign countries may force us to license our patents to third parties on terms that are not commercially reasonable or acceptable to us. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time consuming and inherently uncertain. In addition, the U.S. has recently enacted and is currently implementing wide-ranging patent reform legislation. Recent 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 U.S. Congress, the Federal Courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

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

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

Although we expect all of our employees and consultants to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed. We cannot guarantee that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. For example, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may have a material adverse effect on our business. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. We cannot guarantee that our employees, former employees or consultants will not file patent applications claiming our inventions. Because of the “first-to-file” laws in the U.S., 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 Selexis SA and other vendors (pertaining to cell lines for CHS-1420 and CHS-0214) and with AbbVie (pertaining to AbbVie's intellectual property related to 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 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-1420 and CHS-0214. Because we may find that our programs require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights. We may be unable to acquire or in-license compositions, methods of use, processes or other third party intellectual property rights from third parties that we identify as necessary for our product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, financial resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment.

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

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

The Biologics Price Competition and Innovation Act of 2009, Title VII, Subtitle A of the Patent Protection and Affordable Care Act, Pub.L.No.111-148, 124 Stat.119, Sections 7001-02 signed into law March 23, 2010, and codified in 42 U.S.C. §262, (the "BPCIA"), created an elaborate and complex patent dispute resolution mechanism for biosimilars that, if we choose to implement it, could prevent us from launching our product candidates in the U.S. or could substantially delay such launches. However, even if we elect not to implement this mechanism, the launch of our products in the U.S. could still be prevented or substantially delayed by intellectual property disputes with originator companies that market the reference products on which our biosimilar products are based.

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

1. Disclosure of the Biosimilar Application. Within 20 days after the FDA publishes a notice that its application has been accepted for review, a 351(k) biosimilar applicant may elect to provide a copy of its application to the originator if it chooses to engage in the BPCIA patent exchange mechanism.
2. Identification of Pertinent Patents. Within 60 days of the date of receipt of the application the originator must identify patents owned or controlled by the originator, which it believes could be asserted against the biosimilar applicant.
3. Statement by the Biosimilar Applicant. Following the receipt of the originator's patent list, the biosimilar applicant must state either that it will not market its product until the relevant patents have expired or alternatively provide its arguments that the patents are invalid, unenforceable or would not be infringed by the proposed biosimilar product candidate. The biosimilar applicant may also provide the originator with a list of patents it believes the brand-name firm could assert against the reference product.
4. Statement by the Originator. In the event the biosimilar applicant has asserted that the patents are invalid, unenforceable or would not be infringed by the proposed follow-on product, the originator must provide the biosimilar applicant with a response within 60 days. The response must provide the legal and factual basis of the opinion that such patent will be infringed by the commercial marketing of the proposed biosimilar.
5. Patent Resolution Negotiations. If the originator provides its detailed views that the proposed biosimilar would infringe valid and enforceable patents, then the parties are required to engage in good faith negotiations to identify which of the discussed patents will be the subject of a patent infringement action. If the parties agree on the patents to be litigated, the brand-name firm must bring an action for patent infringement within 30 days.
6. Simultaneous Exchange of Patents. If those negotiations do not result in an agreement within 15 days, then the biosimilar applicant must notify the originator of how many patents (but not the identity of those patents) that it wishes to litigate. Within five days, the parties are then required to exchange lists identifying the patents to be litigated. The number of patents identified by the originator may not exceed the number provided by the biosimilar applicant. However, if the biosimilar applicant previously indicated that no patents should be litigated, then the originator may identify one patent.
7. Commencement of Patent Litigation. The originator must then commence patent infringement litigation within 30 days. That litigation will involve all of the patents on the originator's list and all of the patents on the follow-on applicant's list. The follow-on applicant must then notify the FDA of the litigation. The FDA must then publish a notice of the litigation in the Federal Register.
8. Notice of Commercial Marketing. The BPCIA requires the biosimilar applicant to provide notice to the originator 180 days in advance of its first commercial marketing of its proposed follow-on biologic. The originator is allowed to seek a preliminary injunction blocking such marketing based upon any patents that either party had preliminarily identified, but were not subject to the initial phase of patent litigation. The litigants are required to "reasonably cooperate to expedite such further discovery as is needed" with respect to the preliminary injunction motion. The federal courts have not yet settled the issue as to when, or under what circumstances, the biosimilar applicant must provide the 180 notice of commercial marketing provided in the BPCIA.

On June 12, 2017, the Supreme Court issued its decision in *Amgen v. Sandoz*, holding that (i) the "patent dance" is optional; and (ii) the 180-day pre-marketing notification may be given either before or after receiving FDA approval of the biosimilar product. The Supreme Court declined to rule whether a state injunctive remedy may be available to the originator and remanded that question to the Federal Circuit for further consideration. On December 14, 2017, the Federal Circuit decided that state law claims are preempted by the BPCIA on both field and conflict grounds.

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

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

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

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

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

### **Risks Related to the Discovery and Development of Our Product Candidates**

***We are heavily dependent on the development, 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.***

We 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 of our product candidates. We currently do not have any approved products, other than UDENYCA™.

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. For example, CHS-1420 and CHS-0214 have completed Phase 3 clinical trials or other 351(k) BLA-enabling clinical development. We have not yet initiated clinical trials for CHS-3351, CHS-2020, or CHS-131 in NASH. It may be some time before we file for market approval with the relevant regulatory agencies for these 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. For example, in June 2017, we received a CRL from the FDA in response to our 351(k) BLA for UDENYCA™, identifying certain issues, including a request for reanalysis of a subset of subject samples with a revised immunogenicity assay and requests for certain additional manufacturing related process information, which must be addressed before approval can be granted. If we and our existing or future 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 U.S., the E.U., and 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 and biosimilar products are subject to extensive regulation by the FDA and other regulatory authorities in the U.S., by the EMA and EEA Competent Authorities in the European



Economic Area (“EEA”), and by other regulatory authorities in other countries, where regulations differ from country to country. Neither we nor any existing or future collaboration partners are permitted to market our product candidates in the U.S. until we and our collaboration partners receive approval from the FDA, or in the EEA until we and our collaboration partners receive EC 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, other than UDENYCA™, and it is possible that none of our other 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 an original BLA, an NDA, a biosimilar product application under the 351(k) pathway of the Public Health Service Act (“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 U.S., the EEA or elsewhere;
- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical studies;
- the population studied in the clinical program may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from analytical and bioanalytical studies, nonclinical studies or clinical studies;
- we may be unable to demonstrate to the FDA or comparable foreign regulatory authorities that a product candidate’s risk-benefit ratio for its proposed indication is acceptable;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

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

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

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

It is uncertain if regulatory authorities will grant the full originator label to biosimilar product candidates when they are approved. For example, an infliximab (Remicade) biosimilar molecule was approved in Europe and in the U.S. for the full originator label but received a much narrower originator label when initially approved in Canada. That infliximab biosimilar only received full label extension in Canada in 2016 after providing additional clinical data. A similar outcome could occur with respect to one or more of our product candidates and there is no guarantee that our product candidates will receive a full originator label even after the provision of additional clinical data.

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.

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

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

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

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 (“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 (“IRB”), approval at each clinical study site;
- imposition of a clinical hold by regulatory agencies, after review of an investigational new drug (“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 patients completing 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 altered the manufacturing processes for CHS-1420 and 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. In March 2017, we completed a clinical PK bioequivalence study comparing CHS-1420 to U.S. manufactured Humira. In August 2017, we completed a clinical PK bioequivalence study comparing CHS-1420 to European manufactured Humira.

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

***U.S. Regulatory Framework for Biosimilars***

We and our collaboration partners intend to pursue market authorization globally. In the U.S., an abbreviated pathway for approval of biosimilar products was established by the Biologics Price Competition and Innovation Act of 2009 (“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 (“PHSA”). Subsequent to the enactment of the BPCIA, the FDA issued draft guidance regarding the demonstration of biosimilarity and interchangeability as well as the submission and review of biosimilar applications. Moreover, market acceptance of biosimilar products in the U.S. 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, payers and relevant authorities that such products are similar in quality, safety and efficacy as compared to the reference product.

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

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

The BPCIA is complex and continues to be interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning are evolving and remain 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. Moreover, the Trump administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA’s ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these Executive Orders will be interpreted and implemented, and the extent to which they will impact the FDA’s ability to continue implementing the BPCIA and engage in its other regulatory authorities under the FDCA. If these executive actions impose restrictions on the FDA’s ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

***Regulatory Framework for Biosimilars Outside the U.S.***

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

Under current E.U. regulations, an application for regulatory approval of a biosimilar drug cannot be submitted in the E.U. 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 ten-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 E.U. on March 2, 2000, August 9, 2003 and August 22, 2002, respectively) are subject to a ten-year period of data exclusivity. While the data exclusivity periods for Enbrel, Humira and Neulasta have now expired in Europe, these reference products are presently still subject to unexpired patents and such patents may or may not be susceptible to challenges to their validity and enforceability.

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

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

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

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

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

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

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

We are marketing UDENYCA™ in the United States, and subject to product approvals and relevant patent expirations, we intend to market our other biosimilar products in the U.S. and outside the U.S. on our own or with future collaboration partners. We entered into a distribution agreement with our licensee Orox for the commercialization of biosimilar versions of etanercept (Enbrel), rituximab (Rituxan), adalimumab (Humira) and pegfilgrastim (Neulasta) in certain Caribbean and Latin American countries. We intend to market our biosimilar product candidates in the U.S. and may seek to partner commercially all biosimilars outside the U.S.

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

***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.***

U.S. Adopted Name, and International Nonproprietary Names (“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 made 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 the EMA have final authority regarding names in the U.S. and the E.U. respectively. In a final guidance document issued in January 2017, FDA set forth a policy requiring that each biological product, related biological product and biosimilar product utilize a distinct

four-letter suffix to distinguish between different versions of related or biosimilar products. It is possible that the FDA's current policy, or other policies that regulatory authorities may adopt in the future that require non-proprietary names that are distinct from the reference product, or decisions by such regulatory authorities to assign a competing biosimilar product candidate to our product with a lower degree of nomenclature distinction from the reference product, may lead payers, providers and patients to be more hesitant to use our biosimilar product candidate, believing the difference in nomenclature to be indicative of an important difference in quality of function from the reference product or the competing biosimilar product candidate. If this were to occur, our business could be negatively affected.

### **Risks Related to Our Compliance with Applicable Laws**

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

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

We are subject to Section 404 of The Sarbanes-Oxley Act of 2002 ("Section 404"), and the related rules of the Securities and Exchange Commission ("SEC"), which generally require our management and independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting. During the course of our review and testing, we may identify deficiencies and be unable to remediate them before we must provide the required reports. Furthermore, if we have a material weakness in our internal controls over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. We or our independent registered public accounting firm may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could harm our operating results, cause investors to lose confidence in our reported financial information and cause the trading price of our stock to fall. In addition, as a public company we are required to file accurate and timely quarterly and annual reports with the SEC under the Exchange Act. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from The Nasdaq Global Market or other adverse consequences that would materially harm our business.

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

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

In the U.S., 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, (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. Since its enactment, there have been judicial and Congressional challenges to certain aspects of the PPACA, and we expect there will be additional challenges and amendments to the PPACA in the future, particularly in light of the current presidential administration and U.S. Congress. In addition, Congress could consider subsequent legislation to replace or repeal and replace elements of the PPACA. At the end of 2017, the Tax Cuts and Jobs Act (the “Tax Act”) was enacted, which, among other things, removes penalties for not complying with PPACA’s individual mandate to carry health insurance. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, ruled that the individual mandate is a critical and inseparable feature of the PPACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the PPACA are invalid as well. While the Trump Administration and the CMS have both stated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals, if any, will impact the law. At this time, the full effect that the PPACA and any subsequent legislation would have on our business remains unclear.

In addition, other legislative changes have been proposed and adopted in the U.S. since the PPACA was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and will stay in effect through 2027 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to certain providers, including physicians, hospitals and cancer treatment centers. Recently there has also been heightened government scrutiny over the manner in which manufacturers set prices for their approved products, which has resulted in several Congressional inquiries and proposed and enacted legislation designed to, among other things, reform government program reimbursement methodologies. Individual states in the U.S. have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures, such as a single reimbursement code for biosimilar products.

In the European Union, similar political, economic and regulatory developments may affect our ability to profitably commercialize our product candidates, if approved. In addition to continuing pressure on prices and cost containment measures, legislative developments at the European Union or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the European Union, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than European Union, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most European Union member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing European Union and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize our product candidates, if approved. In markets outside of the United States and European Union, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

***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.***

Our operations are 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 impact, among other things, 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. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation. In addition, 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;

- federal civil and criminal false claims 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 payers that are false or fraudulent and which may apply to entities that provide coding and billing advice to customers;
- federal civil monetary penalties laws, which impose civil fines for, among other things, the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception applies;
- the federal Health Insurance Portability and Accountability Act of 1996 ("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. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;
- federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- 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 payer, 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 pricing information; 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.

Efforts to ensure that our operations and business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. If we 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, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws 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. Further, defending against any such actions can be costly, time-consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.



***If we participate in and then fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs in the U.S., we could be subject to additional reimbursement requirements, penalties, sanctions and fines which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.***

With the approval of UDENYCA™, we anticipate that we will need to participate in the Medicaid Drug Rebate Program, Medicare Coverage Gap Discount Program and a number of other federal and state government pricing programs in the U.S. in order to obtain coverage for the product by certain government healthcare programs. These programs would generally require us to pay rebates or provide discounts to certain private purchasers or government payers in connection with our products when dispensed to beneficiaries of these programs. In some cases, such as with the Medicaid Drug Rebate Program, the rebates are based on pricing and rebate calculations that we report on a monthly and quarterly basis to the government agencies that administer the programs. The terms, scope and complexity of these government pricing programs change frequently. We may also have reimbursement obligations or be subject to penalties if we fail to provide timely and accurate information to the government, pay the correct rebates or offer the correct discounted pricing. Changes to the price reporting or rebate requirements of these programs would affect our obligations to pay rebates or offer discounts. Responding to current and future changes may increase our costs and the complexity of compliance, will be time-consuming, and could have a material adverse effect on our results of operations.

***We are subject to governmental regulation and other legal obligations related to privacy, data protection and information security. Compliance with these requirements could result in additional costs and liabilities to us or inhibit our ability to collect and process data, and the failure to comply with such requirements could have a material adverse effect on our business, financial condition or results of operations.***

Privacy and data security have become significant issues in the U.S., E.U. and in many other jurisdictions where we may in the future conduct our operations. As we receive, collect, process, use and store personal and confidential data, we are subject to diverse laws and regulations relating to data privacy and security, including, in the U.S., HIPAA, and, in the E.U., and shortly in the EEA, Regulation 2016/679, known as the General Data Protection Regulation (“GDPR”). Compliance with these privacy and data security requirements is rigorous and time-intensive and may increase our cost of doing business, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation and reputational harm, which could materially and adversely affect our business, financial condition and results of operations.

In addition, the regulatory framework for the receipt, collection, processing, use, safeguarding, sharing and transfer of personal and confidential data is rapidly evolving and is likely to remain uncertain for the foreseeable future as new global privacy rules are being enacted and existing ones are being updated and strengthened. For example, on May 25, 2018, the GDPR took effect in the E.U. The GDPR is directly applicable in each E.U. member state and applies to companies established in the E.U. as well as companies that collect and use personal data to offer goods or services to, or monitor the behavior of, individuals in the E.U., including, for example, through the conduct of clinical trials. GDPR introduces more stringent data protection obligations for processors and controllers of personal data, and penalties and fines for failure to comply with GDPR are significant, including fines of up to €20 million or 4% of total worldwide annual turnover, whichever is higher.

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

We currently have limited international operations of our own and have and may have in the future 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 payer reimbursement regimes, government payers 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 military intervention in Ukraine in March 2014, the U.S. and the E.U. imposed sanctions on Russia, including sanctions on certain individuals and other entities. In response, Russia has imposed entry bans on certain U.S. lawmakers and officials, and trading sanctions against nations that implemented or supported the anti-Russia sanctions, including the U.S. and the E.U. Our wholly-owned subsidiary, InteKrin Therapeutics, Inc. (“InteKrin”), which we acquired in February 2014, wholly-owns InteKrin Russia, a pharmaceutical development entity in Russia, which holds an immaterial amount of cash in Russian banks as of December 31, 2018. 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 (“PPAR”), gamma modulator that may hold promise in treatment of multiple sclerosis and NASH. While not a biosimilar, this PPAR gamma modulator compound may be complementary to biosimilar business. If the U.S. and the E.U. were to impose broader sanctions on Russia, including sanctions on Russian businesses such as InteKrin, 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 modulator product could be materially adversely affected.

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

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

**Risks Related to Ownership of Our Common Stock**

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

The market price of our common stock has been highly volatile since our IPO and the intraday sales price per share has ranged from \$8.05 to \$38.10 per share during the period from November 6, 2014 through February 22, 2019 and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include those discussed in the “Risk Factors” section of this Annual Report on Form 10-K and others such as:

- adverse results or delays in preclinical or clinical studies;
- any inability to obtain additional funding;
- any delay in filing an IND, NDA, original BLA, 351(k) 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, original BLA, 351(k) BLA or other regulatory submission;
- the perception of limited market sizes or pricing for our product candidates;
- failure to successfully develop and commercialize our product candidates;
- post-marketing safety issues relating to our product candidates or biosimilars generally;

- failure to maintain our existing strategic collaborations or enter into new collaborations;
- failure by us or our licensors and strategic collaboration partners to prosecute, maintain or enforce our intellectual property rights;
- changes in laws or regulations applicable to our products;
- any inability to obtain adequate product supply for our product candidates or the inability to do so at acceptable prices;
- adverse regulatory decisions;
- introduction of new products, services or technologies by our competitors;
- failure to meet or exceed financial projections we may provide to the public;
- failure to meet or exceed the financial projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us, our strategic collaboration partners or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key scientific or management personnel;
- lawsuits, including stockholder litigation and litigation filed by us or filed against us pertaining to patent infringement or other violations of intellectual property rights;
- the outcomes of any citizen petitions filed by parties seeking to restrict or limit the approval of biosimilar products;
- if securities or industry analysts do not publish research or reports about our business or if they issue an adverse or misleading opinion regarding our stock;
- changes in the market valuations of similar companies;
- general market or macroeconomic conditions;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- issuance of patents to third parties that could prevent our ability to commercialize our product candidates;
- reductions in the prices of originator products that could reduce the overall market opportunity for our product candidates intended as biosimilars to such originator products;
- the loss of one or more employees constituting our leadership team; and
- changes in biosimilar regulatory requirements that could make it more difficult for us to develop our product candidates.

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

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

As of December 31, 2018, our executive officers, directors, five percent stockholders and their affiliates beneficially owned approximately 52% of our voting stock (assuming no exercise of outstanding options or conversion of our outstanding convertible notes). These stockholders have the ability to influence us through their ownership positions, which may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may believe are in your best interest as one of our stockholders.

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

If our existing stockholders sell or indicate an intention to sell substantial amounts of our common stock in the public market after the lock-up and other legal restrictions on resale lapse, the market price of our common stock could decline. As of December 31, 2018, there were 68,302,681 shares of common stock outstanding. Of these shares, the shares of our common stock sold in our IPO, our

underwritten follow-on offering, pursuant to our at-the-market equity offering program and in private placement transactions (subject to certain lock-up periods) are currently freely tradable, without restriction (except as otherwise applicable), in the public market.

In addition, as of December 31, 2018, approximately 17.1 million shares of common stock that are either subject to outstanding options and restricted stock units or reserved for future issuance under our equity incentive plans were eligible or may become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold or if it is perceived that they will be sold in the public market, the market price of our common stock could decline.

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

We have needed and anticipate 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. Similar to prior financing transactions, 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. Any future debt financing may involve covenants that restrict our operations, including, among other restrictions, limitations on our ability to incur liens or additional debt, pay dividends, redeem our stock, make certain investments, and engage in certain merger, consolidation, or asset sale transactions. In addition, if we raise additional funds through licensing arrangements, it may be necessary to grant potentially valuable rights to our product candidates or grant licenses on terms that are not favorable to us.

Pursuant to our 2014 Equity Incentive Award Plan (the “2014 Plan”), our management is authorized to grant stock options and other equity-based awards to our employees, directors and consultants. Under the 2014 Plan, the number of shares of our common stock initially reserved for issuance is 2,300,000 plus the number of shares remaining available for future awards under the 2010 Plan. The number of shares available for future grant under the 2014 Plan will be increased by (i) the number of shares pursuant to outstanding awards under the 2010 Plan that are forfeited or lapse unexercised and which following the effective date are not issued under the 2010 Plan and (ii) an annual increase on the first day of each fiscal year beginning in 2015 and ending in 2024, equal to 4% of the shares of stock outstanding as of the last day of the preceding fiscal year, or such smaller number of shares as determined by our board of directors. Pursuant to our 2014 Employee Stock Purchase Plan (“2014 ESPP”), eligible employees are able to acquire shares of our common stock at a discount to the prevailing market price, and an aggregate of 320,000 shares are initially available for issuance under the 2014 ESPP. The number of shares available for issuance under the 2014 ESPP will automatically increase on the first day of each fiscal year beginning in 2015 and ending in 2024, equal to 1% of the shares of common stock outstanding on the last day of the immediately preceding fiscal year or such smaller number of shares as determined by our board of directors. If our board of directors elects to increase the number of shares available for future grant under the 2014 Plan or the 2014 ESPP, our stockholders may experience additional dilution, which could cause our stock price to fall. Pursuant to our 2016 Employment Commencement Incentive Plan (the “2016 Plan”), our management is authorized to grant stock options and other equity-based awards to our new employees. The 2016 Plan is designed to comply with the inducement exemption contained in Nasdaq’s Rule 5635(c)(4), which provides for the grant of non-qualified stock options, restricted stock units, restricted stock awards, performance awards, dividend equivalents, deferred stock awards, deferred stock units, stock payment and stock appreciation rights to a person not previously an employee or director, or following a bona fide period of non-employment, as an inducement material to the individual’s entering into employment with us. As of December 31, 2018, we reserved for future issuance under the 2016 Plan a total of 2,300,000 share of common stock for new employees. In January 2019, we increased the reserve for future issuance under the 2016 Plan to 2,800,000 shares of common stock for new employees. The 2016 Plan does not provide for any annual increases in the number of shares available.

In February 2016, we issued and sold \$100.0 million aggregate principal amount of our 8.2% senior convertible notes due March 2022. The holders may convert their convertible notes at their option at any time prior to the close of business on the business day immediately preceding March 31, 2022. Upon conversion of the convertible notes by a holder, the holder will receive shares of our common stock, together, if applicable, with cash in lieu of any fractional share. The initial conversion rate is 44.7387 shares of common stock per \$1,000 principal amount of convertible notes, which is equivalent to an initial conversion price of approximately \$22.35 per share, and is subject to adjustment in certain events.

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

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

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

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

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

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

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

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

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

Not applicable.

**Item 2. *Properties***

Our headquarters are located in Redwood City, California, where we occupy office space under a lease that will expire in November 2022 with a five-year renewal option. Our analytical and process development laboratories are located in Camarillo, California under a lease that expires in June and December 2020.

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

### **Item 3. Legal Proceedings**

We are a party to the following legal proceedings:

On November 9, 2015, and December 7, 2015, we filed in the USPTO, pursuant to 35 U.S.C. §§ 311–319 AND 37 C.F.R. § 42, petitions for IPR of AbbVie’s U.S. patents 8,889,135 (Case No. IPR2016-00172, filed November 9, 2015) (the “‘135 patent”); 9,017,680 (Case No. IPR2016-00188, filed December 7, 2015) (the “‘680 patent”); and 9,073,987 (Case No. IPR 2016-00189, filed December 7, 2015) (the “‘987 patent”), each entitled “Methods of Administering Anti-TNF $\alpha$  Antibodies” and generally concern a 40 mg biweekly subcutaneous dosing regimen for treating rheumatoid arthritis (“RA”) with Humira® (Adalimumab). On May 16, 2017, the PTAB invalidated all claims of the ‘135 patent, and on June 9, 2017, the PTAB invalidated all claims of the ‘680 patent and ‘987 patent. On July 14, 2017, AbbVie filed a Notice of Appeal in the U.S. Court of Appeals for the Federal Circuit in the ‘135 patent, ‘680 patent and ‘987 patent. We and AbbVie have filed briefs in this matter and a decision on the appeal was expected from the Federal Circuit in 2019. However, pursuant to the global settlement agreements with AbbVie that grant us global, non-exclusive license rights under AbbVie’s intellectual property to commercialize CHS-1420, we resolved all pending disputes between the parties related to our adalimumab biosimilar, and as a result, we have filed a motion to withdraw from the proceedings at the U.S. Court of Appeals for the Federal Circuit related to the ‘135 patent, ‘680 patent and ‘987 patent.

On January 31, 2017, we filed in the USPTO four petitions for IPR (Case Nos. IPR2017-00822; IPR2017-00823; IPR2017-00826; and IPR2017-00827) against AbbVie’s U.S. patent 9,085,619 (the “‘619 patent”) entitled “Anti-TNF Antibody Formulations.” Our IPR petitions against the ‘619 patent address certain aspects of the patent claims directed to pharmaceutical formulations of adalimumab that do not comprise a buffering system. On March 2, 2017, we amended and refiled petitions IPR2017-00826 and IPR2017-00827 as Case Nos. IPR2017-01009 and IPR2017-01008. On September 7, 2017, the PTAB denied institution of all four of our petitions for IPR of the ‘619 patent. As of June 30, 2018, we have determined that these matters are closed and there will be no further action related to the petitions for IPR of the ‘619 patent.

On March 3, 2017, Amgen Inc. and Amgen USA Inc. (collectively “Amgen”) filed an action against us, KBI Biopharma Inc., our employee Howard S. Weiser and Does 1-20 in the Superior Court of the State of California, County of Ventura. The complaint alleges that we engaged in unfair competition and improperly solicited and hired certain former Amgen employees in order to acquire and access trade secrets and other confidential information belonging to Amgen. On June 1, 2017, Amgen filed a Second Amended Complaint, which alleges as to Coherus (i) unfair competition under California Business and Professions Code Section 17200 et seq., (ii) misappropriation of trade secrets, (iii) aiding and abetting breach of duty of loyalty and (iv) tortious interference with contract. As to defendant Weiser, the Second Amended Complaint alleges (i) unfair competition under California Business and Professions Code Section 17200 et seq., (ii) misappropriation of trade secrets, (iii) breach of contract, (iv) violation of Penal Code Section 502 and (v) breach of duty of loyalty. KBI Biopharma Inc. is not named as defendant in the Second Amended Complaint. The Second Amended Complaint seeks injunctive relief and monetary damages. Although Amgen has indicated it intends to seek a preliminary injunction, no motion has been filed yet. In December 2018, the court set a trial date of April 22, 2019.

On May 10, 2017, Amgen Inc. and Amgen Manufacturing Inc. filed an action against us in the U.S. District Court for the District of Delaware (the “District Court”) alleging infringement of one or more claims of Amgen’s U.S. patent 8,273,707 (the “‘707 patent”) under 35 U.S.C. § 271. The complaint seeks injunctive relief, monetary damages and attorney fees. On December 7, 2017, the U.S. Magistrate Judge issued under seal a Report and Recommendation to the District Court recommending that the District Court grant, with prejudice, the Company’s pending motion to dismiss Amgen Inc. and Amgen Manufacturing Inc.’s complaint for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6). On March 26, 2018, Judge Stark of the District Court adopted the U.S. Magistrate Judge’s Report and Recommendation to grant the motion of the Company pursuant to Federal Rule of Civil Procedure 12(b)(6) to dismiss with prejudice the patent infringement complaint alleging infringement of the ‘707 patent on the grounds that such complaint failed to state a claim upon which relief may be granted. In May 2018, Amgen filed a Notice of Appeal in the U.S. Court of Appeals for the Federal Circuit. Amgen and Coherus have filed briefs in this matter and decision on the appeal is expected from the Federal Circuit in 2019.

On August 4, 2017, we filed in the USPTO a petition for IPR against U.S. patent 8,163,522 (the “‘522 patent”). The ‘522 patent, controlled by Amgen, is generally directed to a method for making etanercept, the pharmaceutically active component of Enbrel®. On September 6, 2017, we filed in the USPTO a petition for IPR against U.S. patent 8,063,182, (the “‘182 patent”). The ‘182 patent, controlled by Amgen, is generally directed to the etanercept protein, the pharmaceutically active component of Enbrel. The PTAB denied institution of both petitions for IPR on March 9, 2018. As of September 30, 2018, we have determined that these matters are closed and there will be no further action on the ‘522 or ‘182 IPR petitions.

On January 24, 2019, we filed suit against Amgen in the United States District Court (Delaware) alleging that Amgen's Humira® biosimilar, Amgevita™, infringes Coherus' U.S. patents 10,155,039; 10,159,732; and 10,159,733. Each of the asserted Coherus patents is directed to stable formulations of adalimumab.

We are not a party to any other material legal proceedings on the date of this report.

**Item 4. Mine Safety Disclosures**

Not applicable.

## PART II

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

#### Market Information

Our common stock has been listed on The Nasdaq Global Market under the symbol “CHRS” since November 6, 2014. Prior to that there was no public trading market for our common stock. The following table details the quarterly high and low sales prices for our common stock as reported by The Nasdaq Global Market for CHRS from January 1, 2017 through December 31, 2018.

Year ended December 31, 2018	Price Range	
	High	Low
1st Quarter	\$ 14.50	\$ 8.55
2nd Quarter	17.80	9.85
3rd Quarter	20.66	14.00
4th Quarter	17.25	8.39
<b>Year ended December 31, 2017</b>		
1st Quarter	\$ 29.59	\$ 19.65
2nd Quarter	24.70	13.55
3rd Quarter	15.18	10.80
4th Quarter	14.85	8.05

On February 22, 2019, the closing sale price of our common stock was \$14.74.

#### Common Stockholders

As of January 31, 2019, there were approximately 41 stockholders of record of our common stock. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

#### Dividend Policy

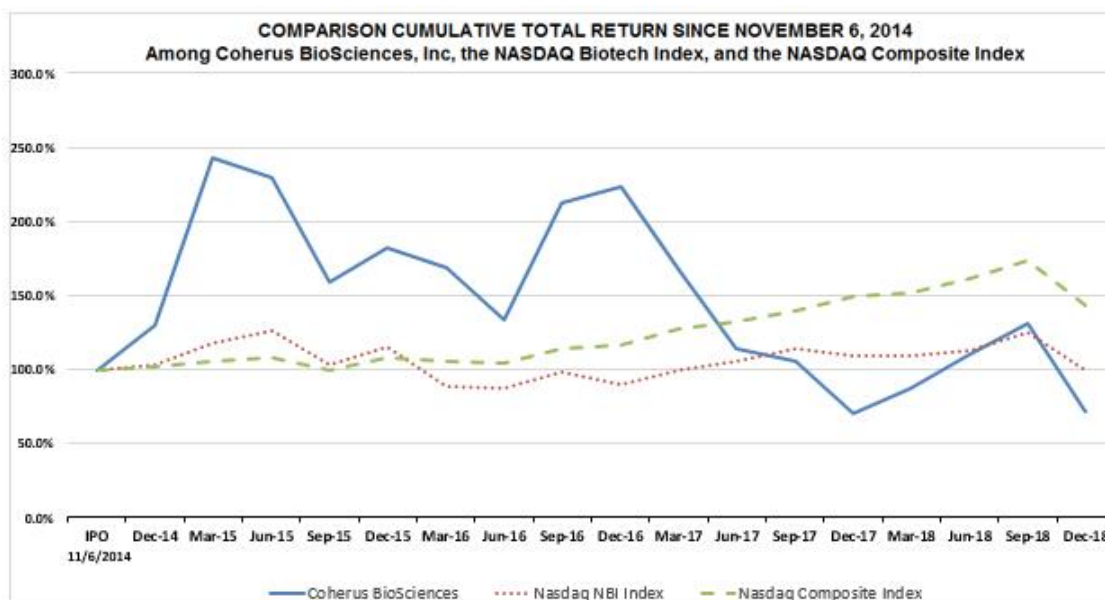
We have never declared or paid any cash dividends on our capital stock and do not anticipate paying any cash dividends in the foreseeable future. Payment of cash dividends, if any, in the future will be at the discretion of our board of directors and will depend on then-existing conditions, including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

#### Stock Performance Graph

The following graph shows the total stockholder’s return on an investment of \$100 in cash at market close on November 6, 2014 (the first day of trading of our common stock), through December 31, 2018 for (i) our common stock, (ii) the Nasdaq Composite Index and (iii) the Nasdaq Biotechnology Index. Pursuant to applicable Securities and Exchange Commission rules, all values assume reinvestment of the full amount of all dividends, however, no dividends have been declared on our common stock to date. The stockholder return shown on the graph below is not necessarily indicative of future performance, and we do not make or endorse any predictions as to future stockholder return. This graph shall not be deemed “soliciting material” or be deemed “filed” for purposes of Section 18 of the Exchange Act, or otherwise subject to



the liabilities under that Section, and shall not be deemed to be incorporated by reference into any of our filings under the Securities Act, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.



### Recent Sales of Unregistered Equity Securities

From January 1, 2018 through December 31, 2018, there were no sales or issuances of unregistered securities that were not otherwise reported in a Form 10-Q or Form 8-K.

### Issuer Purchases of Equity Securities

We did not repurchase any of our equity securities during the fiscal year ended December 31, 2018.

**Item 6. Selected Financial Data**

You should read the following selected consolidated financial data together with the information under “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our consolidated financial statements and related notes included in this Form 10-K. The consolidated statement of operations data for each of the years ended December 31, 2018, 2017 and 2016, and the consolidated balance sheet data as of December 31, 2018 and 2017 are derived from our audited consolidated financial statements included elsewhere in this Form 10-K. The selected consolidated statement of operations data for the year ended December 31, 2015 and 2014, and the consolidated balance sheet data as of December 31, 2016, 2015 and 2014 are derived from our audited financial statements, which are not included in this Annual Report on Form 10-K.

**Consolidated Statement of Operations Data:**

<i>(in thousands, except share and per share data)</i>	<b>Year Ended December 31,</b>				
	<b>2018</b>	<b>2017</b>	<b>2016</b>	<b>2015</b>	<b>2014</b>
<b>Revenue:</b>					
Collaboration and license revenue	\$ —	\$ 1,556	\$ 189,476	\$ 30,041	\$ 28,481
Collaboration and license revenue - related party (1)	—	—	—	—	1,893
Other revenue	—	—	630	—	732
<b>Total revenue</b>	<b>—</b>	<b>1,556</b>	<b>190,106</b>	<b>30,041</b>	<b>31,106</b>
<b>Operating expenses:</b>					
Research and development (2)	110,239	162,389	254,440	213,062	78,224
Selling, general and administrative (2)	94,177	71,303	51,597	36,046	17,564
<b>Total operating expenses</b>	<b>204,416</b>	<b>233,692</b>	<b>306,037</b>	<b>249,108</b>	<b>95,788</b>
Loss from operations	(204,416)	(232,136)	(115,931)	(219,067)	(64,682)
Interest expense	(9,684)	(9,552)	(7,980)	(33)	(3,900)
Other income (expense), net	4,691	3,402	(3,877)	(4,838)	(18,595)
<b>Net loss</b>	<b>(209,409)</b>	<b>(238,286)</b>	<b>(127,788)</b>	<b>(223,938)</b>	<b>(87,177)</b>
Net loss attributable to non-controlling interest	70	116	451	678	44
<b>Net loss attributable to Coherus</b>	<b>\$ (209,339)</b>	<b>\$ (238,170)</b>	<b>\$ (127,337)</b>	<b>\$ (223,260)</b>	<b>\$ (87,133)</b>
Net loss per share attributable to Coherus, basic and diluted (3)	<b>\$ (3.22)</b>	<b>\$ (4.48)</b>	<b>\$ (3.04)</b>	<b>\$ (6.01)</b>	<b>\$ (10.64)</b>
Weighted-average number of shares used in computing net loss per share attributable to Coherus, basic and diluted (3)	<b>65,034,827</b>	<b>53,133,620</b>	<b>41,912,300</b>	<b>37,122,008</b>	<b>8,186,529</b>

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

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

<i>(in thousands)</i>	<b>Year Ended December 31,</b>				
	<b>2018</b>	<b>2017</b>	<b>2016</b>	<b>2015</b>	<b>2014</b>
Research and development	\$ 15,339	\$ 15,104	\$ 13,592	\$ 8,038	\$ 5,625
Selling, general and administrative	19,458	18,293	13,829	8,683	5,437
<b>Total stock-based compensation</b>	<b>\$ 34,797</b>	<b>\$ 33,397</b>	<b>\$ 27,421</b>	<b>\$ 16,721</b>	<b>\$ 11,062</b>

(3) See Note 2 to our audited consolidated financial statements for an explanation of the method used to calculate basic and diluted net loss per share attributable to Coherus and the weighted-average shares outstanding used to calculate the per share amounts.

**Consolidated Balance Sheet Data:**

<i>(in thousands)</i>	December 31,				
	2018	2017	2016	2015	2014
Cash and cash equivalents	\$ 72,356	\$ 126,911	\$ 124,947	\$ 158,226	\$ 150,392
Working capital	51,172	117,082	105,110	91,368	127,353
Total assets	99,467	162,611	178,485	212,384	187,221
Convertible notes	77,319	76,206	75,192	—	—
Convertible notes - related party	25,773	25,402	25,064	—	—
Accumulated deficit	(984,831)	(775,492)	(537,322)	(409,985)	(186,725)
Total stockholder's equity (deficit)	(38,591)	30,535	19,354	(6,929)	66,757

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

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

### Overview

We are a commercial-stage biotherapeutics company focused on the global biosimilar market. Biosimilars are a class of protein-based therapeutics with high similarity to approved originator products on the basis of various structural, physicochemical and biological properties, as well as in terms of safety and efficacy. 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.

On September 25, 2018, we received regulatory approval for the marketing of UDENYCA™ (pegfilgrastim-cbqv), a biosimilar to Neulasta, a long-acting granulocyte-colony stimulating factor, from the European Commission. On November 2, 2018, we received regulatory approval for UDENYCA™ from the U.S. Food and Drug Administration ("FDA"). We initiated U.S. sales of UDENYCA™ in January 2019.

Our clinical-stage pipeline includes the following product candidates:

- CHS-1420 (our adalimumab (Humira) biosimilar candidate). We are developing CHS-1420, an anti-TNF product candidate, as an adalimumab (Humira) biosimilar. In August 2016, we announced positive data from our Phase 3 study in psoriasis patients, followed by confirmatory 24-week results in January 2017, to support a 351(k) BLA in the U.S. In January 2017, we initiated a PK study bridging CHS-1420 to European manufactured Humira and a PK study comparing U.S. Humira to E.U. Humira. We completed two PK bridging studies of CHS-1420, one comparing the Phase 3 CHS-1420 material to U.S. manufactured adalimumab (Humira) in March 2017, and the other comparing CHS-1420 to European manufactured Humira in August 2017. We anticipate that additional investment in manufacturing activities will be required prior to any BLA or MAA submissions. To enable competitive market entry, we plan to set the timing of the 351(k) BLA submission in a manner to be able to launch CHS-1420 in the U.S. on or after December 15, 2023.
- CHS-0214 (our etanercept (Enbrel) biosimilar candidate). We completed two Phase 3 clinical trials with CHS-0214 in rheumatoid arthritis and psoriasis, which met their primary clinical endpoints in November 2015 and January 2016, respectively. In October 2016, we completed two bridging Phase 1 PK studies of CHS-0214, one comparing CHS-0214 to Enbrel manufactured in Europe, and the other providing additional relative bioavailability data for CHS-0214. We anticipate that additional investment in manufacturing activities will be required prior to any MAA or 351(k) BLA submissions for CHS-0214. We have worldwide development and commercial rights to this product except for certain Caribbean and Latin American countries. However, the therapeutic protein in etanercept is subject to certain originator-controlled U.S. patents expiring in 2028 and 2029. Assuming these patents are valid and enforceable until expiration, and that we are unable to obtain a license to them, we do not expect to commercialize CHS-0214 in the U.S. prior to their expiration or invalidation.
- CHS-131 (our oral, small-molecule drug candidate). CHS-131 is a potential novel, first-in-class, well-tolerated, once-daily oral drug candidate under development for non-alcoholic steatohepatitis ("NASH") and other metabolic conditions. CHS-131 is a selective ligand for peroxisome proliferator-activator receptor gamma ("PPAR $\gamma$ ") which is part of a family of nuclear receptors that are expressed in a broad range of tissues and regulate multiple metabolic processes. PPAR $\gamma$  plays a central role in regulating storage and metabolism of dietary fats, and is a relevant target in conditions with loss of normal adipocyte function, hypoadiponectinemia and insulin resistance. The activation of PPAR $\gamma$  drives adiponectin expression and insulin sensitization, addressing a core issue that underpins the NASH disease process. PPAR $\gamma$  is a clinically validated target in NASH by pioglitazone, which is recognized in the American Association for the Study of Liver Disease ("AASLD") guidelines. CHS-131 has a novel chemical scaffold, differentiated from thiazolidinediones. CHS-131 has demonstrated an improved safety profile from thiazolidinediones in preclinical and clinical testing, and has been administered to over 600 human subjects in multiple clinical studies. In June 2016, we reported positive Phase 2b efficacy data on CHS-131 in relapsing remitting multiple sclerosis ("MS"). This six-month study demonstrated significant reduction in contrast-enhancing lesions meeting its primary endpoint. CHS-131 was generally well-tolerated and without evidence of immune suppression or the side-effects commonly seen in other oral MS therapies. Results of a positive Phase 2b study of CHS-131 in Type 2 diabetes mellitus were published in 2014. This six month randomized, double-blind, placebo controlled study of four doses (0.5 mg, 1 mg, 2 mg, 3 mg) of CHS-131 in comparison to 45 mg of pioglitazone in 367 subjects on a background of sulfonylurea or sulfonylurea plus metformin, demonstrated a steep dose response for efficacy as measured by changes in HbA1c. The 2-mg dose demonstrated near-maximal efficacy, which was not statistically different from the efficacy of 45 mg pioglitazone. We believe the CHS-131 mechanism of action is well suited to the treatment of NASH, and we are contemplating filing an investigational new drug application with the FDA for CHS-131 and initiating a clinical program in NASH patients for CHS-131.

Our preclinical-stage pipeline includes the following product candidates:

- CHS-3351 (our ranibizumab (Lucentis) biosimilar candidate). We are conducting process development, preclinical and manufacturing exercises for CHS-3351, an anti-vascular endothelial growth factor (“anti-VEGF”);
- CHS-2020 (our aflibercept (Eylea) biosimilar candidate). We have initiated the preclinical development of CHS-2020, our second anti-VEGF biosimilar candidate.

Our revenue to date has been generated primarily from collaboration and license payments pursuant to our license agreements with Daiichi Sankyo and Baxalta. Since inception, we have not generated any commercial product revenue. We have incurred significant losses in the past. On January 3, 2019, we initiated sales of UDENYCA™, our first commercial product, and we expect to incur significant but decreasing losses in the foreseeable future as we sell UDENYCA™ and advance our product candidates into later stages of development and, if approved, commercialization. Our net losses were \$209.4 million, \$238.3 million and \$127.8 million for the years ended December 31, 2018, 2017 and 2016, respectively. As of December 31, 2018, we had an accumulated deficit of \$984.8 million.

In February 2016, we issued and sold \$100.0 million aggregate principal amount of our 8.2% senior convertible notes due 2022 (the “Convertible Notes”). These Convertible Notes require quarterly interest distributions at a fixed coupon rate of 8.2% until maturity, redemption or conversion, which will be no later than March 31, 2022. If we fail to satisfy certain registration or reporting requirements, then additional interest will accrue on the Convertible Notes at a rate of up to 0.50% per annum in the aggregate. The holders of the Convertible Notes are Healthcare Royalty Partners III, L.P. and three of its related entities, which hold \$75.0 million in aggregate principal amount, and three related party investors, KKR Biosimilar L.P., which holds \$20.0 million, MX II Associates LLC, which holds \$4.0 million, and KMG Capital Partners, LLC, which holds \$1.0 million. The Convertible Notes are convertible into shares of common stock at an initial conversion rate of 44.7387 shares of common stock per \$1,000 principal amount of the Convertible Notes (equivalent to a conversion price of approximately \$22.35 per share of common stock, representing a 60% premium over the average last reported sale price of our common stock over the 15 trading days preceding the date the Convertible Notes were issued), subject to adjustment in certain events. Upon conversion of the Convertible Notes by a holder, the holder will receive shares of our common stock, together, if applicable, with cash in lieu of any fractional share. After March 31, 2020, the full amount of the Convertible Notes not previously converted are redeemable for cash at our option if the last reported sale price per share of our common stock exceeds 160% of the conversion price on 20 or more trading days during the 30 consecutive trading days preceding the date on which we send notice of such redemption to the holders of the Convertible Notes. At maturity or redemption, if not earlier converted, we will pay 109% of the principal amount of the Convertible Notes, together with accrued and unpaid interest, in cash.

In October 2016, we entered into a sales agreement with Cowen and Company, LLC (“Cowen”), under which we may offer and sell our common stock, having aggregate gross proceeds of up to \$100.0 million, from time to time through Cowen as our sales agent in our ATM Offering Program. In 2018, we issued and sold 1,799,504 shares of common stock at a weighted average price of \$12.14 per share under the ATM Offering Program for aggregate net proceeds of \$21.0 million after deducting underwriting discounts and commissions and offering expenses. As of December 31, 2018, we had \$10.1 million remaining under the ATM Offering Program. As of January 18, 2019, our Shelf Registration Statement related to the ATM Offering Program expired and accordingly the ATM Offering Program was terminated.

In May 2018, we completed an underwritten public offering of 5,948,274 shares of our common stock at a price to the public of \$14.50 per share, which includes the closing of the full exercise of the underwriters’ option to purchase an additional 775,861 shares of common stock. We received gross proceeds from the offering of \$86.3 million. After deducting underwriting discounts and commissions of \$5.2 million and offering expenses of \$0.3 million, the net proceeds to us were \$80.8 million.

In September 2018, InteKrin acquired the remainder of InteKrin Russia’s non-controlling interest of 17.5% for \$0.7 million. As a result of this purchase, InteKrin Russia became a wholly-owned subsidiary in our consolidated financial statements as of September 30, 2018.

On January 7, 2019 (the “Credit Agreement Closing Date”), we entered into a credit agreement (the “Credit Agreement”) with affiliates of Healthcare Royalty Partners (together, the “Lenders”). The Credit Agreement consists of a six-year term loan facility for an aggregate principal amount of \$75.0 million (the “Borrowings”). Our obligations under the loan documents are guaranteed by our material domestic U.S. subsidiaries (the “Guarantors”).

The Borrowings under the Agreement bear interest through maturity at 7.00% per annum plus LIBOR (customarily defined). If the consolidated net sales (customarily defined) for UDENYCA™ for the fiscal year ending December 31, 2019, are in excess of \$250.0 million, then the interest rate will be reduced as of January 1, 2020 to 6.75% per annum plus LIBOR. Interest is payable quarterly in arrears.

We are required to pay principal on the Borrowings in equal quarterly installments beginning on the four year anniversary of the Credit Agreement Closing Date (or, if consolidated net sales of UDENYCA™ in the fiscal year ending December 31, 2021 are less than \$375.0 million, beginning on the three year anniversary of the Credit Agreement Closing Date), with the outstanding balance to be repaid on January 7, 2025, the maturity date.

We are also required to make mandatory prepayments of the Borrowings under the Credit Agreement, subject to specified exceptions, with the proceeds of asset sales, extraordinary receipts, debt issuances and specified other events including the occurrence of a change in control.

If all or any of the Borrowings are prepaid or required to be prepaid under the Credit Agreement, then we shall pay, in addition to such prepayment, a prepayment premium equal to (i) with respect to any prepayment paid or required to be paid on or prior to the three year anniversary of the Credit Agreement Closing Date, 5.00% of the Borrowings prepaid or required to be prepaid, plus all required interest payments that would have been due on the Borrowings prepaid or required to be prepaid through and including the three year anniversary of the Credit Agreement Closing Date, (ii) with respect to any prepayment paid or required to be paid after the three year anniversary of the Credit Agreement Closing Date but on or prior to the four year anniversary of the Credit Agreement Closing Date, 5.00% of the Borrowings prepaid or required to be prepaid, (iii) with respect to any prepayment paid or required to be paid after the four year anniversary of the Credit Agreement Closing Date but on or prior to the five year anniversary of the Credit Agreement Closing Date, 2.50% of the Borrowings prepaid or required to be prepaid, and (iv) with respect to any prepayment paid or required to be prepaid thereafter, 1.25% of the Borrowings prepaid or required to be prepaid.

In connection with the Credit Agreement, we paid a fee to the Lenders of approximately \$1.1 million at closing in the form of an original issue discount. Upon the prepayment or repayment of the Borrowings (or upon the date such prepayment or repayment is required to be paid), we are required to pay an additional exit fee in an amount equal to 4.00% of the total principal amount of the Borrowings.

The obligations under the Credit Agreement are secured by a lien on substantially all of our and our Guarantors' tangible and intangible property, including intellectual property. The Credit Agreement contains certain affirmative covenants, negative covenants and events of default, including, covenants and restrictions that among other things, restrict our ability and our subsidiaries to, incur liens, incur additional indebtedness, make loans and investments, engage in mergers and acquisitions, in asset sales, and declare dividends or redeem or repurchase capital stock. Additionally, the consolidated net sales for UDENYCA™ must not be lower than \$70.0 million for the fiscal year ending December 31, 2019, (b) \$125.0 million for the fiscal year ending December 31, 2020, and (c) \$150.0 million for each fiscal year thereafter. A failure to comply with these covenants could permit the Lenders under the Credit Agreement to declare the Borrowings, together with accrued interest and fees, to be immediately due and payable.

## **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, under which we received license fees, milestone payments and other contingent payments.

### ***Research and Development Expense***

Research and development expense represents 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 research and development costs incurred on a product candidate basis only for external research and development expenses. Our external research and development expense consists primarily of:

- expense incurred under agreements with consultants, third-party contract research organizations ("CROs"), and investigative sites where a substantial portion of our preclinical studies and all of our clinical trials are conducted;
- costs of acquiring originator comparator materials and manufacturing preclinical study and clinical trial supplies and other materials from contract manufacturing organizations ("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 expense, which include salaries, benefits and stock-based compensation; and
- facilities and other allocated expense, which include direct and allocated expense for rent and maintenance of facilities, depreciation and amortization of leasehold improvements and equipment, laboratory and other supplies.

The largest component of our total operating expense has historically been our investment in research and development activities, including the clinical development and manufacturing process development of our product candidates. We expect our research and development expense to be lower in 2019 as the manufacturing costs for UDENYCA™ will be capitalized as inventory after receiving FDA approval on

November 2, 2018, and subsequently expensed as costs of goods sold upon the sale of finished goods inventory or upon the occurrence of inventory impairment.

We consider regulatory approval of product candidates to be uncertain, and any products manufactured prior to regulatory approval may not be sold unless regulatory approval is obtained. We expense manufacturing costs for product candidates incurred prior to regulatory approval as research and development expense as we incur them. If, and when, regulatory approval of a product candidate is obtained, we will begin capitalizing manufacturing costs related to the approved product into inventory.

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, 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 not succeed in achieving regulatory approval for our other product candidates. In addition, we may enter into other collaboration arrangements for our other product candidates, which could affect our development plans or capital requirements.

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

	Phase of Development as of December 31, 2018	Year ended December 31,		
		2018	2017	2016
<i>(in thousands)</i>				
External costs incurred by product candidate:				
UDENYCA™	Approved	\$ 42,975	\$ 31,247	\$ 32,934
CHS-1420	Completed	5,989	52,275	70,276
CHS-0214 (1)	Completed	4,243	17,596	77,799
CHS-131	Phase 2	1,181	2,052	3,558
Other research and development expenses (2)		3,774	4,878	17,608
Internal costs		52,077	54,341	52,265
Total research and development expenses (1)		<u>\$ 110,239</u>	<u>\$ 162,389</u>	<u>\$ 254,440</u>

(1) Our research and development expense for the years ended December 31, 2017 and 2016 has been reduced by reimbursements of certain research and development expense pursuant to the cost-sharing provision of our licensing agreement with Daiichi Sankyo. Reimbursement of research and development expense under the Baxalta licensing agreement was recognized as revenue pursuant to the revenue recognition accounting policy applicable to that agreement.

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

#### ***Selling, General and Administrative Expense***

Selling, general and administrative expense consists primarily of personnel costs, allocated facilities costs and other expense for outside professional services, including legal, insurance, human resources, outside marketing, advertising, audit and accounting services, as well as costs associated with establishing commercial capabilities in support of the commercialization of UDENYCA™. Personnel costs consist of salaries, benefits and stock-based compensation. We expect to incur significant additional expense associated with the establishment of our sales force in the U.S., as we undertake commercial infrastructure initiatives to implement information technology systems, quality and compliance systems and personnel support for the commercial organization.

#### ***Interest Expense***

Interest expense consists primarily of interest incurred on our outstanding indebtedness and non-cash interest related to the amortization of debt discount and debt issuance costs associated with our various debt agreements outstanding during the years ended December 31, 2018 and 2017.

#### ***Other Income (Expense), Net***

Other income (expense), net for the years ended December 31, 2018 and 2017, consists primarily of gains and losses resulting from the remeasurement of our contingent consideration, interest earned from our investments in marketable securities and foreign exchange gains and losses resulting from currency fluctuations. We will continue to record adjustments to the estimated fair value of our contingent consideration related to the Compound Transaction Payment until the contingency settles or expires.

## Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with United States generally accepted accounting principles ("U.S. 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 expense incurred during the reporting periods. As appropriate, we periodically evaluate our critical accounting policies and estimates. Our estimates are based on our historical experience and on various other factors that we believe to be reasonable under the circumstances. These estimates form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Accounting estimates and judgements are inherently uncertain and the actual results could differ from these estimates.

### Revenue Recognition

We adopted ASU No. 2014-09, *Revenue from Contracts with Customers* (Topic 606), ASU No. 2014-09: ASU No. 2016-08, *Revenue from Contracts with Customers* (Topic 606): *Principal versus Agent Considerations*; ASU No. 2016-10, *Revenue from Contracts with Customers* (Topic 606): *Identifying Performance Obligations and Licensing*; and ASU No. 2016-12, *Revenue from Contracts with Customers* (Topic 606): *Narrow-Scope Improvements and Practical Expedients*, (collectively, the "New Revenue Standard") on January 1, 2018 using the modified retrospective method.

We did not have any sources of revenue or active revenue arrangement upon adoption of the New Revenue Standard, therefore, no adjustment to our retained earnings was required. If, and when, we initiate product sales or enter into a new revenue arrangement, we will apply the New Revenue Standard accordingly. On September 25, 2018, we received regulatory approval for the marketing of UDENYCA™ from the European Commission, and received regulatory approval from the FDA on November 2, 2018. We initiated U.S. sales of UDENYCA™ on January 3, 2019, which will be accounted for under Topic 606 *Revenue from Contracts with Customers* in 2019.

Prior to the adoption of the New Revenue Standard, we recognized revenue in accordance with Accounting Standards Codification (ASC) 605, *Revenue Recognition* when persuasive evidence of an arrangement existed; transfer of technology had been completed, services had been performed or products had been delivered; the fee was fixed and determinable; and collection was reasonably assured.

Our collaboration and license agreements may provide for reimbursement by our collaborators of a portion of our research and development expense, and we made judgments that affected how these reimbursements were recorded. In collaborations where we and our partner were actively and jointly engaged in the research activities and for which both parties were sharing costs, amounts reimbursed by our partner were recognized as a reduction of research and development expense. For example, prior to the termination of the Daiichi Sankyo Agreement, Daiichi Sankyo reimbursed certain of our research and development costs in quarterly advance payments pursuant to the cost-sharing provision of our collaboration and license agreement. Because Daiichi Sankyo was an active participant in the research and development activities, we accounted for these reimbursements as reductions to our research and development expense when the applicable research and development activity had been performed. Under our prior agreement with Baxalta, on the other hand, we recognized reimbursement of our research and development expense, thereunder, as revenue because Baxalta was not actively participating in research and development activities.

For revenue agreements with multiple-elements, we identified the deliverables included within the agreement and evaluated which deliverables may represent separate units of accounting based on the achievement of certain criteria, including whether the deliverable had stand-alone value to the collaborator. Upfront payments received in connection with licenses of our technology rights were deferred if facts and circumstances dictated that the license did not have stand-alone value and were recognized as license revenue over the estimated period of performance, which was generally consistent with the terms of the research and development obligations contained in the specific collaboration and license agreement. We periodically reviewed our estimated periods of performance based on the progress under each arrangement and accounted for the impact of any changes in estimated periods of performance on a prospective basis.

At the inception of each agreement which included milestone payments, we evaluated whether each milestone was substantive and at risk to both parties on the basis of the contingent nature of the milestone. We evaluated 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 was reasonable relative to all deliverables and payment terms in the arrangement in making this assessment. Non-refundable payments that were contingent upon achievement of a substantive milestone were recognized in their entirety in the period in which the milestone was achieved, assuming all other revenue recognition criteria were met. Other contingent payments, in which a portion of the milestone consideration was refundable or adjustable based on future performance or non-performance (e.g., through a penalty or claw-back provision), were not considered to relate solely to past performance, and therefore, not considered substantive. Amounts that were not recognized as revenue, due to the uncertainty as to whether they would be retained or because they were expected to be refunded, were recorded as a liability. We recognized non-substantive milestone payments over the remaining estimated period of performance once the milestone was achieved.



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

## **Inventory**

Prior to the regulatory approval of our product candidates, we incurred expenses for the manufacture of drug product that could potentially be available to support the commercial launch of our products. We began to capitalize inventory costs associated with UDENYCA™ after receiving regulatory approval for UDENYCA™ in November 2018 when it was determined that the inventory had a probable future economic benefit.

Our inventory is stated at the lower of cost or estimated net realizable value with cost determined under the first-in first-out method. Inventory costs include third-party contract manufacturing, third-party packaging services, freight, labor costs for personnel involved in the manufacturing process, and indirect overhead costs. We primarily use actual costs to determine the cost basis for inventory. The determination of whether inventory costs will be realizable requires our review of the expiration dates of our product UDENYCA™ compared to our forecasted sales. If actual market conditions are less favorable than projected by us, write-downs of inventory may be required which would be recorded as cost of sales in our consolidated statement of operations.

## **Research and Development Expense and Related Accruals**

Research and development costs are charged to expense as incurred. Research and development expense includes, among other costs, salaries and other personnel-related costs, consultant fees, preclinical costs, cost to manufacture drug candidates, clinical trial costs and supplies, laboratory supply 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 manufacturing drug candidates and preclinical and clinical support activities. In certain cases, amounts received as reimbursement of research and development activities from our collaborators are recognized as a reduction in research and development expense when we engage 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. 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 rendered.

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

- communicating with appropriate internal personnel to identify services that have been performed on our behalf and estimating 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 rendered 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 the services are expected to be incurred and the level of effort to be expended in each period. If we are unable to identify costs associated with activities that have been initiated or if we underestimate or overestimate the amount of services performed or the costs of these services, our actual expenses could differ from our estimates.

Accounting estimates and judgements related to clinical trials are inherently uncertain. We base our estimates on the best information available at the time. As appropriate, estimates are assessed periodically and updated to reflect current information and any changes will generally be reflected in the period first identified.

We consider regulatory approval of our product candidates to be uncertain, and product manufactured prior to regulatory approval may not be sold unless regulatory approval is obtained. We expense manufacturing costs as incurred to research and development expense for product candidates prior to regulatory approval. If, and when, regulatory approval of a product is obtained, we will begin capitalizing manufacturing costs related to the approved product into inventory.

### ***Derivative Liabilities***

There were two contingent payments associated with the acquisition of InteKrin: (i) the completion of the first dosing of a human subject in the first Phase 2 clinical trial for InteKrin (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 (the “Compound Transaction Payment”). The contingent consideration is accounted for as a liability and remeasured to estimated fair value as of each balance sheet date and the related remeasurement adjustment is recognized as other income (expense), net in the consolidated statement of operations through the date of settlement. We determined the fair value of the remaining contingent consideration associated with the Compound Transaction Payment using a probability-weighted discounted cash flow approach. A probability-weighted value was determined by summing the probability of achieving the contingent payment threshold by the respective contingent payment. The expected cash flows were discounted at a rate selected to capture the risk of achieving the contingent payment thresholds and earning the contingent payment. This risk is comprised of InteKrin’s continued development, a specific risk factor associated with meeting the contingent consideration threshold and related payout and counterparty risk associated with the payment of the contingent consideration.

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

#### ***Common Stock Options***

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

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

We recorded non-cash stock-based compensation expense related to options granted to employees and non-employees of \$34.8 million, \$33.4 million and \$27.4 million for the years ended December 31, 2018, 2017 and 2016, 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 and contractual term. We have elected to use the “simplified method” for estimating the expected term, which is calculated as the mid-point between the vesting period and the contractual term of the options.
- *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 sufficient trading history for our common stock.
- *Risk-free interest rate.* The risk free interest rate is based on the U.S. Treasury constant maturity rate in effect at the time of the grant for periods corresponding with the expected term.
- *Expected dividends.* We have not paid and do not anticipate paying any dividends in the near future, and therefore we used an expected dividend yield of zero in the valuation model.

In addition to the Black-Scholes assumptions, we adopted the ASU No. 2016-09, Compensation-Stock Compensation: Improvements to Employee Share-Based Payment, electing to account for the forfeitures as they occur as of January 1, 2017.

We estimate the fair value of restricted stock units (“RSUs”), based on the fair market value of the underlying stock on the dates of grant. The estimated fair value of RSUs is expensed over the vesting period.

We granted performance stock options (“PSO”) to purchase shares of our common stock, which will vest upon the achievement of specified conditions. We determined the fair values of these PSOs using the Black-Scholes option pricing model at the date of grant. For the portion of the PSOs for which the performance condition is considered probable, we recognize stock-based compensation expense on the related estimated fair value of such options on a straight-line basis from the date of grant up to the date when we expect the performance condition will be achieved.

We expect to continue to grant stock options and awards in the future, and to the extent that we do, actual stock-based compensation expense recognized in future periods will likely increase.

## Income Taxes

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

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

On December 22, 2017, the Tax Cuts and Jobs Act of 2017 (the "Tax Act") was signed into law. The Tax Act contains several key provisions that may have significant financial statement effects including the remeasurement of deferred taxes and the recognition of liabilities for taxes on mandatory repatriation and certain other foreign income. The Tax Act reduces the corporate tax rate from 35% to 21% effective January 1, 2018. Because ASC 740 requires us to recognize the effect of tax law changes in the period of enactment, the effects must be recognized by our December 2017 financial statements, even though the effective date for most provisions of the Tax Act was January 1, 2018. In December 2017, the SEC staff issued Staff Accounting Bulletin No. 118, Income Tax Accounting Implications of the Tax Cuts and Jobs Act (SAB 118) which allows companies to record provisional amounts during a measurement period not to extend beyond one year of the enactment date. Since the Tax Act was passed late in the fourth quarter of 2017, and ongoing guidance and accounting interpretation was yet to be issued, our accounting of the transition tax and deferred tax re-measurements were incomplete as of December 31, 2017. We filed our 2017 Federal corporate income tax return in the fourth quarter of 2018. Our final analysis and impact of the Tax Act is reflected in the tax provision and related tax disclosures for the year ended December 31, 2018. There was a gross increase of approximately \$2.9 million to the originally estimated \$87.9 million remeasurement of deferred tax assets. The \$2.9 million remeasurement had no impact on the income statement or balance sheet due to the corresponding valuation allowance offsetting deferred taxes.

As of December 31, 2018, our total net deferred tax assets, net of gross deferred tax liabilities, were \$237.1 million. Due to our lack of earnings history, the net deferred tax assets have been fully offset by a valuation allowance. The deferred tax assets were primarily comprised of federal and state tax net operating losses and tax credit carryforwards. Utilization of the net operating loss and tax credit carryforwards may be subject to an annual limitation due to historical or future ownership changes under Section 382 and 383 of the Internal Revenue Code of 1986, as amended, and similar state provisions.

## Recent Accounting Pronouncements

We adopted the following recent accounting pronouncements in 2018:

In January 2016, the FASB issued ASU No. 2016-01, *Recognition and Measurement of Financial Assets and Financial Liabilities* (ASU 2016-01). ASU 2016-01 makes amendments to the classification and measurement of financial instruments and revises the accounting related to: (1) the classification and measurement of investments in equity securities, and (2) the presentation of certain fair value changes for financial liabilities measured at fair value. In addition, the update also amends certain disclosure requirements associated with the fair value of financial instruments. ASU 2016-01 is effective for our interim and annual reporting periods during the year ending December 31, 2018, and all annual and interim reporting periods thereafter. Early adoptions of certain amendments within the update are permitted. We adopted ASU 2016-01 on January 1, 2018 and the adoption did not have a material impact on our consolidated financial statements and related disclosures.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows: Classification of Certain Cash Receipts and Cash Payments* (ASU 2016-15). The amendment to this update addresses eight specific cash flow issues with the objective of reducing the existing diversity in practice. ASU 2016-15 is effective for our interim and annual reporting periods during the year ending December 31, 2018, and all annual and interim reporting periods thereafter. Early adoption is permitted. We adopted ASU 2016-15 on January 1, 2018 and the adoption did not have a material effect on our consolidated financial statements and related disclosures.

In October 2016, the FASB issued ASU No. 2016-16, *Income Taxes: Intra-Entity Transfers of Assets Other Than Inventory* (ASU 2016-16). This update improves the accounting for the income tax consequences of intra-entity transfers of assets other than inventory. ASU 2016-16 amends the guidance to recognize the income tax consequences of an intra-entity transfer of an asset other than inventory when the transfer occurs. Consequently, the amendments in this update eliminate the exception for an intra-entity transfer of an asset other than inventory. The amendments in this update do not include new disclosure requirements; however, existing disclosure requirements might be applicable when accounting for the current and deferred income taxes for an intra-entity transfer of an asset other than inventory. ASU 2016-16 is effective for our interim and annual reporting periods during the year ending December 31, 2018, and all annual and interim reporting periods thereafter. Early adoption is permitted. We early adopted ASU 2016-16 on January 1, 2018 and the adoption did not have a material effect on our consolidated financial statements and related disclosures.

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash — a consensus of the FASB Emerging Issues Task Force* (ASU 2016-18). The purpose of ASU 2016-18 is to provide guidance on the presentation of restricted cash or restricted cash equivalents in the statement of cash flows. Specifically, ASU 2016-18 requires companies to include amounts generally

described as restricted cash and restricted cash equivalents in cash and cash equivalents when reconciling beginning-of-period and end-of-period total amounts shown on the statement of cash flows. ASU 2016-18 is effective for our interim and annual reporting periods during the year ending December 31, 2018, and all annual and interim periods thereafter. The amendments in ASU 2016-18 should be applied using a retrospective transition method to each period presented. Early adoption is permitted. We adopted ASU 2016-18 on January 1, 2018 and the adoption did not have a material effect on our consolidated financial statements and related disclosures.

In August 2018, the FASB issued ASU No. 2018-15, *Intangibles – Goodwill and Other – Internal-Use Software (Subtopic 350-40): Customer’s Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract*. (ASU 2018-15). ASU 2018-15 requires a customer in a cloud computing arrangement that is a service contract to follow the internal-use software guidance in Accounting Standards Codification 350-40 to determine which implementation costs to defer and recognize as an asset. ASU 2018-15 is effective for our interim and annual reporting periods during the year ending December 31, 2020, and all annual and interim reporting periods thereafter. Early adoption is permitted. We early adopted ASU 2018-15 in the third quarter of 2018, and the adoption did not have a material effect on our consolidated financial statements and related disclosures.

The following are the recent accounting pronouncements that we have not yet adopted:

In February 2016, the FASB issued ASU No. 2016-02, *Leases* (ASU 2016-02). ASU 2016-02 aims to make leasing activities more transparent and comparable, and requires substantially all leases be recognized by lessees on their balance sheet as a right-of-use asset and corresponding lease liability, including leases currently accounted for as operating leases. ASU 2016-02 is effective for our interim and annual reporting periods during the year ending December 31, 2019, and all annual and interim reporting periods thereafter. Early adoption is permitted. In July 2018, FASB issued additional authoritative guidance, ASU 2018-11, providing companies with an optional prospective transition method. We plan to adopt the new standards in the first quarter of 2019 using the optional prospective transition method and will recognize a right-of-use asset and lease liability on the adoption date. Based on our lease portfolio as of December 31, 2018, we anticipate upon adoption the recognition of lease assets in the range of \$6.7 million to \$7.7 million and lease liabilities in the range of \$8.7 million to \$9.7 million on our consolidated balance sheet, primarily comprised of lease facility agreements for our corporate headquarters and our laboratory facilities in California. We do not anticipate any material impact to our consolidated statements of operations. We will elect the package of practical expedients upon transition, which allows us to apply the guidance prospectively, without reassessing prior conclusions related to contracts containing leases, lease classification and initial direct costs. We will also elect an accounting policy that does not recognize right-of-use assets and lease liabilities related to short-term leases. We will not elect to apply the hindsight expedient. We are in the process of updating our controls and procedures for maintaining and accounting for our lease portfolio under the new guidance.

In January 2017, the FASB issued ASU No. 2017-04, *Intangibles-Goodwill and Other: Simplifying the Test for Goodwill Impairment* (ASU 2017-04), which simplifies the current requirements for testing goodwill for impairment by eliminating the second step of the two-step impairment test to measure the amount of an impairment loss. ASU 2017-04 is effective for our interim and annual reporting periods during the year ending December 31, 2020, and all annual and interim reporting periods thereafter. Early adoption is permitted. We are currently evaluating the impact that the adoption of ASU 2017-04 will have on our consolidated financial statements and related disclosures.

In June 2018, the FASB issued ASU No. 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting* (ASU 2018-07), which simplifies the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payment to employees, with certain exceptions. The amendments in ASU 2018-07 are effective for our interim and annual reporting periods during the year ending December 31, 2019, and all annual and interim reporting periods thereafter. Early adoption is permitted. We do not anticipate that the adoption of this ASU will have a material impact on our consolidated financial statements and related disclosures.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurements* (ASU 2018-13), which eliminates certain disclosure requirements for fair value measurements, and requires public entities to disclose certain new information and modifies some disclosure requirements. The new guidance is effective for our interim and annual reporting periods during the year ending December 31, 2020, and all annual and interim reporting periods thereafter. Early adoption is permitted. We are currently evaluating the impact that the adoption of ASU 2018-13 will have on our consolidated financial statements and related disclosures.

In August 2018, the SEC adopted amendments to certain disclosure requirements in Securities Act Release No. 33-10532, *Disclosure Update and Simplification*. These amendments eliminate, modify, or integrate into other SEC requirements certain disclosure rules. Among the amendments is the requirement to present an analysis of changes in stockholders’ equity in the interim financial statements included in quarterly reports on Form 10-Q. The analysis, which can be presented as a footnote or separate statement, is required for the current and comparative quarter and year-to-date interim periods. The amendments are effective for all filings made on or after November 5, 2018. In light of the anticipated timing of effectiveness of the amendments and expected proximity of effectiveness to the filing date for most filers’ quarterly reports, the SEC’s Division of Corporate Finance issued a Compliance and Disclosure Interpretation related to Exchange Act Forms, or CDI – Question 105.09, that provides transition guidance related to this disclosure requirement. CDI – Question 105.09 states that the SEC would not object if the filer’s first presentation of the changes in stockholders’ equity is included in its Form 10-Q for the quarter that begins after the effective date of the amendments. As such, we adopted these SEC amendments on November 5, 2018 and will present the analysis of changes in stockholders’ equity in its interim financial statements in its March 31, 2019 Form 10-Q. We do not anticipate that the adoption of these SEC amendments will have a material effect on our financial position, results of operations, cash flows or stockholders’ equity.

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

## Results of Operations

### Comparison of Years Ended December 31, 2018, 2017 and 2016

#### Revenue

	Year Ended December 31,			2018 vs 2017 Change	2017 vs 2016 Change
	2018	2017	2016		
	<i>(in thousands)</i>			<i>(in thousands)</i>	
Revenue:					
Collaboration and license revenue	\$ —	\$ 1,556	\$ 189,476	\$ (1,556)	\$ (187,920)
Other revenue	—	—	630	—	(630)
Total revenue	\$ —	\$ 1,556	\$ 190,106	\$ (1,556)	\$ (188,550)

We recognized no revenue for the year ended December 31, 2018.

Total revenue for the year ended December 31, 2017 was \$1.6 million compared to \$190.1 million for the same period in 2016, a decrease of \$188.6 million. The decrease was primarily due to revenue recognized in connection with the termination of the Baxalta Agreement in 2016, partially offset by the recognition of the remaining deferred revenue as a result of Daiichi Sankyo's decision to opt-out of the development of CHS-0214 in Japan in the second quarter of 2017.

In June 2016, Shire completed its acquisition of Baxalta and as part of its strategic portfolio review issued a termination notice of the Baxalta Agreement in its entirety on September 26, 2016. As such, we regained from Shire all development and commercial rights previously licensed under CHS-0214 to Baxalta for Europe, Canada, Brazil, the Middle East and other territories, and recognized the outstanding balances of deferred revenue and contingent liability to collaborator related to the Baxalta Agreement of \$85.8 million and \$76.7 million, respectively, as revenue in 2016.

#### Research and Development Expense

	Year Ended December 31,			2018 vs 2017 Change	2017 vs 2016 Change
	2018	2017	2016		
	<i>(in thousands)</i>			<i>(in thousands)</i>	
Research and development	\$ 110,239	\$ 162,389	\$ 254,440	\$ (52,150)	\$ (92,051)

Research and development expense for the year ended December 31, 2018 was \$110.2 million compared to \$162.4 million for the same period in 2017, a decrease of \$52.2 million. The decrease in research and development expense was primarily due to:

- a decrease of \$46.3 million in costs incurred for CHS-1420 due to the completion of our Phase 3 and Phase 1 studies in the first quarter of 2017;
- a decrease of \$13.3 million in costs incurred for CHS-0214 due to the completion of patient treatment in our Phase 3 open-label extension study in the fourth quarter of 2017, which also includes a decrease of \$4.2 million in cost reimbursements from Daiichi Sankyo that was recognized as a reduction in research and development expense;
- a decrease of \$4.6 million in personnel, consulting and other related expenses primarily due to the restructuring charges related to the one-time termination severance costs and a reduction in headcount as our restructuring plan was completed in June 2017; and
- a decrease of \$2.0 million related to the development of other biosimilar product candidates and CHS-131 as we completed the Phase 2b study in late 2017 and prioritized our resources primarily on UDENYCA™.

The decrease in research and development expense was partially offset by the following:

- an increase of \$11.7 million in research and development costs primarily due to the manufacturing of our pre-commercial supplies of UDENYCA™ in preparation for our commercial launch and costs incurred for the BLA resubmission activities of UDENYCA™, which were partially offset by \$5.7 million of manufacturing costs which were capitalized as inventory after November 2, 2018, following the approval of UDENYCA™;

- an increase of \$2.1 million in facilities, supplies and materials and other infrastructure primarily due to \$3.9 million in impairment of equipment charges, which were partially offset by a decrease in overall costs due to the implementation of our restructuring plan in June 2017; and
- an increase of \$0.2 million in stock-based compensation expense as a result of additional stock options granted in 2018.

We expect our research and development expense to be lower in 2019 as the manufacturing costs for UDENYCA™ will be capitalized after receiving FDA approval on November 2, 2018, and will no longer be recognized as a research and development cost, and we do not anticipate large clinical development costs for our pipeline products.

Research and development expense for the year ended December 31, 2017 was \$162.4 million compared to \$254.4 million for the same period in 2016, a decrease of \$92.1 million. The decrease in research and development expense was primarily due to:

- a decrease of \$60.2 million in costs incurred for CHS-0214 due to fully enrolled and completed Phase 3 clinical studies during 2016, which also includes a decrease of \$5.5 million in cost reimbursements from Daiichi Sankyo that was recognized as a reduction of research and development expense;
- a decrease of \$18.0 million in costs incurred for CHS-1420 as a result of completing our Phase 3 trial for CHS-1420 in the first quarter of 2017;
- a decrease of \$14.2 million related to the development of CHS-131 and other biosimilar product candidates as we prioritized and focus our resources primarily on advancing UDENYCA™, our first commercial product;
- a decrease of \$1.7 million in costs incurred for UDENYCA™ as we completed the clinical development of UDENYCA™ in 2016; and
- a decrease of \$0.5 million in personnel, consulting and other related expenses.

The decrease in research and development expense for the year ended December 31, 2017 was partially offset by:

- an increase of \$1.5 million in stock-based compensation due to the acceleration of stock options and the extension of post-termination stock option exercise periods as a result of our restructuring in June 2017, additional stock options granted since the end of 2016, and an increase in headcount in the six month period before the restructuring plan was completed in June 2017; and
- an increase of \$1.0 million in facilities, supplies and materials and other infrastructure to support our research and development growth prior to the implementation of the restructuring plan in June 2017.

#### *Selling, General and Administrative Expense*

	<u>Year Ended December 31,</u>			<u>2018 vs 2017</u> <u>Change</u>	<u>2017 vs 2016</u> <u>Change</u>
	<u>2018</u>	<u>2017</u>	<u>2016</u>		
	<i>(in thousands)</i>			<i>(in thousands)</i>	
Selling, general and administrative	\$ 94,177	\$ 71,303	\$ 51,597	\$ 22,874	\$ 19,706

Selling, general and administrative expense for the year ended December 31, 2018 was \$94.2 million compared to \$71.3 million for the same period in 2017, an increase of \$22.9 million. The increase in selling, general and administrative expense was primarily due to:

- an increase of \$14.3 million in personnel, consulting and other related expenses due to an increase in headcount as we build our sales force and supporting commercial functions in connection with the commercial launch of UDENYCA™, which was partially offset by one-time termination severance charges of \$1.1 million incurred in connection with our restructuring plan completed in June 2017;
- an increase of \$6.9 million for legal, marketing, advertising, recruiting and other professional services associated with commercial and marketing initiatives to support the launch of UDENYCA™ and \$0.5 million in facility related expense to support our growing infrastructure; and
- an increase of \$1.2 million in stock-based compensation expense due to additional stock options granted in 2018 and the increase in headcount due to the commercialization of UDENYCA™. The increase was partially offset by \$1.2 million of restructuring charges related to the acceleration of stock options and the extension of the post-termination stock option exercise period incurred in connection with our restructuring plan completed in June 2017.

We expect selling, general and administrative expense to increase significantly in 2019 as we initiated sales of UDENYCA™ starting in January 2019.

Selling, general and administrative expense for the year ended December 31, 2017 was \$71.3 million compared to \$51.6 million for the same period in 2016, an increase of \$19.7 million. The increase in selling, general and administrative expense was primarily due to:

- an increase of \$5.8 million in personnel, consulting and other related expenses due to an increase in headcount in the first six months of 2017 as we expanded our pre-commercial activities before the restructuring plan was implemented in June 2017;
- an increase of \$4.5 million for stock-based compensation due to the acceleration of stock options and the extension of post-termination stock option exercise periods as a result of our restructuring in June 2017, additional stock options granted since the end of 2016 and an increase in headcount for the six month period before the restructuring plan was implemented in June 2017;
- an increase of \$8.6 million for legal and other professional services as we implemented and supported our legal strategies; and
- an increase of \$0.8 million for facilities, supplies and materials to support our growing infrastructure as we expanded our pre-commercial activities prior to the implementation of our restructuring plan in June 2017.

#### Interest Expense

	Year Ended December 31,			2018 vs 2017 Change	2017 vs 2016 Change
	2018	2017	2016		
	(in thousands)			(in thousands)	
Interest expense	\$ 9,684	\$ 9,552	\$ 7,980	\$ 132	\$ 1,572

Interest expense for the year ended December 31, 2018 was \$9.7 million compared to \$9.6 million for the same period in 2017, an increase of \$0.1 million. Interest expense for the year ended December 31, 2017 was \$9.6 million compared to \$8.0 during the same period in 2016, an increase of \$1.6 million. The increase in both years was due to the recognition of interest expense and non-cash accretion of the debt discount and debt issuance costs related to the Convertible Notes issued on February 29, 2016.

#### Other Income (Expense), Net

	Year Ended December 31,			2018 vs 2017 Change	2017 vs 2016 Change
	2018	2017	2016		
	(in thousands)			(in thousands)	
Other income (expense), net	\$ 4,691	\$ 3,402	\$ (3,877)	\$ 1,289	\$ 7,279

Other income (expense), net for the year ended December 31, 2018 was a gain of \$4.7 million compared to a gain of \$3.4 million for the same period in 2017, an increased gain of \$1.3 million. The gain of \$4.7 million in 2018 is due to the decrease in the fair value of our contingent consideration related to the Compound Transaction Payment associated with our InteKrin acquisition as a result of a decrease in the probability of occurrence from 33% to 10% and an extension in the timing of occurrence to a later date.

Other income (expense), net for the year ended December 31, 2017 was a gain of \$3.4 million compared to a loss of \$3.9 million for the same period in 2016, an increased gain of \$7.3 million. The gain of \$3.4 million in 2017 was primarily due to a decrease in the fair value of our contingent consideration related to the compound transaction payment associated with our InteKrin acquisition during the second quarter of 2017, as a result of reducing the estimated licensing, collaboration or similar agreement value by 32% and extending the timing of occurrence to a later date. The loss of \$3.9 million in 2016 was primarily due to an increase in the fair value of our contingent consideration driven by our positive Phase 2b data on CHS-131, and as such, the probability of occurrence increased from 10% to 33%.

#### Liquidity and Capital Resources

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

In October 2016, we entered into a sales agreement with Cowen, under which we may offer and sell our common stock, having aggregate gross proceeds of up to \$100.0 million, from time to time through Cowen as our sales agent in our ATM Offering Program. In 2018, we issued and sold an aggregate of 1,799,504 shares of common stock at a weighted average price of \$12.14 per share under the ATM Offering Program for aggregate net proceeds of \$21.0 million after deducting underwriting discounts and commissions and offering expenses. As of December 31, 2018, we had \$10.1 million remaining under the ATM Offering Program. As of January 18, 2019, our Shelf Registration Statement related to the ATM Offering Program expired and accordingly the ATM Offering Program was terminated.

In May 2018, we completed an underwritten public offering of 5,948,274 shares of our common stock at a price to the public of \$14.50 per share, which includes the closing of the full exercise of the underwriters' option to purchase an additional 775,861 shares of common stock.

We received net proceeds from the offering of \$80.8 million, after deducting the underwriting discounts and commissions and offering expenses.

In 2018, we purchased investments in marketable securities in accordance with our investment policy in order to obtain interest income on our cash balances. As of December 31, 2018, we did not have any investments in marketable securities.

As of December 31, 2018, we had an accumulated deficit of \$984.8 million and cash and cash equivalents of \$72.4 million. We entered into the Credit Agreement with affiliates of Healthcare Royalty Partners which consists of a six-year term loan facility for an aggregate principal of \$75.0 million in January 2019. We believe that our current available cash, cash equivalents, and the proceeds from the Credit Agreement of \$73.1 million, net of offering and original issue discount costs will be sufficient to fund our planned expenditures and meet our obligations for at least the next 12 months following our financial statement issuance date. We will need to raise additional funds in the future; however, there can be no assurance that such efforts will be successful or that, in the event that they are successful, the terms and conditions of such financing will be favorable to us.

### Summary Statement of Cash Flows

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

	Year Ended December 31,		
	2018	2017	2016
	<i>(in thousands)</i>		
Net cash used in operating activities	\$ (159,266)	\$ (200,286)	\$ (252,545)
Net cash used in investing activities	(1,188)	(4,417)	(6,515)
Net cash provided by financing activities	105,421	206,787	226,179
Effect of exchange rate changes in cash, cash equivalents and restricted cash	468	(120)	(398)
Net increase (decrease) in cash, cash equivalents and restricted cash	<u>\$ (54,565)</u>	<u>\$ 1,964</u>	<u>\$ (33,279)</u>

#### Net cash used in operating activities

Cash used in operating activities was \$159.3 million for the year ended December 31, 2018, which was primarily due to the following:

- a net loss of \$209.4 million;
- a non-cash gain of \$3.2 million related to the fair value remeasurement of our contingent consideration obligation and \$0.3 million related to the accretion of short-term investments;
- an increase in inventory of \$5.5 million as we began capitalizing inventory in November 2018 upon receiving FDA approval for UDENYCA™; and
- a decrease in accounts payable, accounts payable-related parties, accrued liabilities and other liabilities of \$0.9 million primarily due to the payments to our CROs and CMOs as a result of the progression of our clinical trial programs that are winding down, and the timing of certain vendor payments;

The cash used in operating activities was partially offset by the following:

- non-cash charges related to stock-based compensation of \$34.8 million;
- impairment of fixed asset equipment of \$3.9 million, depreciation and amortization of property and equipment of \$3.2 million and non-cash interest related to the amortization of debt discount and debt issuance cost of \$1.5 million;
- an increase in accrued compensation of \$8.5 million primarily due to the timing of bonus settlement as 2017 bonuses were paid in RSU's in December 2017; and
- a decrease in prepaid manufacturing, other prepaid and other assets of \$8.2 million as we utilized the prepayment for our pre-commercial manufacturing of UDENYCA™.

Cash used in operating activities was \$200.3 million for the year ended December 31, 2017, which was primarily due to the following:

- a net loss of \$238.3 million;
- non-cash charges related to the fair value remeasurement of our contingent consideration obligation of \$2.3 million;
- a decrease in accounts payable, accounts payable-related parties, accrued compensation and accrued and other liabilities of \$23.4 million primarily due to the winding down of our clinical research and manufacturing activities and the timing of vendor payments;



- a decrease in deferred revenue of \$1.6 million as we recognized revenue from our Daiichi Sankyo collaboration agreement; and
- a decrease in advance payments from a collaboration and licensing partner of \$1.1 million.

The cash used in operating activities was partially offset by the following:

- a decrease in prepaid manufacturing, other prepaid and other current assets of \$18.8 million primarily due to the winding down of our clinical research and manufacturing activities related to CHS-0214 and CHS-1420, and the timing of vendor payments;
- a decrease in receivables from a collaboration and license agreement of \$1.9 million; and
- non-cash charges related to stock-based compensation of \$33.4 million, manufacturing postponement fee of \$4.1 million, non-cash bonus payment settled in common stock of \$2.7 million, depreciation and amortization of property and equipment of \$3.4 million, non-cash interest related to the amortization of debt discount and debt issuance cost of \$1.4 million and impairment of property and equipment of \$0.6 million.

Cash used in operating activities was \$252.5 million for the year ended December 31, 2016, which was primarily due to the following:

- a net loss of \$127.8 million;
- non-cash reduction of \$1.3 million in other receivables due to the reversal of a provision;
- a decrease of \$93.2 million in deferred revenue and \$66.3 million in contingent liability to collaborator primarily due to the recognition of all Baxalta deferred revenue and contingent liability to collaborator as a result of the termination of the Baxalta license agreement during the third quarter of 2016; and
- a decrease in accounts payable, accounts payable-related parties, accrued compensation and accrued and other liabilities of \$3.6 million primarily due to the payments to our clinical research organizations and clinical manufacturing organizations as a result of the progression of our Phase 3 clinical trial programs that are winding down, and the timing of the vendor payments.

The cash used in operating activities was partially offset by the following:

- non-cash charges related to stock-based compensation of \$27.4 million, fair value remeasurement of our contingent consideration obligation of \$4.3 million, non-cash interest expense of \$1.0 million, and depreciation and amortization of property and equipment of \$3.0 million; and
- a decrease in prepaid manufacturing, other prepaid and other current assets of \$4.2 million primarily due to the progression of our Phase 3 clinical trial programs that are winding down and the timing of the vendor payments.

#### *Net cash used in investing activities*

Cash used in investing activities of \$1.2 million for the year ended December 31, 2018 was due to the purchase of short-term investments in marketable securities of \$42.9 million, the purchase of the non-controlling interest of \$0.7 million and purchases of property and equipment of \$0.8 million. The cash used in investing activities was partially offset by proceeds from maturities of investments in marketable securities of \$43.2 million.

Cash used in investing activities of \$4.4 million for the year ended December 31, 2017 was due to the purchase of short-term investments in marketable securities of \$74.3 million and capital equipment of \$4.6 million, partially offset by proceeds from the sales and maturities of investments in marketable securities of \$74.5 million.

Cash used in investing activities of \$6.5 million for the year ended December 31, 2016 was due to the purchase of capital equipment and leasehold improvements.

#### *Net cash provided by financing activities*

Cash provided by financing activities of \$105.4 million for year ended December 31, 2018 was primarily due to net proceeds of \$102.3 million from the issuance of our common stock from an underwritten public offering in May 2018 and our ATM Offering Program, net of underwriting discounts and commissions, \$2.0 million from the exercise of stock options, and \$1.6 million in proceeds related to our ESPP. The proceeds were partially offset by payments of \$0.5 million for offering expenses related to the issuance of common stock.

Cash provided by financing activities of \$206.8 million for year ended December 31, 2017 was primarily related to proceeds of \$131.8 million from the issuance of our common stock from a follow-on offering and the ATM Offering Program, net of underwriting discounts and commissions, \$75.0 million related to our private placement, and \$0.5 million from the exercise of stock options. The proceeds were partially offset by payments of offering expenses of \$0.5 million related to the issuance of common stock.

Cash provided by financing activities of \$226.2 million for year ended December 31, 2016 was primarily related to proceeds of \$100.0 million from the issuance of the Convertible Notes, the proceeds of \$124.3 million from the issuance of our common stock from a follow-on offering and the ATM Offering Program, net of underwriting discounts and commissions, and proceeds from the exercise of stock options of \$3.3 million, partially offset by payments of convertible debt issuance costs of \$0.7 million and offering expenses of \$0.7 million related to the issuance of common stock.

## Funding Requirements

We believe that our current available cash and cash equivalents, the proceeds from our Credit Agreement executed in January 2019, and the cash collected from the sales of UDENYCA™ will be sufficient to fund our planned expenditures and meet our obligations through at least 12 months following our financial statement issuance date. 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. 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:

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

We may need to raise additional capital to fund our operations in the near future. Funding may not be available to us on acceptable terms, or at all. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of or suspend one or more of our clinical trials, or research and development programs. We may seek to raise any necessary additional capital through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. We will seek to enter into strategic partnerships to commercialize our biosimilar candidates in ex-US territories or globally for certain therapeutic areas. To the extent that we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we do raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to additional 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, 2018 were as follows:

<u>Contractual Obligations:</u>	<u>Payments Due by Period</u>				
	<u>Total</u>	<u>Less than 1 year</u>	<u>1 to 3 years</u>	<u>3 to 5 years</u>	<u>More than 5 years</u>
Long-term debt obligations (1)	\$ 135,650	\$ 8,200	\$ 16,400	\$ 111,050	\$ —
Non-cancelable operating lease obligations and purchase commitments (2)	38,682	6,422	29,742	2,518	—
Contingent payments to InteKrin Stockholders	60	—	—	60	—
Total contractual obligations	<u>\$ 174,392</u>	<u>\$ 14,622</u>	<u>\$ 46,142</u>	<u>\$ 113,628</u>	<u>\$ —</u>

- (1) The long-term debt obligation is comprised of future minimum payments related to the Convertible Notes.  
(2) These amounts are comprised of the rent payments on our facility leases and purchase commitments to our CMO's.

In February 2016, we issued and sold \$100.0 million aggregate principal amount of Convertible Notes that require quarterly interest distributions at a fixed coupon rate of 8.2% until maturity, redemption or conversion, which will be no later than March 31, 2022. After March 31, 2020, the full amount of the Convertible Notes not previously converted are redeemable for cash at our option if the last reported sale price per share of our common stock exceeds 160% of the conversion price on 20 or more trading days during the 30 consecutive trading days preceding the date on which we send notice of such redemption to the holders of the Convertible Notes. At maturity or redemption, if not earlier converted, we will pay 109% of the principal amount of the Convertible Notes, together with accrued and unpaid interest, in cash.

The Company enters into contracts in the normal course of business with CROs for preclinical studies and clinical trials and CMOs for the manufacture of drug materials. The contracts are cancellable, with varying provisions regarding termination. If a contract with a specific vendor were to be terminated, the Company would only be obligated for products or services that the Company had received as of the effective date of the termination and any applicable cancellation fees.

### Item 7A. Quantitative and Qualitative Disclosures about Market Risk

As of December 31, 2018, we had cash and cash equivalents of \$72.4 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.

COHERUS BIOSCIENCES, INC.

ANNUAL REPORT ON FORM 10-K

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Stockholders and the Board of Directors of Coherus BioSciences, Inc.,

**Opinion on the Financial Statements**

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

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated February 28, 2019 expressed an unqualified opinion thereon.

**Basis for Opinion**

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

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

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2012.

Redwood City, California

February 28, 2019

**Coherus BioSciences, Inc.**  
**Consolidated Balance Sheets**  
(in thousands, except share and per share data)

	December 31,	
	2018	2017
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 72,356	\$ 126,911
Restricted cash	50	60
Inventory	1,659	—
Prepaid manufacturing	7,906	14,969
Other prepaid assets (includes related parties of \$0 and \$908 as of December 31, 2018 and 2017, respectively)	2,379	3,395
Other assets	83	142
<b>Total current assets</b>	<b>84,433</b>	<b>145,477</b>
Property and equipment, net	6,660	12,773
Inventory, non-current	4,012	—
Intangible assets	2,620	2,620
Goodwill	943	943
Restricted cash, non-current	785	785
Other assets, non-current	14	13
<b>Total assets</b>	<b>\$ 99,467</b>	<b>\$ 162,611</b>
<b>Liabilities and Stockholders' Equity (Deficit)</b>		
Current liabilities:		
Accounts payable	\$ 15,294	\$ 15,481
Accounts payable - related parties	—	233
Accrued compensation	10,540	2,074
Accrued liabilities (includes related parties of \$0 and \$510 as of December 31, 2018 and 2017, respectively)	7,008	6,976
Contingent consideration, current	—	3,290
Other current liabilities	419	341
<b>Total current liabilities</b>	<b>33,261</b>	<b>28,395</b>
Contingent consideration, non-current	60	—
Convertible notes	77,319	76,206
Convertible notes - related parties	25,773	25,402
Other liabilities, non-current	1,645	2,073
<b>Total liabilities</b>	<b>138,058</b>	<b>132,076</b>
Commitments and contingencies (Note 8)		
Stockholders' equity (deficit):		
Preferred stock, \$0.0001 par value; Shares authorized: 5,000,000; Shares issued and outstanding: no shares at December 31, 2018 and 2017.	—	—
Common stock, \$0.0001 par value; Shares authorized: 300,000,000; Shares issued and outstanding: 68,302,681 and 59,840,467 at December 31, 2018 and 2017, respectively	7	6
Additional paid-in capital	946,515	808,060
Accumulated other comprehensive loss	(282)	(750)
Accumulated deficit	(984,831)	(775,492)
<b>Total Coherus stockholders' equity (deficit)</b>	<b>(38,591)</b>	<b>31,824</b>
Non-controlling interest	—	(1,289)
<b>Total stockholders' equity (deficit)</b>	<b>(38,591)</b>	<b>30,535</b>
<b>Total liabilities and stockholders' equity (deficit)</b>	<b>\$ 99,467</b>	<b>\$ 162,611</b>

See accompanying notes to consolidated financial statements.

**Coherus BioSciences, Inc.**  
**Consolidated Statements of Operations**  
(in thousands, except share and per share data)

	Year Ended December 31,		
	2018	2017	2016
<b>Revenue:</b>			
Collaboration and license revenue	\$ —	\$ 1,556	\$ 189,476
Other revenue	—	—	630
Total revenue	—	1,556	190,106
<b>Operating expenses:</b>			
Research and development (includes related party of \$1,609, \$8,199 and \$34,705 for the years ended December 31, 2018, 2017 and 2016, respectively)	110,239	162,389	254,440
Selling, general and administrative (includes related party of \$181, \$62 and \$178 for the years ended December 31, 2018, 2017 and 2016, respectively)	94,177	71,303	51,597
Total operating expenses	204,416	233,692	306,037
Loss from operations	(204,416)	(232,136)	(115,931)
Interest expense (includes related party of \$2,421, \$2,388 and \$1,980 for the years ended December 31, 2018, 2017 and 2016, respectively)	(9,684)	(9,552)	(7,980)
Other income (expense), net	4,691	3,402	(3,877)
Net loss	(209,409)	(238,286)	(127,788)
Net loss attributable to non-controlling interest	70	116	451
Net loss attributable to Coherus	\$ (209,339)	\$ (238,170)	\$ (127,337)
Net loss per share attributable to Coherus, basic and diluted	\$ (3.22)	\$ (4.48)	\$ (3.04)
Weighted-average number of shares used in computing net loss per share attributable to Coherus, basic and diluted	65,034,827	53,133,620	41,912,300

See accompanying notes to consolidated financial statements.

**Coherus BioSciences, Inc.**  
**Consolidated Statements of Comprehensive Loss**  
(in thousands)

	Year Ended December 31,		
	2018	2017	2016
Net loss	\$ (209,409)	\$ (238,286)	\$ (127,788)
Other comprehensive loss:			
Foreign currency translation adjustments, net of tax	468	(120)	(229)
Comprehensive loss	(208,941)	(238,406)	(128,017)
Comprehensive loss attributable to non-controlling interest	70	116	451
Comprehensive loss attributable to Coherus	\$ (208,871)	\$ (238,290)	\$ (127,566)

See accompanying notes to consolidated financial statements.



Coherus BioSciences, Inc.

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

	Common Stock		Additional	Accumulated	Accumulated	Total Coherus	Non-	Total
	Shares	Amount	Paid-In	Other		Stockholders'		controlling
			Capital	Comprehensive	Deficit	Equity	Interest	Equity
				Loss		(Deficit)		(Deficit)
Balances at December 31, 2015	39,005,589	\$ 4	\$ 404,175	\$ (401)	\$ (409,985)	\$ (6,207)	\$ (722)	\$ (6,929)
Issuance of common stock in connection with common stock offerings, net	6,040,987	1	123,566	—	—	123,567	—	123,567
Issuance of common stock upon exercise of stock options	761,587	—	3,312	—	—	3,312	—	3,312
Stock-based compensation expense	—	—	27,421	—	—	27,421	—	27,421
Cumulative translation adjustment	—	—	—	(229)	—	(229)	—	(229)
Distributions to non-controlling interest	—	—	—	—	—	—	(451)	(451)
Net loss attributable to Coherus	—	—	—	—	(127,337)	(127,337)	—	(127,337)
Balances at December 31, 2016	45,808,163	5	558,474	(630)	(537,322)	20,527	(1,173)	19,354
Issuance of common stock in connection with common stock offerings, net	6,220,901	—	131,849	—	—	131,849	—	131,849
Issuance of common stock in connection with private placements	7,332,220	1	81,809	—	—	81,810	—	81,810
Offering costs associated with common stock offering and private placements	—	—	(619)	—	—	(619)	—	(619)
Issuance of common stock upon exercise of stock options	162,978	—	482	—	—	482	—	482
Stock-based compensation expense	—	—	33,397	—	—	33,397	—	33,397
Issuance of common stock upon vesting of RSU's	14,750	—	—	—	—	—	—	—
Issuance of common stock upon 2017 bonus payout	301,455	—	2,668	—	—	2,668	—	2,668
Cumulative translation adjustment	—	—	—	(120)	—	(120)	—	(120)
Distributions to non-controlling interest	—	—	—	—	—	—	(116)	(116)
Net loss attributable to Coherus	—	—	—	—	(238,170)	(238,170)	—	(238,170)
Balances at December 31, 2017	59,840,467	6	808,060	(750)	(775,492)	31,824	(1,289)	30,535
Issuance of common stock in connection with common stock offerings, net	7,747,778	1	102,260	—	—	102,261	—	102,261
Offering costs associated with common stock offering	—	—	(473)	—	—	(473)	—	(473)
Issuance of common stock upon exercise of stock options	477,019	—	2,153	—	—	2,153	—	2,153
Stock-based compensation expense	—	—	34,984	—	—	34,984	—	34,984
Issuance of common stock upon vesting of RSUs	61,804	—	—	—	—	—	—	—
Issuance of common stock upon ESPP purchase	175,613	—	1,591	—	—	1,591	—	1,591
Cumulative translation adjustment	—	—	—	468	—	468	—	468
Distributions to non-controlling interest	—	—	(2,060)	—	—	(2,060)	(70)	(2,130)
Purchase of the remaining non-controlling interest	—	—	—	—	—	—	1,359	1,359
Net loss attributable to Coherus	—	—	—	—	(209,339)	(209,339)	—	(209,339)
Balances at December 31, 2018	68,302,681	\$ 7	\$ 946,515	\$ (282)	\$ (984,831)	\$ (38,591)	\$ —	\$ (38,591)

See accompanying notes to consolidated financial statements.

**Coherus BioSciences, Inc.**  
**Consolidated Statements of Cash Flows**  
(in thousands)

	Years Ended December 31,		
	2018	2017	2016
<b>Operating activities</b>			
Net loss	\$ (209,409)	\$ (238,286)	\$ (127,788)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	3,235	3,398	2,996
Remeasurement of fair-value contingent consideration	(3,230)	(2,260)	4,305
Non-cash accretion of discount on marketable securities	(301)	(156)	—
Non-cash interest expense from amortization of debt discount	1,484	1,352	1,041
Provision for other receivables	—	—	(1,300)
Stock-based compensation expense	34,797	33,397	27,421
Non-cash bonus payment settled in common stock	—	2,668	—
Non-cash manufacturing postponement fee settled in common stock	—	4,125	—
Loss (gain) on disposal of property and equipment	—	51	(6)
Impairment of property and equipment	3,861	558	—
Changes in operating assets and liabilities:			
Receivables from collaboration and license agreement	—	1,859	(299)
Inventory	(5,484)	—	—
Prepaid manufacturing	7,063	7,788	(16,119)
Other prepaid assets	1,016	8,170	19,246
Other assets	130	2,844	1,111
Other assets, non-current	(1)	—	88
Accounts payable	(301)	(3,810)	(4,965)
Accounts payable - related parties	(233)	(644)	(2,671)
Accrued compensation	8,466	(4,871)	2,279
Accrued liabilities	(9)	(14,162)	1,674
Other liabilities	78	83	65
Deferred revenue	—	(1,562)	(93,236)
Advance payments under license agreements	—	(1,070)	(260)
Contingent liability to collaborator	—	—	(66,255)
Other liabilities, non-current	(428)	242	128
Net cash used in operating activities	<u>(159,266)</u>	<u>(200,286)</u>	<u>(252,545)</u>
<b>Investing activities</b>			
Purchases of property and equipment	(789)	(4,573)	(6,515)
Purchases of investments in marketable securities	(42,869)	(74,344)	—
Proceeds from maturities of investments in marketable securities	43,170	74,500	—
Purchase of non-controlling interest related to InteKrin Russia	(300)	—	—
Purchase of non-controlling interest related to InteKrin Russia - related party	(400)	—	—
Net cash used in investing activities	<u>(1,188)</u>	<u>(4,417)</u>	<u>(6,515)</u>
<b>Financing activities</b>			
Proceeds from issuance of convertible notes	—	—	75,000
Proceeds from issuance of convertible notes - related parties	—	—	25,000
Proceeds from private placement	—	75,000	—
Proceeds from common stock offering, net of underwriters discounts, commissions and offering costs	101,748	131,305	123,606
Payments of convertible notes issuance costs	—	—	(739)
Proceeds from ESPP purchase	1,591	—	—
Proceeds from issuances of common stock upon exercise of stock options	2,082	482	3,312
Net cash provided by financing activities	<u>105,421</u>	<u>206,787</u>	<u>226,179</u>
Effect of exchange rate changes in cash, cash equivalents and restricted cash	468	(120)	(398)
Net increase (decrease) in cash, cash equivalents and restricted cash	(54,565)	1,964	(33,279)
Cash, cash equivalents and restricted cash at beginning of period	127,756	125,792	159,071
Cash, cash equivalents and restricted cash at end of period	<u>\$ 73,191</u>	<u>\$ 127,756</u>	<u>\$ 125,792</u>
<b>Supplemental disclosure of cash flow information</b>			
Cash paid for interest	\$ 8,200	\$ 8,200	\$ 6,939
<b>Supplemental disclosures of noncash investing and financing activities</b>			
Purchase of property and equipment in accounts payable and accrued liabilities	194	(430)	507
Non-cash non-controlling interest reflected in additional paid in capital	1,359	—	—
Common stock offering costs in accounts payable and accrued liabilities	(39)	75	39
Manufacturing services settled in common stock	—	6,810	—

See accompanying notes to consolidated financial statements.

## Notes to Consolidated Financial Statements

**1. Organization and Operations****Description of the Business**

The Company is a commercial-stage biopharmaceuticals company, focused on the global biosimilar market. Biosimilars are a class of protein-based therapeutics with high similarity to approved originator products on the basis of various structural, physicochemical and biological properties, as well as in terms of safety and efficacy. The Company's headquarters and laboratories are located in Redwood City, California and in Camarillo, California, respectively.

On September 25, 2018, the Company received regulatory approval for the marketing of UDENYCA™ (pegfilgrastim-cbqv), a biosimilar to Neulasta, a long-acting granulocyte-colony stimulating factor, from the European Commission, and received regulatory approval for UDENYCA™ from the U.S. Food and Drug Administration ("FDA") on November 2, 2018. The Company initiated U.S. sales of UDENYCA™ on January 3, 2019.

**Need to Raise Additional Capital**

As of December 31, 2018, the Company had an accumulated deficit of \$984.8 million and cash and cash equivalents of \$72.4 million. In 2018, the Company issued and sold 1,799,504 shares of common stock at a weighted average price of \$12.14 per share through its ATM Offering Program and received total net proceeds of \$21.0 million after deducting the underwriting discounts and commissions and offering expenses. In May 2018, the Company completed an underwritten public offering of 5,948,274 shares of its common stock at a price to the public of \$14.50 per share, which includes the closing of the full exercise of the underwriters' option to purchase an additional 775,861 shares of common stock. The Company received net proceeds from the offering of \$80.8 million, after deducting the underwriting discounts and commissions and offering expenses (see Note 9). The Company also entered into a credit agreement (the "Credit Agreement") with affiliates of Health Royalty Partners consisting of a six-year term loan facility for an aggregate principal of \$75.0 million in January 2019. The Company believes that its current available cash and cash equivalents, the proceeds from the Credit Agreement of \$73.1 million, net of offering and original issue discount costs, and cash collected from UDENYCA™ sales will be sufficient to fund its planned expenditures and meet the Company's obligations for at least 12 months following its financial statement issuance date. 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. If the Company is unable to obtain adequate financing when needed, it may have to delay, reduce the scope of or suspend one or more of its clinical trials, or research and development programs.

**2. Basis of Presentation and Summary of Significant Accounting Policies****Basis of Consolidation**

The accompanying consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP"). The accompanying consolidated financial statements include the accounts of Coherus and its wholly owned subsidiaries as of December 31, 2018: Coherus Intermediate Corp, InteKrin Therapeutics Inc. ("InteKrin") and InteKrin's subsidiary, InteKrin Russia. In September 2018, InteKrin acquired the remainder of InteKrin Russia's non-controlling interest of 17.5% for \$0.7 million in cash. 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 financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts and disclosures reported in the financial statements. Management uses significant judgment when making estimates related to its stock-based compensation, valuation of deferred tax assets, impairment of goodwill and long-lived assets, the valuation of acquired intangible assets, valuation and reserves for inventory, clinical trial accruals, revenue recognition periods, contingent consideration, convertible notes valuation, as well as certain accrued liabilities. Management bases its estimates on historical experience and on other various assumptions that are believed to be reasonable under the circumstances. These estimates form the basis for making judgments about the carrying values of assets and liabilities when these values are not readily apparent from other sources. Accounting estimates and judgements are inherently uncertain and the actual results could differ from these estimates.

**Foreign Currency**

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

## Notes to Consolidated Financial Statements

For the years ended December 31, 2018, 2017 and 2016, the foreign exchange gains and losses recorded in other income (expense), net in the consolidated statements of operations were a net loss of \$571,000, a net gain of \$52,000 and a net loss of \$53,000, respectively.

### Segment Reporting and Customer Concentration

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

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

	Year Ended December 31,		
	2018	2017	2016
United States	\$ —	\$ —	\$ 188,292
Rest of world	—	1,556	1,814
Total revenue	\$ —	\$ 1,556	\$ 190,106

### Customer Concentration

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

	Year Ended December 31,		
	2018	2017	2016
Baxalta	N/A	N/A	99%
Daiichi Sankyo	N/A	100%	*

\* less than 10%

### Cash and Cash Equivalents

Cash, cash equivalents and restricted cash are comprised of cash and highly liquid investments with remaining maturities of 90 days or less at the date of purchase. The Company limits cash investments to financial institutions with high credit standings; therefore, management believes that there is no significant exposure to any credit risk in the Company's cash, cash equivalents and restricted cash.

The following table provides a reconciliation of cash, cash equivalents and restricted cash within the consolidated balance sheets and which, in aggregate, represent the amount reported in the consolidated statements of cash flows.

	December 31, 2018	December 31, 2017
Cash and cash equivalents	\$ 72,356	\$ 126,911
Restricted cash	50	60
Restricted cash - non-current	785	785
Total cash, cash equivalents and restricted cash	\$ 73,191	\$ 127,756

Restricted cash consists of cash held in money market accounts at banks. The restricted cash is used as collateral against the Company's corporate credit cards and is classified as current; restricted cash non-current is held to cover the standby letter of credit issued by the Company's landlord to drawdown on in the event the facility lease is breached (see Note 8).

### Investments in Marketable Securities

Management determines the appropriate classification of investments in marketable securities at the time of purchase based upon management's intent with regards to such investments and reevaluates such designation as of each balance sheet date. All investments in marketable securities are held as "available-for-sale" and are carried at the estimated fair value as determined based upon quoted market prices or pricing models for similar securities.

## Notes to Consolidated Financial Statements

The Company classifies investments in marketable securities as short-term when they have remaining contractual maturities of one year or less from the balance sheet date. Unrealized gains and losses are excluded from earnings and are reported as a component of accumulated comprehensive income (loss). Realized gains and losses and declines in value judged to be other than temporary, if any, on available-for-sale securities are included in other income (expense), net, based on specific identification method. The Company started investing in marketable securities in 2017. For the years ended December 31, 2018 and 2017, interest income from marketable securities was \$1.4 million and \$0.8 million, respectively.

**Concentration of Credit Risk**

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

The Company entered into a strategic commercial supply agreement with KBI Biopharma ("KBI") for the supply of UDENYCA™. The Company currently has not engaged back-up suppliers or vendors for this single-sourced service. If KBI is not able to manufacture the supply needed in the quantities and timeframe required, the Company may not be able to supply the product in a timely manner.

**Fair Value of Financial Instruments**

Fair value accounting is applied to 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.

**Inventory**

Prior to the regulatory approval of the product candidates, the Company incurred expenses for the manufacture of drug product that could potentially be available to support the commercial launch of its products. The Company began to capitalize inventory costs associated with UDENYCA™ after receiving regulatory approval for UDENYCA™ in November 2018 when it was determined that the inventory had a probable future economic benefit.

Inventory is stated at the lower of cost or estimated net realizable value with cost determined under the first-in first-out method. Inventory costs include third-party contract manufacturing, third-party packaging services, freight, labor costs for personnel involved in the manufacturing process, and indirect overhead costs. The Company primarily uses actual costs to determine the cost basis for inventory. The determination of whether inventory costs will be realizable requires management review of the expiration dates of the Company's product UDENYCA™ compared to its forecasted sales. If actual market conditions are less favorable than projected by management, write-downs of inventory may be required which would be recorded as cost of sales in the consolidated statement of operations.

**Property and Equipment**

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

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

**Impairment of Long Lived Assets and Acquired Intangible Asset**

The Company reviews long-lived assets, including property and equipment, and indefinite-lived intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be fully recoverable. An impairment loss would be recognized when the estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition is less than its carrying amount. Impairment, if any, is measured as the amount by which the carrying value of a long-lived asset exceeds its fair value. For the years ended December 31, 2018, 2017 and 2016, the Company recorded an impairment of property and equipment of \$3.9 million, \$558,000 and \$0, respectively, in research and development within the statement of operations.

## Notes to Consolidated Financial Statements

Acquired in-process research and development (“IPR&D”) represents the fair value assigned to research and development assets that have not reached technological feasibility. The Company reviews amounts capitalized as acquired IPR&D for impairment at least annually, and whenever events or changes in circumstances indicate that the carrying value of the assets might not be recoverable. If the carrying value of the acquired IPR&D exceeds its fair value, then the intangible asset is written-down to its fair value. As of December 31, 2018, there have been no such impairments. Once the product candidate derived from the indefinite-lived intangible asset has been developed and commercialized, the useful life will be determined, and the carrying value of the finite-lived asset will be amortized prospectively over the estimated useful life. Alternatively, if the product candidate is abandoned, the carrying value of the intangible will be charged to research and development expense.

**Goodwill**

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

The Company compares the fair value of its reporting unit to its carrying value. If the carrying value of the net assets assigned to the reporting unit exceeds the fair value of the reporting unit, then the Company would need to determine the implied fair value of the reporting unit’s goodwill. If the carrying value of the reporting unit’s goodwill exceeds its implied fair value, then the Company would record an impairment loss equal to the difference. No goodwill impairment was identified through December 31, 2018.

**Derivative Liability**

The Company has a derivative liability related to the contingent consideration associated with the acquisition of InteKrin in 2014. There were two contingent payments payable upon the achievement of certain events: (i) the completion of the first dosing of a human subject in the first Phase 2 clinical trial for InteKrin, (“Earn-Out Payment”) and (ii) upon the execution of any license, sublicense, development, collaboration, joint venture, partnering or similar agreement between the Company and the third party (“Compound Transaction Payment”). The derivative related to the contingent consideration is accounted for as a liability and remeasured to fair value as of each balance sheet date and the related remeasurement adjustment is recognized as other income (expense), net in the consolidated statements of operations. The Company determined the fair value of the two contingent consideration scenarios (the Earn-Out Payment and the Compound Transaction Payment) using a probability-weighted discounted cash flow approach. A probability-weighted value was determined by summing the probability of achieving a contingent payment threshold by the respective contingent payments. The expected cash flows were discounted at a rate selected to capture the risk of achieving the contingent payment thresholds and earning the contingent payment. This risk is comprised of InteKrin’s continued development, a specific risk factor associated with meeting the contingent consideration threshold and related payout, and counterparty risk associated with the payment of the contingent consideration.

**Accrued Research and Development Expense**

Clinical trial costs are a component of research and development expense. The Company accrues and expenses clinical trial activities performed by third parties based upon actual work completed in accordance with agreements established with clinical research organizations and clinical sites. The Company determines the actual costs through monitoring patient enrollment, discussions with internal personnel and external service providers regarding 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 adopted ASU No. 2014-09, *Revenue from Contracts with Customers* (Topic 606) (ASU 2014-09), ASU No. 2016-08, *Revenue from Contracts with Customers* (Topic 606): *Principal versus Agent Considerations*; ASU No. 2016-10, *Revenue from Contracts with Customers* (Topic 606): *Identifying Performance Obligations and Licensing*; and ASU No. 2016-12, *Revenue from Contracts with Customers* (Topic 606): *Narrow-Scope Improvements and Practical Expedients*, (collectively, the “New Revenue Standard”) on January 1, 2018 using the modified retrospective method.

The Company did not have any sources of revenue or active revenue arrangements upon adoption of the New Revenue Standard, therefore, no adjustment to its retained earnings was required. If, and when, the Company initiates product sales or enters into a new revenue arrangement, the Company will apply the New Revenue Standard accordingly. On September 25, 2018, the Company received regulatory approval for the marketing of UDENYCA™ from the European Commission, and received regulatory approval from the FDA on November 2, 2018. The Company initiated U.S. sales of UDENYCA™ on January 3, 2019, which will be accounted for under Topic 606 *Revenue from Contracts with Customers* in 2019.

## Notes to Consolidated Financial Statements

Prior to the adoption of the New Revenue Standard, the Company recognized revenue in accordance with Accounting Standards Codification (ASC) 605, Revenue Recognition when persuasive evidence of an arrangement existed; transfer of technology had been completed, services had been performed or products had been delivered; the fee was fixed and determinable; and collection was reasonably assured.

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

The Company determined 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 was based on vendor-specific objective evidence, if available, third party evidence if vendor-specific objective evidence was not available or estimated selling price if neither vendor-specific nor third-party evidence was available. Management was required to exercise considerable judgment in determining whether a deliverable was 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 were deferred if facts and circumstances dictated that the license did not have stand-alone value. Such payments were recognized as license revenue over the estimated period of performance, which was generally consistent with the terms of the research and development obligations contained in the specific collaboration and license agreement. The Company regularly reviewed the estimated period of performance based on the progress made under each arrangement. Amounts received as funding of research and development activities were recognized as revenue if the collaboration arrangement involved the sale of the Company's research or development services. However, such funding was recognized as a reduction in research and development expense when the Company engaged 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 were contingent upon the achievement of a substantive milestone were recognized in their entirety in the period in which the milestone was achieved, assuming all other revenue recognition criteria were met. A milestone was defined as an event that could only be achieved based on the Company's performance where there was substantive uncertainty about whether the event would be achieved at the inception of the arrangement. Events that were contingent upon the passage of time or counterparty performance were not considered milestones under accounting guidance. The Company's evaluation included an assessment of whether (a) the consideration was 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 related solely to past performance and (c) the consideration was reasonable relative to all of the deliverables and payment terms within the arrangement. The Company evaluated 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 was reasonable relative to all deliverables and payment terms in the arrangement in making this assessment.

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

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

### Research and Development Expense

Research and development costs are charged to expense as incurred. Research and development expense includes, among other costs, salaries and other personnel-related costs, consultant fees, preclinical costs, cost to manufacture drug candidates, clinical trial costs and supplies, laboratory supply 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. Third-party costs include costs associated with manufacturing drug candidates, preclinical and clinical support activities. In certain cases, amounts received as reimbursement for 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 sharing costs and potential benefits of the arrangement. Costs incurred under arrangements where the Company provides research

## Notes to Consolidated Financial Statements

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 rendered.

The Company considers regulatory approval of product candidates to be uncertain, and product manufactured prior to regulatory approval may not be sold unless regulatory approval is obtained. The Company expenses manufacturing costs as incurred to research and development expense for product candidates prior to regulatory approval. If, and when, regulatory approval of a product is obtained, the Company will begin capitalizing manufacturing costs related to the approved product into inventory.

**Stock-Based Compensation**

The Company measures the cost of equity-based service awards based on the grant-date fair value of the award. The compensation cost is recognized as expense on a straight-line basis over the vesting period for options and restricted stock units (RSUs).

The Company granted performance stock options (“PSO”) to purchase shares of its common stock, which will vest upon the achievement of specified conditions. The Company determined the fair values of these PSOs using the Black-Scholes option pricing model at the date of grant. For the portion of the PSOs for which the performance condition is considered probable, the Company recognizes stock-based compensation expense on the related estimated fair value of such options on a straight-line basis from the date of grant up to the date when it expects the performance condition will be achieved.

The Company adopted the ASU No. 2016-09, *Compensation-Stock Compensation Improvements to Employee Share-Based Payment*, electing to account for forfeitures as they occur as of January 1, 2017.

The Company accounts for equity instruments issued to non-employees 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 ESPP granted. Option valuation models, including the Black-Scholes option-pricing model, require the input of highly subjective assumptions, and changes in the assumptions used can materially affect the grant-date fair value of an award. These assumptions include the risk-free rate of interest, expected dividend yield, expected volatility and the expected life of the award. For RSUs, the Company bases the fair value of awards on the closing market value of the common stock at the date of grant.

**Selling, General and Administrative Expenses**

Selling, general and administrative expenses are primarily comprised of compensation and benefits associated with sales and marketing, finance, human resources, legal, information technology and other administrative personnel, outside marketing, advertising and legal expenses and other general and administrative costs. The Company expenses the cost of advertising, including promotional expenses, as incurred. Advertising expenses were \$2.8 million, \$0, and \$0 for the years ended December 31, 2018, 2017 and 2016, respectively.

**Income Taxes**

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

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

The Company’s policy is to recognize interest and/or penalties related to income tax matters in income tax expense. The Company had accrued no amounts for interest and penalties related to income tax matters in the Company’s consolidated balance sheet at December 31, 2018 and 2017.



## Notes to Consolidated Financial Statements

**Comprehensive Loss**

Comprehensive loss is composed of two components: net loss and other comprehensive loss. Other comprehensive loss refers to gains and losses that under U.S. GAAP are recorded as an element of stockholders' equity, but are excluded from net loss. The Company's other comprehensive loss included unrealized gains and losses from available-for-sale marketable securities and foreign currency translation adjustments for the years ended December 31, 2018, 2017 and 2016.

**Net Loss per Share Attributable to Coherus**

Basic net loss per share attributable to Coherus is calculated by dividing the net loss attributable to Coherus by the weighted-average number of shares of common stock outstanding for the period, without consideration for potential dilutive common shares. Since the Company was in a loss position for all periods presented, basic net loss per share attributable to Coherus is the same as diluted net loss per share attributable to Coherus as the inclusion of all potential dilutive common shares would have been anti-dilutive for all periods presented.

The following outstanding dilutive potential shares have been excluded from the calculation of diluted net loss per share attributable to Coherus due to their anti-dilutive effect:

	Year Ended December 31,		
	2018	2017	2016
Stock options, including purchases from contributions to ESPP	14,743,547	11,433,069	10,150,136
Restricted stock units	44,387	120,377	—
Shares issuable upon conversion of Convertible Notes	4,473,871	4,473,871	4,473,871
Total	<u>19,261,805</u>	<u>16,027,317</u>	<u>14,624,007</u>

In January 2019, the Company's board of directors approved a refresh option grant of 2,556,000 shares at an exercise price of \$12.37 to the employees and directors.

**Recent Accounting Pronouncements**

The following are the recent accounting pronouncements adopted by the Company in 2018:

In January 2016, the FASB issued ASU No. 2016-01, *Recognition and Measurement of Financial Assets and Financial Liabilities* (ASU 2016-01). ASU 2016-01 makes amendments to the classification and measurement of financial instruments and revises the accounting related to: (1) the classification and measurement of investments in equity securities, and (2) the presentation of certain fair value changes for financial liabilities measured at fair value. In addition, the update also amends certain disclosure requirements associated with the fair value of financial instruments. ASU 2016-01 is effective for the Company's interim and annual reporting periods during the year ending December 31, 2018, and all annual and interim reporting periods thereafter. Early adoptions of certain amendments within the update are permitted. The Company adopted ASU 2016-01 on January 1, 2018 and the adoption did not have a material impact on its consolidated financial statements and related disclosures.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows: Classification of Certain Cash Receipts and Cash Payments* (ASU 2016-15). The amendment to this update addresses eight specific cash flow issues with the objective of reducing the existing diversity in practice. ASU 2016-15 is effective for the Company's interim and annual reporting periods during the year ending December 31, 2018, and all annual and interim reporting periods thereafter. Early adoption is permitted. The Company adopted ASU 2016-15 on January 1, 2018 and the adoption did not have a material effect on its consolidated financial statements and related disclosures.

In October 2016, the FASB issued ASU No. 2016-16, *Income Taxes: Intra-Entity Transfers of Assets Other Than Inventory* (ASU 2016-16). This update improves the accounting for the income tax consequences of intra-entity transfers of assets other than inventory. ASU 2016-16 amends the guidance to recognize the income tax consequences of an intra-entity transfer of an asset other than inventory when the transfer occurs. Consequently, the amendments in this update eliminate the exception for an intra-entity transfer of an asset other than inventory. The amendments in this update do not include new disclosure requirements; however, existing disclosure requirements might be applicable when accounting for the current and deferred income taxes for an intra-entity transfer of an asset other than inventory. ASU 2016-16 is effective for the Company's interim and annual reporting periods during the year ending December 31, 2018, and all annual and interim reporting periods thereafter. Early adoption is permitted. The Company adopted ASU 2016-16 on January 1, 2018 and the adoption did not have a material effect on its consolidated financial statements and related disclosures.

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash — a consensus of the FASB Emerging Issues Task Force* (ASU 2016-18). The purpose of ASU 2016-18 is to provide guidance on the presentation of restricted cash or restricted cash equivalents in the statement of cash flows. Specifically, ASU 2016-18 requires companies to include amounts generally

## Notes to Consolidated Financial Statements

described as restricted cash and restricted cash equivalents in cash and cash equivalents when reconciling beginning-of-period and end-of-period total amounts shown on the statement of cash flows. ASU 2016-18 is effective for the Company's interim and annual reporting periods during the year ending December 31, 2018, and all annual and interim periods thereafter. The amendments in ASU 2016-18 should be applied using a retrospective transition method to each period presented. The Company adopted ASU 2016-18 on January 1, 2018 and the adoption did not have a material effect on its consolidated financial statements and related disclosures.

In August 2018, the FASB issued ASU No. 2018-15, *Intangibles – Goodwill and Other – Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract*. (ASU 2018-15). ASU 2018-15 requires a customer in a cloud computing arrangement that is a service contract to follow the internal-use software guidance in Accounting Standards Codification 350-40 to determine which implementation costs to defer and recognize as an asset. ASU 2018-15 is effective for the Company's interim and annual reporting periods during the year ending December 31, 2020, and all annual and interim reporting periods thereafter. Early adoption is permitted. The Company early adopted ASU 2018-15 in the third quarter of 2018 on a prospective basis, and the adoption did not have a material effect on its consolidated financial statements and related disclosures.

The following are the recent accounting pronouncements that the Company has not yet adopted:

In February 2016, the FASB issued ASU No. 2016-02, *Leases* (ASU 2016-02). ASU 2016-02 aims to make leasing activities more transparent and comparable, and requires substantially all leases be recognized by lessees on their balance sheet as a right-of-use asset and corresponding lease liability, including leases currently accounted for as operating leases. ASU 2016-02 is effective for the Company's interim and annual reporting periods during the year ending December 31, 2019, and all annual and interim reporting periods thereafter. Early adoption is permitted. In July 2018, FASB issued additional authoritative guidance, ASU 2018-11, providing companies with an optional prospective transition method. The Company plans to adopt the new standards in the first quarter 2019 using the optional prospective transition method and will recognize a right-of-use asset and lease liability on the adoption date. Based on its lease portfolio as of December 31, 2018, the Company anticipates upon adoption the recognition of lease assets in the range of \$6.7 million to \$7.7 million, and lease liabilities in the range of \$8.7 million to \$9.7 million on its consolidated balance sheet, primarily comprised of facility lease agreements for its corporate headquarters and laboratory facilities in California. The Company does not anticipate any material impact to its consolidated statements of operations. The Company will elect the package of practical expedients upon transition, which allows it to apply the guidance prospectively, without reassessing prior conclusions related to contracts containing leases, lease classification and initial direct costs. The Company will also elect an accounting policy that does not recognize right-of-use assets and lease liabilities related to short-term leases. The Company will not elect to apply the hindsight expedient. The Company is in the process of updating its controls and procedures for maintaining and accounting for its lease portfolio under the new guidance.

In January 2017, the FASB issued ASU No. 2017-04, *Intangibles-Goodwill and Other: Simplifying the Test for Goodwill Impairment* (ASU 2017-04), which simplifies the current requirements for testing goodwill for impairment by eliminating the second step of the two-step impairment test to measure the amount of an impairment loss. ASU 2017-04 is effective for the Company's interim and annual reporting periods during the year ending December 31, 2020, and all annual and interim reporting periods thereafter. Early adoption is permitted. The Company is currently evaluating the impact that the adoption of ASU 2017-04 will have on its consolidated financial statements and related disclosures. The Company has reviewed other recent accounting pronouncements and concluded they are either not applicable to the business or that no material effect is expected on the consolidated financial statements as a result of future adoption.

In June 2018, the FASB issued ASU No. 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting* (ASU 2018-07), which simplifies the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payment to employees, with certain exceptions. The amendments in ASU 2018-07 are effective for the Company's interim and annual reporting periods during the year ending December 31, 2019, and all annual and interim reporting periods thereafter. Early adoption is permitted. The Company does not anticipate that the adoption of this ASU will have a material impact on its consolidated financial statements and related disclosures.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurements* (ASU 2018-13), which eliminates certain disclosure requirements for fair value measurements, and requires public entities to disclose certain new information and modifies some disclosure requirements. The new guidance is effective for the Company's interim and annual reporting periods during the year ending December 31, 2020, and all annual and interim reporting periods thereafter. Early adoption is permitted. The Company is currently evaluating the impact that the adoption of ASU 2018-13 will have on its consolidated financial statements and related disclosures.

In August 2018, the SEC adopted amendments to certain disclosure requirements in Securities Act Release No. 33-10532, *Disclosure Update and Simplification*. These amendments eliminate, modify, or integrate into other SEC requirements certain disclosure rules. Among the amendments is the requirement to present an analysis of changes in stockholders' equity in the interim financial statements included in quarterly reports on Form 10-Q. The analysis, which can be presented as a footnote or separate statement, is required for the current and comparative quarter and year-to-date interim periods. The amendments are effective for all filings made on or after November 5, 2018. In light of the anticipated timing of effectiveness of the amendments and expected proximity of effectiveness to the filing date for most filers' quarterly reports, the SEC's Division of Corporate Finance issued a Compliance and Disclosure Interpretation related to Exchange Act Forms, or CDI – Question 105.09, that provides transition guidance related to this disclosure requirement. CDI – Question 105.09 states that

## Notes to Consolidated Financial Statements

the SEC would not object if the filer's first presentation of the changes in stockholders' equity is included in its Form 10-Q for the quarter that begins after the effective date of the amendments. As such, the Company adopted these SEC amendments on November 5, 2018 and will present the analysis of changes in stockholders' equity in its interim financial statements in its March 31, 2019 Form 10-Q. The Company does not anticipate that the adoption of these SEC amendments will have a material effect on the Company's financial position, results of operations, cash flows or stockholders' equity.

The Company has reviewed other recent accounting pronouncements and concluded they are either not applicable to the business or that 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, restricted cash, investments in marketable securities, accounts receivable, accounts payable and other current liabilities approximate their fair value due to their short maturities. Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The accounting guidance describes a fair value hierarchy based on three levels of inputs that may be used to measure fair value, of which the first two are considered observable and the last is considered unobservable. These levels of inputs are the following:

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

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

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

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

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

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

	Fair Value Measurements December 31, 2018			
	Total	Level 1	Level 2	Level 3
<b>Assets:</b>				
Money market funds	\$ 71,062	\$ 71,062	\$ —	\$ —
Restricted cash (money market funds)	835	835	—	—
Total financial assets	<u>\$ 71,897</u>	<u>\$ 71,897</u>	<u>\$ —</u>	<u>\$ —</u>
<b>Liabilities:</b>				
Contingent consideration	<u>\$ 60</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 60</u>
	Fair Value Measurements December 31, 2017			
	Total	Level 1	Level 2	Level 3
<b>Assets:</b>				
Money market funds	\$ 125,373	\$ 125,373	\$ —	\$ —
Restricted cash (money market funds)	845	845	—	—
Total financial assets	<u>\$ 126,218</u>	<u>\$ 126,218</u>	<u>\$ —</u>	<u>\$ —</u>
<b>Liabilities:</b>				
Contingent consideration	<u>\$ 3,290</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 3,290</u>

There were no transfers between Level 1, Level 2 and Level 3 during the periods presented.

## Notes to Consolidated Financial Statements

**Contingent Consideration**

As part of the InteKrin acquisition in February 2014, the Company recognized contingent consideration associated with potential payments to be made to the former InteKrin stockholders upon the achievement of certain events specified in the agreements. This fair value measurement is based on significant inputs not observable in the market and thus represents a Level 3 measurement within the fair value hierarchy. The InteKrin purchase agreement provides for contingent consideration to be paid upon (i) the first dosing of a human subject in the first Phase 2 Clinical Trial for CHS-131 ("Earn-Out Payment"), which was achieved and settled by the Company in March 2015, and (ii) per a compound transaction agreement as defined in the purchase agreement (the "Compound Transaction Payment"). The size of the Compound Transaction Payment consideration is tiered based on the size of a license or similar agreement with a third party and the timing of such agreement.

The fair value measurement of the Compound Transaction Payment uses a probability-weighted discounted cash flow approach, and the change in the fair value of the contingent consideration liability is recognized in other income (expense), net within the consolidated statement of operations. The Compound Transaction analysis as of December 31, 2018 applied a 25% risk-adjusted discount rate to measure present value and also captured an additional 8.0% credit spread for counterparty credit risk given the cash payment. Additionally, the Company's management estimates the probability of occurrence and the timing to formulate an expected cash flow. During 2018, the fair value of the compound transaction payment decreased as a result of reducing estimates of a payout to former InteKrin stockholders. Generally, increases or decreases in the probability of occurrence would result in a directionally similar impact in the fair value measurement of the Compound Transaction Payment and it is estimated that a 1% increase (decrease) in the probability of occurrence would result in an immaterial fair value fluctuation. For the years ended December 31, 2018, 2017 and 2016, the Company recognized a gain of \$3.2 million, a gain of \$2.3 million and a loss of \$4.3 million in other income (expense), net in the consolidated statement of operations, respectively, as a result of the change in the fair value of the Compound Transaction Payment.

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

Balance as of December 31, 2016	\$ 5,550
Change in fair value of the contingent consideration liability	(2,260)
Balance as of December 31, 2017	\$ 3,290
Change in fair value of the contingent consideration liability	(3,230)
Balance as of December 31, 2018	<u>\$ 60</u>

The decrease of \$3.2 million in the fair value of the Compound Transaction Payment during the year ended December 31, 2018 was primarily a result of a decrease in the probability of occurrence from 33% to 10% and an extension in the timing of occurrence to a later date.

**Convertible Notes**

The estimated fair value of the 8.2% Convertible Senior Notes Due 2022, which the Company issued on February 29, 2016 (see Note 7) is based on an income approach. The estimated fair value was approximately \$91.1 million (par value \$100.0 million) as of December 31, 2018 and represents a Level 3 valuation. When determining the estimated fair value of the Company's long-term debt, the Company uses a single factor binomial lattice model which incorporates the terms and conditions of the convertible notes and market based risk measurement that are indirectly observable, such as credit risk. The lattice model produces an estimated fair value based on changes in the price of the underlying common shares price over successive periods of time. An estimated yield based on market data is used to discount straight debt cash flows.

**4. Inventory**

The Company began capitalizing inventory in November 2018 once the FDA approved UDENYCA™. Inventory consisted of the following (in thousands):

	<b>December 31, 2018</b>
Raw materials	\$ 2,851
Work in process	1,576
Finished goods	1,244
Total	<u>\$ 5,671</u>

Balance sheet classification (in thousands):

## Notes to Consolidated Financial Statements

	December 31, 2018	
Inventory	\$	1,659
Inventory, non-current		4,012
Total	\$	5,671

Inventory expected to be sold in periods more than twelve months from the date presented is classified as inventory, non-current on the balance sheet. As of December 31, 2018, the non-current portion of inventory consisted of raw materials and a portion of work in process.

As of December 31, 2018, prepaid manufacturing on the consolidated balance sheet includes a prepayment of \$6.6 million made to a contract manufacturing organization (“CMO”) for manufacturing services which the Company expects to be converted into inventory within the next twelve months.

## 5. Balance Sheet Components

### Property and Equipment, Net

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

	December 31, 2018	December 31, 2017
Machinery and equipment	\$ 11,505	\$ 15,229
Computer equipment and software	1,651	1,586
Furniture and fixtures	714	714
Leasehold improvements	4,364	4,344
Construction in progress	1,463	702
Total property and equipment	19,697	22,575
Accumulated depreciation and amortization	(13,037)	(9,802)
Property and equipment, net	\$ 6,660	\$ 12,773

Depreciation and amortization expense was \$3.2 million, \$3.4 million and \$3.0 million for the years ended December 31, 2018, 2017 and 2016, respectively. In the third quarter of 2018, the Company identified an impairment indicator in machinery and equipment and upon further analysis recorded an impairment loss of \$3.9 million within research and development expense in the consolidated statement of operations, given the undiscounted future cash flows were less than the carrying amount of the related machinery and equipment. Impairment of property and equipment was \$3.9 million and \$0.6 million for the years ended December 31, 2018 and 2017, respectively.

### Accrued Liabilities

Accrued liabilities are as follows (in thousands):

	December 31, 2018	December 31, 2017
Accrued clinical - related parties (see Note 13)	\$ —	\$ 510
Accrued clinical and manufacturing	3,950	5,462
Accrued other	3,058	1,004
Accrued liabilities	\$ 7,008	\$ 6,976

## Notes to Consolidated Financial Statements

## 6. Collaboration and License Agreement

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

	Year Ended December 31,		
	2018	2017	2016
Baxalta	\$ —	\$ —	\$ 188,292
Daiichi Sankyo	—	1,556	1,184
Total collaboration and license revenue	\$ —	\$ 1,556	\$ 189,476

**Daiichi Sankyo**

In January 2012, the Company entered into a license agreement with Daiichi Sankyo (the “License Agreement”), under which the Company granted certain licenses to Daiichi Sankyo to develop and commercialize biosimilar forms of etanercept and rituximab in Japan, Taiwan, and South Korea with an option to develop in China. Upon execution of the agreement, Daiichi Sankyo paid a non-refundable, upfront license fee of \$10.0 million. The agreement had an initial term of ten years.

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 concluded that the license was not a separate unit of accounting because Daiichi Sankyo could not benefit from the use of the license rights for their intended purpose without the products manufactured by the Company. Daiichi Sankyo relied 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 were accounted for as a single unit of accounting with the upfront fee recognized as revenue on a straight-line basis over its estimated period of performance of approximately three years, which was regularly evaluated for reasonableness and revised as deemed appropriate on a prospective basis. The Company determined that the straight-line method of revenue recognition was most appropriate for this agreement given there is no discernable pattern of its performance under the arrangement.

In January 2014, the Company and Daiichi Sankyo entered into the Memorandum of Understanding No. 2 (the “MOU 2”) in which both parties agreed to cooperate to conduct a global Phase 3 clinical trial in rheumatoid arthritis. In June 2015, the parties also entered into the Memorandum of Understanding No. 3 (the “MOU 3”) in which both parties agreed to cooperate further on a global Phase 3 clinical trial for an open label, safety extension study (“OLSES”) in rheumatoid arthritis. Daiichi Sankyo was responsible for a minimum of 20% of the cost of the clinical trial. The Company also entered into a clinical supply agreement as part of MOU 2 and MOU 3 in which the Company supplied finished study drug and study comparator drug for Daiichi Sankyo’s use in the Japanese portion of the product’s clinical trial. Daiichi Sankyo reimbursed these research and development costs in quarterly advance payments, and the Company recognized these advance payments as a reduction in the research and development expense when the research and development activity was performed.

In July 2016 and December 2016, the Company entered into three memoranda of understanding (“MOU 4,” “MOU 5” and “MOU 6,” and together with MOU 1, MOU 2 and MOU 3, the “MOUs”) with Daiichi Sankyo. Under MOU 4, MOU 5 and MOU 6, the Company received \$4.5 million for reimbursements of certain past costs incurred and the Company recognized these reimbursements as a reduction of research and development expenses when the research and development activity was performed. The Company accounted for the above MOUs as a separate arrangement, which was not deemed to be a material modification of the License Agreement.

In July 2017, Daiichi Sankyo announced its decision, which was accepted by the Company, to discontinue development of the Company’s etanercept (Enbrel) biosimilar product candidate, CHS-0214, in Japan and to conclude the parties’ global open-label safety extension study in rheumatoid arthritis. Pursuant to the License Agreement, the Company regained the rights to develop and commercialize CHS-0214 in Japan. As a result of Daiichi Sankyo’s decision to opt-out of the development of CHS-0214 in Japan and not having any further performance obligations under the license arrangement, the Company recognized the remaining deferred revenue of \$1.4 million as a collaboration and license revenue during the second quarter of 2017 in its consolidated statement of operations. As a result, there was no deferred revenue reflected in the consolidated balance sheets as of December 31, 2018 and 2017.

On August 9, 2017, the Company and Daiichi Sankyo entered into a letter of agreement, dated July 29, 2017 to terminate the License Agreement, including, any and all MOUs and other agreements executed between the parties relating to CHS-0214. As a result, the Company did not recognize any MOU cost reimbursement as a reduction of research and development expense in 2018, and recognized \$4.2 million and \$9.7 million for the years ended December 31, 2017 and 2016, respectively, in its consolidated statements of operations.

## Notes to Consolidated Financial Statements

**Baxalta**

The Company entered into a license agreement in August 2013 and two subsequent amendments thereto with Baxalta Incorporated, Baxalta US Inc., and Baxalta GmbH (collectively “Baxalta”) (then Baxter International, Inc., part of Shire plc as of June 2016), to develop and commercialize an etanercept biosimilar molecule, CHS-0214 worldwide, excluding the U.S., Japan, Taiwan, South Korea, China and most of the Caribbean and South American nations (as amended, the “Baxalta Agreement”).

Under the terms of the agreement, the Company was responsible in conducting the development and the regulatory activities, and Baxalta was responsible in conducting the commercialization of the etanercept biosimilar product. In consideration of the exclusive, royalty-bearing license to develop, commercialize and use the etanercept biosimilar product, the Company received an upfront payment and was eligible to receive contingent payments composed of clinical development payments and regulatory milestone payments. If the cumulative development costs exceed the cumulative contingent payments, Baxalta would reimburse the Company for the excess cost as set forth in the agreement up to predetermined limits. Once the etanercept biosimilar product commercializes, the Company was 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 were subject to certain offsets and reductions. The agreement had an initial term of ten years and contained provisions allowing Baxalta to renew the agreement for another three years on a country-by-country basis.

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

The Company considered the provisions of the multiple-element arrangement guidance in determining how to recognize the total consideration of the agreement. The Company determined that the license did not have standalone value to Baxalta without the Company’s technical expertise as it relates to the development of the product candidate and committee participation. Additionally, the license to Baxalta did 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 and clinical development payments included contingent payments that were intended to cover development related expenses incurred by the Company, but potentially reimbursable, in part, to Baxalta under certain limited circumstances. The Company concluded that the contingent payments that contain potentially reimbursable amounts to Baxalta are not substantive milestones under the relevant accounting guidance, since the guidance does not allow the substantive milestone components of a payment to be bifurcated from non-substantive milestone components. The amounts that were contingent payments also contained a claw-back feature that, in the event that the Company commercializes the etanercept biosimilar molecule in the U.S. without Baxalta, the Company would have been required to refund a portion of those contingent payments to Baxalta. Therefore, the Company recorded the portion of the non-substantive contingent payment that contained the claw-back feature as a liability and would have continued to record such liability until the earlier of: (1) expiration of the license agreement pursuant to its terms in August 2023, (2) the earlier termination of the license agreement, or (3) the determination, pursuant to the terms of the license agreement, of the third party to commercialize CHS-0214 in the U.S. These amounts were included in the contingent liability to collaborator on the consolidated balance sheets. The portion of the non-substantive milestone payment that did not contain the claw-back feature were recorded as deferred revenue and recognized as license revenue on a straight-line basis over the remaining estimated performance period of approximately three years, which was regularly evaluated for reasonableness and revised as deemed appropriate on a prospective basis. The Company determined that there was no other method that was more appropriate than the straight-line method of revenue recognition for this agreement given there was no discernable pattern of performance under the arrangement. The Company regularly evaluated the reasonableness of the estimated period of performance and revised the amortization of deferred revenue on a prospective basis, as such, the performance period were extended in September 2014 for two quarters, December 2014 for one quarter, and September 2015 for two months, prior to the termination of the Baxalta Agreement.

The regulatory milestone payments were considered substantive as the achievement was 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 included efforts associated with the clinical trials and filing and approval of drug applications by regulatory authorities in various countries. Therefore, the Company recognized revenue associated with these respective contingent payments when each of the specific events were achieved.

On September 26, 2016, Shire issued a termination notice of the Baxalta Agreement, in its entirety as part of its strategic portfolio review after its acquisition of Baxalta. Upon the termination of the Baxalta Agreement, the Company regained from Shire all development and commercial rights previously licensed under the CHS-0214. There were no further contractual obligations and the Company recognized the outstanding balances of deferred revenue of \$85.8 million and contingent liability to collaborator of \$76.7 million as revenue in its consolidated statements of operations in 2016.

## Notes to Consolidated Financial Statements

## 7. Debt Obligations

## Convertible Notes

On February 29, 2016, the Company issued and sold \$100.0 million aggregate principal amount of its 8.2% Convertible Senior Notes (the “Convertible Notes”) and received total net proceeds of approximately \$99.2 million, after deducting issuance costs of \$0.8 million. The Convertible Notes constitute general, senior unsubordinated obligations of the Company and are guaranteed by certain subsidiaries of the Company. The Convertible Notes bear interest at a fixed coupon rate of 8.2% per annum payable quarterly in arrears on March 31, June 30, September 30 and December 31 of each year, which commenced on March 31, 2016, and mature on March 31, 2022, unless earlier converted, redeemed or repurchased. If the Company fails to satisfy certain registration or reporting requirements, then additional interest will accrue on the Convertible Notes at a rate of up to 0.50% per annum in the aggregate. The Convertible Notes also bear a premium of 9% of their principal amount, which is payable when the Convertible Notes mature or are repurchased or redeemed by the Company.

The Convertible Notes were issued to Healthcare Royalty Partners III, L.P., for \$75.0 million in aggregate principal amount, and to three related party investors, KKR Biosimilar L.P., MX II Associates LLC, and KMG Capital Partners, LLC, for \$20.0 million, \$4.0 million, and \$1.0 million, respectively, in aggregate principal amount.

The Convertible Notes are convertible at the option of the holder at any time prior to the close of business on the business day immediately preceding March 31, 2022 at the initial conversion rate of 44.7387 shares of common stock per \$1,000 principal amount of Convertible Notes, which is equivalent to an initial conversion price of approximately \$22.35 per share, and is subject to adjustment in certain events. Upon conversion of the Convertible Notes by a holder, the holder will receive shares of the Company’s common stock together, if applicable, with cash in lieu of any fractional share.

The Convertible Notes are redeemable in whole, and not in part, at the Company’s option on or after March 31, 2020, if the last reported sale price per share of common stock exceeds 160% of the conversion price on 20 or more trading days during the 30 consecutive trading days preceding the date on which the Company sends notice of such redemption to the holders of the Convertible Notes. At maturity or redemption, if not earlier converted, the Company will pay 109% of the principal amount of the Convertible Notes maturing or being redeemed, together with accrued and unpaid interest, in cash.

The Convertible Notes contain customary events of default (as defined in the Convertible Note purchase agreement), the occurrence of which could result in the acceleration of all amounts due under the Convertible Notes. These events of default include, among others, certain failures to pay amounts due on the Convertible Notes, to deliver the consideration due upon conversion or to settle uninsured judgments, decrees or orders exceeding \$10.0 million, and certain defaults on other indebtedness for money borrowed of at least \$10.0 million, insolvency-related events and breaches of representations, subject, in some cases, to a cure period. The Convertible Notes also contain covenants restricting the Company’s ability to incur additional indebtedness for borrowed money or convertible preferred stock and to pay dividends or make distributions on the Company’s equity interests, subject to certain exceptions. As of December 31, 2018, the Company was in full compliance with these covenants and there were no events of default under the Convertible Notes.

The Convertible Notes are accounted for in accordance with ASC Subtopic 470-20, *Debt with Conversion and Other Options*. Pursuant to ASC Subtopic 470-20, the Company evaluated the features embedded in the Convertible Notes and concluded that the embedded features are not required to be bifurcated and accounted for separately from the host debt instrument.

The Company granted the holders of the Convertible Notes certain registration rights requiring the Company to register, under the Securities Act of 1933, as amended, the resale of the shares of common stock issuable upon conversion or settlement of the Convertible Notes.

The following table summarizes information about the components of the Convertible Notes as of December 31, 2018 and 2017 (in thousands):

	December 31, 2018	December 31, 2017
Principal amount of the Convertible Notes	\$ 81,750	\$ 81,750
Unamortized debt discount and debt issuance costs	(4,431)	(5,544)
Convertible Notes	\$ 77,319	\$ 76,206
Principal amount of the Convertible Notes - related parties	\$ 27,250	\$ 27,250
Unamortized debt discount and debt issuance costs - related parties	(1,477)	(1,848)
Convertible Notes - related parties	\$ 25,773	\$ 25,402
Total Convertible Notes	\$ 103,092	\$ 101,608



## Notes to Consolidated Financial Statements

If the Convertible Notes were converted on December 31, 2018, the holders of the Convertible Notes would receive common shares with an aggregate value of \$40.5 million based on the Company's closing stock price of \$9.05.

The following table presents the components of interest expense of the Convertible Notes for the year ended December 31, 2018 and 2017 (in thousands):

	Year Ended December 31,		
	2018	2017	2016
Stated coupon interest	\$ 6,150	\$ 6,150	\$ 5,159
Accretion of debt discount and debt issuance costs	1,113	1,014	781
Interest expense	\$ 7,263	\$ 7,164	\$ 5,940
Stated coupon interest - related parties	\$ 2,050	\$ 2,050	\$ 1,720
Accretion of debt discount and debt issuance costs - related parties	371	338	260
Interest expense - related parties	\$ 2,421	\$ 2,388	\$ 1,980
Total interest expense	\$ 9,684	\$ 9,552	\$ 7,920

The remaining unamortized debt discount and debt offering costs related to the Company's Convertible Notes of approximately \$5.9 million as of December 31, 2018, will be amortized using the effective interest rate over the remaining term of the Convertible Notes of 3.25 years. The annual effective interest rate is 9.48% for the Convertible Notes. The Company recognized total interest expense and amortization of the debt discount of \$9.7 million and \$9.6 million related to the Convertible Notes for the years ended December 31, 2018 and 2017, respectively.

Future payments on the Convertible Notes as of December 31, 2018 are as follows (in thousands):

Year ending December 31,	
2019	\$ 8,200
2020	8,200
2021	8,200
2022	111,050
Total minimum payments	135,650
Less amount representing interest	(26,650)
Convertible Notes, principal amount	109,000
Less debt discount and debt issuance costs on Convertible Notes	(5,908)
Net carrying amount of Convertible Notes	\$ 103,092

## 8. Commitments and Contingencies

### Facility Leases

In July 2015, the Company entered into the office lease space for its corporate headquarters in Redwood City, California under operating lease agreement, which has been subject to an amendment to secure additional space such that the total headquarters lease space is approximately 40,341 square feet. The lease agreement, as amended, provided for aggregate tenant improvement allowance of \$1.4 million, which are amortized as a reduction to rent expense on a straight-line basis over the lease term. Additionally, the lease agreement, as amended, provides for certain limited rent abatement and contains annual scheduled rent increases over the lease term. The lease terminates on November 2022 and contains a one-time option to extend the lease term for five years. As part of the lease agreement, the Company obtained a standby letter of credit (the "Letter of Credit") in an amount of approximately \$0.8 million, which may be drawn down by the Landlord to be applied for certain purposes upon the Company's breach of any provisions under of the lease. The Company will be entitled to periodically reduce the amount of the Letter of Credit during the lease term. The Letter of Credit of \$0.8 million is recorded as restricted cash, non-current within the consolidated balance sheet at December 31, 2018 and 2017.

The Company also lease laboratory facilities in Camarillo, California under an operating lease agreement, which has been subject to several amendments necessary to secure additional space and extend the lease term to June 30, 2020, and December 31, 2020 on the two facility structures.

Rent expense is recognized on a straight-line basis over the term of the leases and accordingly, the Company records the difference between cash rent payments and the recognition of rent expense as a deferred rent liability.

## Notes to Consolidated Financial Statements

**Purchase Commitments**

The Company entered into agreements for the manufacturing of commercial supply of UDENYCATM with a CMO. Under the terms of the agreements, the Company is contractually obligated to make certain payments to the CMO.

The Company enters into contracts in the normal course of business with contract research organizations for preclinical studies and clinical trials and CMO for the manufacture of drug materials. The contracts are cancellable, with varying provisions regarding termination. If a contract with a specific vendor were to be terminated, the Company would only be obligated for products or services that the Company had received as of the effective date of the termination and any applicable cancellation fees.

As of December 31, 2018, the future minimum lease payments under the non-cancellable facility leases and non-cancellable purchase commitment were as follows (in thousands):

<b>Year ending December 31,</b>		
2019	\$	6,422
2020		27,070
2021		2,672
2022		2,518
Total minimum lease payments	\$	<u>38,682</u>

Rent expense was \$2.2 million, \$2.3 million and \$1.7 million for the years ended December 31, 2018, 2017 and 2016, respectively.

**Contingencies**

On March 3, 2017, Amgen Inc. and Amgen USA Inc. (collectively "Amgen") filed an action against the Company, KBI Biopharma Inc., the Company's employee Howard S. Weiser and Does 1-20 in the Superior Court of the State of California, County of Ventura. The complaint alleges that the Company engaged in unfair competition and improperly solicited and hired certain former Amgen employees in order to acquire and access trade secrets and other confidential information belonging to Amgen. On June 1, 2017, Amgen filed a Second Amended Complaint, which alleges as to Coherus (i) unfair competition under California Business and Professions Code Section 17200 et seq., (ii) misappropriation of trade secrets, (iii) aiding and abetting breach of duty of loyalty and (iv) tortious interference with contract. As to defendant Weiser, the Second Amended Complaint alleges (i) unfair competition under California Business and Professions Code Section 17200 et seq., (ii) misappropriation of trade secrets, (iii) breach of contract, (iv) violation of Penal Code Section 502 and (v) breach of duty of loyalty. KBI Biopharma Inc. is not named as a defendant in the Second Amended Complaint. The Second Amended Complaint seeks injunctive relief and monetary damages. Although Amgen has indicated it intends to seek a preliminary injunction, no motion has been filed yet. The court has set a trial date of April 22, 2019.

On May 10, 2017, Amgen Inc. and Amgen Manufacturing Inc. filed an action against the Company in the U.S. District Court for the District of Delaware (the "District Court") alleging infringement of one or more claims of Amgen's U.S. patent 8,273,707 (the "'707 patent") under 35 U.S.C. § 271. The complaint seeks injunctive relief, monetary damages and attorney fees. On December 7, 2017, the U.S. Magistrate Judge issued under seal a Report and Recommendation to the District Court recommending that the District Court grant, with prejudice, the Company's pending motion to dismiss Amgen Inc. and Amgen Manufacturing Inc.'s complaint for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6). On March 26, 2018, Judge Stark of the District Court adopted the U.S. Magistrate Judge's Report and Recommendation to grant the motion of the Company pursuant to Federal Rule of Civil Procedure 12(b)(6) to dismiss with prejudice the patent infringement complaint alleging infringement of the '707 patent on the grounds that such complaint failed to state a claim upon which relief may be granted. In May 2018, Amgen filed a Notice of Appeal in the U.S. Court of Appeals for the Federal Circuit. Amgen and Coherus have filed briefs in this matter and decision on the appeal is expected from the Federal Circuit in 2019.

The Company believes that these lawsuits are without merit and intends to vigorously defend its position. However, if Amgen were to be successful in its effort to seek injunctive relief, these legal actions may negatively affect the Company's future revenues and results of operations. It is not possible at this time to determine the likelihood of an unfavorable outcome or an estimate of the amount or range of any potential loss.

**Guarantees and Indemnifications**

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

## 9. Stockholders' Equity

### Common Stock Offerings

In January 2016, the Company's shelf registration statement on Form S-3 (File No. 333-208625) (the "Shelf Registration Statement") was declared effective by the SEC. As of January 18, 2019, the Company's Shelf Registration Statement expired.

On October 28, 2016, the Company entered into a sales agreement (the "Sales Agreement") with Cowen to sell shares of the Company's common stock, with aggregate gross sales proceeds of up to \$100,000,000, from time to time, through an at-the-market equity offering program under which Cowen will act as its sales agent (the "ATM Offering Program"). Cowen is entitled to compensation for its services equal to 3.0% of the gross proceeds of any shares of common stock sold through Cowen under the Sales Agreement. The Company has no obligation to sell any shares under the Sales Agreement, and may at any time suspend solicitation and offers under the Sales Agreement. The shares will be issued pursuant to the Company's Shelf Registration Statement. The Company filed a prospectus supplement, dated October 28, 2016, with the SEC in connection with the offer and sale of the shares pursuant to the Sales Agreement. In January and December 2017, the Company sold 925,999 shares of common stock at a weighted average price of \$12.42 per share through its ATM Offering Program and received total gross proceeds of \$11.5 million. After deducting commission of \$0.3 million and offering expense of \$0.1 million, the net proceeds were \$11.1 million. In 2018, the Company issued and sold 1,799,504 shares of common stock at a weighted average price of \$12.14 per share through its ATM Offering Program and received total gross proceeds of \$21.8 million. After deducting commission of \$0.7 million and offering expense of \$0.1 million, the net proceeds were \$21.0 million. As of December 31, 2018, the Company had \$10.1 million remaining under the ATM Offering Program. In January 2019, the Company issued and sold 761,130 shares of common stock at a weighted average price of \$11.17 per share through its ATM Program and received total net proceeds of \$8.2 million. As of January 18, 2019, the Company's Shelf Registration Statement expired and accordingly the ATM Offering Program was terminated.

In February and March 2017, the Company issued and sold 5,294,902 shares of common stock at a price of \$24.25 per share. The Company received total gross proceeds from the offering of \$128.4 million. After deducting underwriting discounts and commissions of \$7.7 million and offering expense of \$0.3 million, the net proceeds were \$120.4 million.

In August 2017, the Company issued and sold an aggregate of 6,556,116 shares of common stock to V-Sciences Investments Pte Ltd, a private limited Singapore company, ("Temasek") in a private placement transaction at an offering price of \$11.4397 per share for gross proceeds of \$75.0 million. After deducting offering expenses of \$0.1 million, the net proceeds were \$74.9 million. Pursuant to the stock purchase agreement, Temasek may purchase additional shares of common stock equal to gross proceeds of \$75.0 million, subject to certain conditions. On September 22, 2017, the Company filed a registration statement with the SEC registering the resale of the common stock sold and issued in the private placement transaction as of August 2017, and it was declared effective by the SEC on October 16, 2017.

In December 2017, the Company issued an aggregate of 776,104 shares of common stock to KBI Biopharma, Inc., a contract manufacturing organization ("KBI"), in a private placement transaction at an offering price of \$8.7746 per share amounting to \$6.8 million. Pursuant to the purchase agreement, as consideration for the issuance of the shares, the Company will not be charged the (i) \$4.1 million postponement fee, owed by the Company pursuant to the master service agreement for the postponement of the start of the 2017 manufacturing campaign of UDENYCA™, (ii) \$2.7 million campaign reservation fee for the second 2018 manufacturing campaign of UDENYCA™ and (iii) increase of certain batch fees until the 2018 manufacturing campaign of UDENYCA™ begins. The Company provided to KBI the right to receive contingent cash royalty payments, in an amount not to exceed \$0.7 million in aggregate, upon the achievement of certain conditions related to the timing of the delivery by KBI to the Company of UDENYCA™. In 2018, KBI was unsuccessful in meeting these conditions, and therefore, the contingent royalty payments expired.

In May 2018, the Company completed an underwritten public offering of 5,948,274 shares of its common stock at a price to the public of \$14.50 per shares, which includes the closing of the full exercise of the underwriters' option to purchase an additional 775,861 shares of common stock. The Company received total gross proceeds from the offering of \$86.3 million. After deducting underwriting discounts and commissions of \$5.2 million and offering expenses of \$0.3 million, the net proceeds were \$80.8 million.

## 10. Stock Option Plans and Stock-Based Compensation

### Equity Incentive Plans

In October 2014, the Company's board of directors and its stockholders adopted the 2014 Equity Incentive Plan (the "2014 Plan"), which became effective upon the closing of the Company's IPO on November 6, 2014. The 2014 Plan is subject to automatic annual increases in the number of shares available for issuance on the first business day of each fiscal year equal to four percent (4%) of the number of shares of the Company's common stock outstanding as of such date or a lesser number of shares as determined by the Company's board of directors. All remaining shares under the Company's 2010 Stock Plan (the "2010 Plan") were transferred to the 2014 Plan upon adoption and any additional shares than would otherwise return to the 2010 Plan as a result of forfeiture, termination or expiration of the awards will return to the 2014 Plan. The 2014 Plan provided for the Company to grant shares and/or options to purchase shares of common stock to employees, directors, consultants and other service providers. As of December 31, 2018, the Company had 388,873 shares of common stock available for future issuance.

## Notes to Consolidated Financial Statements

In June 2016, the Company adopted the 2016 Employment Commencement Incentive Plan (the “2016 Plan”). The 2016 Plan is designed to comply with the inducement exemption contained in Nasdaq’s Rule 5635(c)(4), which provides for the grant of non-qualified stock options, restricted stock units, restricted stock awards, performance awards, dividend equivalents, deferred stock awards, deferred stock units, stock payment and stock appreciation rights to a person not previously an employee or director of the Company, or following a bona fide period of non-employment, as an inducement material to the individual’s entering into employment with the Company. The Company reserved for future issuance under the 2016 Plan a total of 2,300,000 shares of its common stock for new employees. The 2016 Plan does not provide for any annual increases in the number of shares available. As of December 31, 2018, the Company is authorized to issue 2,300,000 shares of common stock under the 2016 Plan and had 90,750 shares of common stock available for future issuance.

**Stock Options**

Incentive stock options and non-statutory stock options may be granted with exercise prices of not less than the fair value of the common stock on the date of grant. These stock options were granted to generally vest over four years, expire in ten years from the date of grant and are generally exercisable after vesting.

The following table sets forth the summary of option activities under the 2016 and 2014 Plans:

	Options Outstanding	
	Number of Options	Weighted-Average Exercise Price
Balances at December 31, 2017	11,406,219	\$ 15.321
Granted - at fair value	4,963,100	11.971
Exercised	(477,019)	4.513
Forfeited /cancelled	(1,217,747)	19.389
Balances at December 31, 2018	14,674,553	\$ 14.202

Additional information related to the status of options as of December 31, 2018 is summarized as follows:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Contractual Terms (Years)	Aggregate Intrinsic Value (in thousands)
Options outstanding	14,674,553	\$ 14.202	7.23	\$ 22,368
Options vested and expected to vest	14,674,553	\$ 14.202	7.23	\$ 22,368
Options vested and exercisable	8,531,888	\$ 13.969	6.11	\$ 22,365

During the years ended December 31, 2018, 2017 and 2016, the total estimated fair value of the options vested was \$29.9 million, \$29.4 million and \$23.2 million, respectively, the estimated weighted-average grant-date fair value of options granted was \$7.77, \$11.70 and \$13.32 per share, respectively, and the aggregate intrinsic value of options exercised was \$4.9 million, \$2.1 million and \$15.8 million, respectively.

The Company recognized stock-based compensation expenses of \$31.4 million, \$29.0 million and \$23.2 million in 2018, 2017 and 2016, respectively, related to employee stock options. As of December 31, 2018, total unrecognized stock-based compensation expenses related to unvested employee stock options was \$49.7 million, which is expected to be recognized on a straight-line basis over a weighted-average period of approximately 2.6 years.

**Restricted Stock Units**

In August 2017, the Compensation Committee of the Company’s board of directors approved the granting of restricted stock units (“RSUs”) to its employees. RSUs are share awards that entitle the holder to receive freely tradable shares of our common stock upon vesting. The RSUs cannot be transferred and are subject to forfeiture if the holder’s employment terminates prior to the release of the vesting restrictions. The Company’s RSUs generally vest from the applicable grant date according to the following vesting schedules: 50% after twelve months, 25% after 18 months, and 25% after 24 months, provided the employee remains continuously employed with the Company. The fair value of RSUs is equal to the closing price of our common stock on the applicable grant date of the RSUs.

## Notes to Consolidated Financial Statements

The following table sets forth the summary of RSUs activity, under the 2014 Plan:

	RSUs Outstanding	
	Number of RSUs	Weighted-Average Grant Date Fair Value
Balances at December 31, 2017	120,377	\$ 13.975
RSUs granted	5,000	15.600
RSUs vested	(61,804)	18.622
RSUs cancelled	(19,186)	12.700
Balances at December 31, 2018	44,387	\$ 12.700

The total fair value of RSUs vested was \$1.0 million during the year ended December 31, 2018 and \$2.9 million, which included a \$2.7 million bonus payout settled in RSUs, during the year ended December 31, 2017. The total estimated grant date fair value of RSUs was \$78,000 during the year ended December 31, 2018 and \$6.4 million, which included a \$4.3 million bonus payout settled in RSUs during the year ended December 31, 2017. The estimated weighted-average grant-date fair value of RSUs granted was \$15.60 per share and \$10.43 per share during the years ended December 31, 2018 and 2017, respectively.

The Company recognized stock-based compensation expenses related to RSUs of \$0.7 million and \$0.6 million for the year ended December 31, 2018 and 2017, respectively. As of December 31, 2018, total unrecognized stock-based compensation expenses related to unvested RSUs was \$0.3 million, which is expected to be recognized on a straight-line basis over a weighted-average period of approximately 0.6 years.

### Performance Stock Options (“PSOs”)

In April 2018, the Compensation Committee of the Company’s board of directors approved the granting of performance stock option awards to senior officers. PSOs represent a contingent right to purchase the common stock of the Company upon achievement of specified conditions. The PSOs granted will vest upon the achievement of commercial launch and certain sales goals related to UDENYCATM. The Company recognized stock-based compensation expense of \$0.5 million in 2018 related to PSOs.

### Nonemployees Stock-Based Compensation

The Company granted 147,500, 60,000 and 248,650 stock options to purchase shares of common stock to nonemployees during the years ended December 31, 2018, 2017 and 2016, respectively. The weighted-average exercise price of the options granted in 2018, 2017 and 2016 was \$14.32, \$13.47 and \$18.16 per share, respectively. For the years ended December 31, 2018, 2017 and 2016, the Company recorded stock-based compensation expense related to options granted to nonemployees of \$1.6 million, \$1.9 million and \$4.2 million, respectively. The Company remeasures the fair value of the unvested nonemployee options at each period using the Black-Scholes option-pricing model reflecting the same assumptions as applied to employee options in each of the reported years, other than the expected life, which is assumed to be the remaining contractual life of the options.

### Employee Stock Purchase Plan

In October 2014, the Company’s board of directors and its stockholders approved the establishment of the 2014 Employee Stock Purchase Plan (“ESPP”). The ESPP provides for annual increases in the number of shares available for issuance on the first business day of each fiscal year, equal to the lesser of one percent (1%) of the number of shares of the Company’s common stock outstanding as of such date, 320,000 shares of common stock, or a number of shares as determined by the Company’s board of directors. The ESPP had 1,923,506 shares of common stock available for future issuance as of December 31, 2018. Eligible employees may purchase common stock at 85% of the lesser of the fair market value of the Company’s common stock on the first or last day of the offering period. The offering periods of ESPP are on May 16 and November 16. The Company recognized stock-based compensation expenses related to ESPP of \$0.8 million and \$80,000 for the year ended December 31, 2018 and 2017, respectively. As of December 31, 2018, there was \$0.7 million of unrecognized compensation expense associated with the ESPP, which is expected to be recognized over an estimated weighted-average period of five months.

## Notes to Consolidated Financial Statements

## Stock-Based Compensation

The stock-based compensation expense is reflected in the consolidated statements of operations as follows (in thousands):

	Year Ended December 31,		
	2018	2017	2016
Research and development	\$ 15,339	\$ 15,104	\$ 13,592
General and administrative	19,458	18,293	13,829
	<u>\$ 34,797</u>	<u>\$ 33,397</u>	<u>\$ 27,421</u>

Stock-based compensation of \$187,000 was capitalized into inventory for the year ended December 31, 2018. Stock-based compensation capitalized into inventory is recognized as cost of sales when the related product is sold.

The Company has a change of control and involuntary termination benefit agreement in place with the Company's senior executives. The agreement provided for severance terms, acceleration of options and extension of exercise period in the event of a change of control or involuntary termination. For the year ended December 31, 2017, the Company recorded a non-cash stock-based compensation expense for option modifications of \$0.5 million and \$1.3 million, which was reflected in research and development and selling, general and administrative expenses in the consolidated statement of operations, respectively. The stock-based compensation expense for the option modifications were primarily due to the Company's restructuring plan completed in June 2017 (see Note 11).

## Valuation Assumptions of Awards Granted to Employees

The Company estimated the fair value of each stock option and awards granted under the ESPP on the date of grant using the Black-Scholes option-pricing model. The following table illustrates the weighted average assumptions for the Black-Scholes option-pricing model used in determining the fair value of the awards during the years ended December 31, 2018, 2017 and 2016:

	Year Ended December 31,		
	2018	2017	2016
Expected term (years)			
Stock options	6.00	6.00	6.00
ESPP	0.50	0.50	—
Expected volatility			
Stock options	71%	76%	75%
ESPP	71%	68%	—
Risk-free interest rate			
Stock options	2.77%	2.01%	1.42%
ESPP	2.40%	1.42%	—
Expected dividend yield			
Stock options	0%	0%	0%
ESPP	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 and contractual term. The Company elected to use the "simplified method" for estimating the expected term, which is calculated as the mid-point between the vesting period and the contractual term of the options.

*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 sufficient 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.

## Notes to Consolidated Financial Statements

**11. Restructuring**

On June 21, 2017, the Company commenced and completed a restructuring plan to reduce operating costs to better align its workforce with the needs of its business following the FDA's June 2017 issuance of a CRL for its BLA for UDENYCA™, in which the FDA stated that it cannot approve the Company's BLA for UDENYCA™ in its present form and provided recommendations to the Company to address the issues raised in the letter.

In connection with the restructuring, the Company recorded aggregate restructuring charges in its consolidated statement of operations of \$3.6 million in June 2017. The restructuring charges included one-time termination fees and other employee-related costs of \$1.0 million and \$1.1 million in research and development and selling, general and administrative expenses in the consolidated statement of operations, respectively. Additionally, non-cash stock-based compensation expense related to the acceleration of stock options and the extension of post-termination stock option exercise periods of \$0.3 million and \$1.2 million was reflected in research and development and selling, general and administrative expenses in the consolidated statement of operations, respectively. In the first quarter of 2018, the Company fully settled the \$2.1 million of personnel-related restructuring charges, therefore there were no restructuring balances reflected in the Company's balance sheet as of December 31, 2018.

**12. Income Taxes**

The Company utilizes the liability method of accounting for deferred income taxes. Under this method, deferred tax liabilities and assets are recognized for the expected future tax consequences of temporary differences between the carrying amounts and the tax basis of assets and liabilities. A valuation allowance is established against deferred tax assets because, based on the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. The Company's policy is to record interest and penalties on uncertain tax positions as income tax expense.

The components of loss before income taxes are as follows (in thousands):

	Year Ended December 31,		
	2018	2017	2016
Domestic	\$ (208,843)	\$ (222,674)	\$ (95,776)
Foreign	(496)	(15,496)	(31,561)
Total	\$ (209,339)	\$ (238,170)	\$ (127,337)

There was no provision for income taxes for all years presented due to the establishment of a full valuation allowance against the Company's deferred tax assets.

A reconciliation of the statutory U.S. federal rate to the Company's effective tax rate is as follows:

	Year Ended December 31,		
	2018	2017	2016
Percent of pre-tax income:			
U.S. federal statutory income tax rate	21.00%	34.00%	34.00%
State taxes, net of federal benefit	0.16	0.80	1.98
Foreign rate differences	(0.05)	(2.21)	(8.43)
Permanent items	0.15	(0.19)	(2.02)
Research and development credit	2.61	2.10	8.38
Effect in NOLs due to adoption of ASU 2016-09	—	4.55	—
U.S. Tax Reform tax rate change	—	(36.90)	—
Other	2.23	(0.21)	(0.13)
Change in valuation allowance	(26.10)	(1.94)	(33.78)
Effective income tax rate	—%	—%	—%

## Notes to Consolidated Financial Statements

Significant components of the Company's net deferred tax assets as of December 31, 2018 and 2017 consist of the following (in thousands):

	December 31,	
	2018	2017
Net operating loss carryforwards	\$ 168,753	\$ 134,420
Research and development credits	39,891	34,435
Depreciation and amortization	7,901	336
Stock-based compensation	17,123	13,119
Other accruals	3,942	655
Gross deferred tax assets	237,610	182,965
In-process research and development	(552)	(550)
Gross deferred tax liabilities	(552)	(550)
Total net deferred tax asset	237,058	182,415
Less valuation allowance	(237,058)	(182,415)
Net deferred tax assets	\$ —	\$ —

On December 22, 2017, the Tax Cuts and Jobs Act of 2017 (the "Tax Act") was signed into law. The Tax Act contains several key provisions that may have significant financial statement effects including the remeasurement of deferred taxes and the recognition of liabilities for taxes on mandatory repatriation and certain other foreign income. The Tax Act reduces the corporate tax rate from 35% to 21% effective January 1, 2018. Because ASC 740 requires companies to recognize the effect of tax law changes in the period of enactment, the effects must be recognized by companies' December 2017 financial statements, even though the effective date for most provisions of the Tax Act was January 1, 2018. In December 2017, the SEC staff issued Staff Accounting Bulletin No. 118, Income Tax Accounting Implications of the Tax Cuts and Jobs Act (SAB 118) which allows companies to record provisional amounts during a measurement period not to extend beyond one year of the enactment date. Since the Tax Act was passed late in the fourth quarter of 2017, and ongoing guidance and accounting interpretation was yet to be issued, the accounting of the transition tax and deferred tax re-measurements were incomplete as of December 31, 2017. The Company filed its 2017 Federal corporate income tax return in the fourth quarter of 2018. The final analysis and impact of the Tax Act is reflected in the tax provision and related tax disclosures for the year ended December 31, 2018. There was a gross increase of approximately \$2.9 million to the originally estimated \$87.9 million remeasurement of deferred tax assets. The \$2.9 million remeasurement had no impact on the income statement or balance sheet due to the corresponding valuation allowance offsetting deferred taxes.

The valuation allowance increased \$54.6 million, \$4.6 million and \$43.0 million during the years ended December 31, 2018, 2017 and 2016, respectively.

As of December 31, 2018, the Company had federal net operating loss carryforwards of approximately \$783.1 million, which will start to expire beginning in 2031, and various state net operating loss carryforwards of approximately \$49.1 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. Under the new enacted tax law, the carry forward period of net operating losses generated from 2018 forward is indefinite. However, the carryforward period for net operating losses generated prior to 2018 remains the same. Therefore, the annual limitation may result in the expiration of certain net operating losses and tax credit carryforwards before their utilization.

As of December 31, 2018, the Company had federal research and development credit carryforwards of approximately \$44.1 million, which will start to expire in 2031, and state research and development credit carryforwards of approximately \$16.2 million, which can be carried forward indefinitely.

In assessing the realizability of deferred tax assets, the Company considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which the temporary differences representing net future deductible amounts become deductible. Due to the Company's history of losses, and lack of other positive evidence, the Company has determined that it is more likely than not that its net deferred tax assets will not be realized, and therefore, the net deferred tax assets are fully offset by a valuation allowance at December 31, 2018 and 2017. The deferred tax assets were primarily comprised of federal and state tax net operating losses and tax credit carryforwards. Utilization of the net operating loss and tax credit carryforwards may be subject to an annual limitation due to historical or future ownership percentage change rules provided by the Internal Revenue Code of 1986, as amended, and similar state provisions. The annual limitation may result in the expiration of certain net operating loss and tax credit carryforwards before their utilization.



## Notes to Consolidated Financial Statements

The Company files U.S, California and other state income tax returns with varying statutes of limitations. The tax years from 2011 forward remain open to examination due to the carryover of unused net operating losses and tax credits.

A reconciliation of the Company's unrecognized tax benefits for the years ended December 31, 2018, 2017 and 2016 is as follows (in thousands):

	Year Ended December 31,		
	2018	2017	2016
Balance at beginning of year	\$ 15,682	\$ 18,682	\$ 10,605
Additions based on tax positions related to current year	1,276	3,387	6,111
Additions for tax positions of prior years	1,157	(6,387)	1,966
Balance at end of year	\$ 18,115	\$ 15,682	\$ 18,682

As of December 31, 2018, 2017 and 2016, the Company had approximately \$18.1 million, \$15.7 million, and \$18.7 million, respectively, of unrecognized benefits, none of which would currently affect the Company's effective tax rate if recognized due to the Company's deferred tax assets being fully offset by a valuation allowance. The Company does not believe there will be any material changes in its unrecognized tax positions over the next twelve months. During the years ended December 31, 2018, 2017 and 2016, the Company did not recognize accrued interest and penalties related to unrecognized tax benefits. The Company does not anticipate a material adjustment of unrecognized tax benefits during the next 12 months as reductions for tax positions of prior years.

### 13. Related Party Transactions

#### Transactions Associated with Medpace Agreement

A prior member of the Company's board of directors is also the president and chief executive officer of Medpace Inc. ("Medpace"). As such, Medpace was deemed to be a related party until the director's resignation on March 1, 2018. As a result, the Company no longer reflects balances and transactions associated with Medpace as related party in its consolidated financial statements as of March 1, 2018. As of December 31, 2017, the Company had \$0.9 million in prepaid assets (prepaid clinical and other-related parties), \$0.2 million in accounts payable-related parties, and \$0.5 million in accrued and other liabilities (accrued clinical-related parties), all reflected on the Company's consolidated balance sheet associated with Medpace. The Company recognized \$1.5 million, \$8.2 million and \$34.6 million during years ended December 31, 2018, 2017 and 2016, respectively, for services rendered by Medpace within research and development expense in the consolidated statements of operations.

#### Recruiting Services

One member of the Company's board of directors is a partner of a firm that provides recruiting services to the Company. As such, the recruiting services provided were deemed to be related party transactions. As of December 31, 2018 and 2017, there were no such related party balances in the Company's consolidated balance sheets. The Company recorded in research and development expense in its consolidated statements of operations, \$130,000, \$17,000 and \$135,000 for the years ended December 31, 2018, 2017 and 2016, respectively, for services rendered by the recruiting company. The Company recorded in selling, general and administrative expense in its consolidated statements of operations, \$181,000, \$62,000 and \$178,000 for the year ended December 31, 2018, 2017 and 2016, respectively, for services rendered by the recruiting company.

#### Convertible Notes — Related Parties

In February 2016, the Company issued Convertible Notes to certain related parties (some companies affiliated with members of the Company's board of directors), for an aggregate principal amount of \$25.0 million (see Note 7 for related party disclosure).

#### InteKrin Acquisition

In February 2014, the Company completed the acquisition of the InteKrin for total consideration of \$5.0 million. Mr. Dennis M. Lanfear, the chief executive officer of the Company, was the chairman of the board and acting president of InteKrin at the time of the acquisition. As such, the InteKrin acquisition was a related party transaction. Mr. Lanfear also owned 10% of the outstanding securities of InteKrin Russia, a majority owned subsidiary of InteKrin.

In September 2018, InteKrin acquired the outstanding 17.5% of securities of InteKrin Russia held by its non-controlling owners for \$0.7 million. As a result of this purchase of the non-controlling ownership in InteKrin Russia, Mr. Lanfear, who was one of the non-controlling stockholders of InteKrin Russia, received \$0.4 million in consideration for his shares.

## 14. Subsequent Events

### Term Loan

On January 7, 2019 (the “Credit Agreement Closing Date”), the Company entered into a credit agreement (the “Credit Agreement”) with affiliates of Healthcare Royalty Partners (together, the “Lenders”). The Credit Agreement consists of a six-year term loan facility for an aggregate principal amount of \$75.0 million (the “Borrowings”). The obligations of the Company under the loan documents are guaranteed by the Company’s material domestic U.S. subsidiaries (the “Guarantors”).

The Borrowings under the Credit Agreement bear interest through maturity at 7.00% per annum plus LIBOR (customarily defined). If the consolidated net sales (customarily defined) for UDENYCA™, the Company’s pegfilgrastim (Neulasta®) biosimilar, for the fiscal year ending December 31, 2019, are in excess of \$250.0 million, then the interest rate will be reduced as of January 1, 2020 to 6.75% per annum plus LIBOR. Interest is payable quarterly in arrears.

Principal payments on the Borrowings are required to be paid in equal quarterly installments beginning on the four year anniversary of the Credit Agreement Closing Date (or, if consolidated net sales of UDENYCA™ in the fiscal year ending December 31, 2021 are less than \$375.0 million, beginning on the three year anniversary of the Credit Agreement Closing Date), with the outstanding balance to be repaid on January 7, 2025 (the “Maturity Date”).

The Company is also required to make mandatory prepayments of the Borrowings under the Credit Agreement, subject to specified exceptions, with the proceeds of asset sales, extraordinary receipts, debt issuances and specified other events including the occurrence of a change in control.

If all or any of the Borrowings are prepaid or required to be prepaid under the Credit Agreement, then the Company shall pay, in addition to such prepayment, a prepayment premium (the “Prepayment Premium”) equal to (i) with respect to any prepayment paid or required to be paid on or prior to the three year anniversary of the Credit Agreement Closing Date, 5.00% of the Borrowings prepaid or required to be prepaid, plus all required interest payments that would have been due on the Borrowings prepaid or required to be prepaid through and including the three year anniversary of the Credit Agreement Closing Date, (ii) with respect to any prepayment paid or required to be paid after the three year anniversary of the Credit Agreement Closing Date but on or prior to the four year anniversary of the Credit Agreement Closing Date, 5.00% of the Borrowings prepaid or required to be prepaid, (iii) with respect to any prepayment paid or required to be paid after the four year anniversary of the Credit Agreement Closing Date but on or prior to the five year anniversary of the Credit Agreement Closing Date, 2.50% of the Borrowings prepaid or required to be prepaid, and (iv) with respect to any prepayment paid or required to be prepaid thereafter, 1.25% of the Borrowings prepaid or required to be prepaid.

In connection with the Credit Agreement, the Company paid a fee to the Lenders of \$1.1 million at closing in the form of an original issue discount. Upon the prepayment or repayment of the Borrowings (or upon the date such prepayment or repayment is required to be paid), the Company is required to pay an additional exit fee in an amount equal to 4.00% of the total principal amount of the Borrowings.

The obligations under the Credit Agreement are secured by a lien on substantially all of the Company’s and the Guarantors’ tangible and intangible property, including intellectual property. The Credit Agreement contains certain affirmative covenants, negative covenants and events of default, including, covenants and restrictions that among other things, restrict the ability of the Company and its subsidiaries to, incur liens, incur additional indebtedness, make loans and investments, engage in mergers and acquisitions, in asset sales, and declare dividends or redeem or repurchase capital stock. Additionally, the consolidated net sales for UDENYCA™ must not be lower than \$70.0 million for the fiscal year ending December 31, 2019, (b) \$125.0 million for the fiscal year ending December 31, 2020, and (c) \$150.0 million for each fiscal year thereafter. A failure to comply with these covenants could permit the Lenders under the Credit Agreement to declare the Borrowings, together with accrued interest and fees, to be immediately due and payable.

## Notes to Consolidated Financial Statements

## 15. Supplementary Data – Quarterly Financial Data (Unaudited)

The following table presents certain unaudited consolidated quarterly financial information for each of the quarters ended December 31, 2018 and 2017:

<i>(in thousands, except per share data)</i>	2018 Quarter End			
	March 31	June 30	September 30	December 31
Total revenue	\$ —	\$ —	\$ —	\$ —
Total operating expenses	42,032	44,910	56,972	60,502
Net loss	(44,302)	(43,685)	(58,826)	(62,596)
Net loss attributable to Coherus	(44,297)	(43,638)	(58,808)	(62,596)
Net loss per share attributable to Coherus, basic and diluted	(0.74)	(0.68)	(0.87)	(0.92)

	2017 Quarter End			
	March 31	June 30	September 30	December 31
Total revenue	\$ 161	\$ 1,395	\$ —	\$ —
Total operating expenses	72,578	58,033	56,615	46,466
Net loss	(74,822)	(55,402)	(58,993)	(49,069)
Net loss attributable to Coherus	(74,778)	(55,336)	(58,989)	(49,067)
Net loss per share attributable to Coherus, basic and diluted	(1.54)	(1.08)	(1.09)	(0.84)

**Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure**

None

**Item 9A. Controls and Procedures**

**(a) Evaluation of Effectiveness of Disclosure Controls and Procedures**

We carried out an evaluation, under the supervision of our Chief Executive Officer and our Chief Financial Officer, and evaluated the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of the end of the period covered by this Annual Report on Form 10-K. Based on that evaluation, our President and Chief Executive Officer and our Chief Financial Officer have concluded that, as of the end of the period covered by this Annual Report on Form 10-K, our disclosure controls and procedures were, in design and operation, effective.

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and that such information is accumulated and communicated to our management, including our chief executive officer, principal financial officer and principal accounting officer, as appropriate, to allow for timely decisions regarding required disclosure.

We intend to review and evaluate the design and effectiveness of our disclosure controls and procedures on an ongoing basis and to correct any material deficiencies that we may discover. Our goal is to ensure that our management has timely access to material information that could affect our business. While we believe the present design of our disclosure controls and procedures is effective to achieve our goal, future events affecting our business may cause us to modify our disclosure controls and procedures. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

**(b) Management's Annual Report on Internal Control Over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f). Under the supervision and with the participation of our management, including our principal executive officer, principal financial officer and principal accounting officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 Framework). Based on our evaluation under the framework in *Internal Control—Integrated Framework*, our management concluded that our internal control over financial reporting was effective as of December 31, 2018. Ernst & Young LLP, our independent registered public accounting firm, has attested to and issued a report on the effectiveness of our internal control over financial reporting, which is included herein.

## Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Coherus BioSciences, Inc.

### Opinion on Internal Control over Financial Reporting

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

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of Coherus BioSciences, Inc. as of December 31, 2018 and 2017, and the related consolidated statements of operations, comprehensive loss, stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2018, and the related notes and our report dated February 28, 2019 expressed an unqualified opinion thereon.

### Basis for Opinion

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

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

### Definition and Limitations of Internal Control Over Financial Reporting

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

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

/s/ Ernst & Young LLP

Redwood City, California  
February 28, 2019

**Changes in Internal Control Over Financial Reporting.**

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended December 31, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Item 9B. *Other Information***

Not applicable.

### PART III

Certain information required by Part III is omitted from this Annual Report on Form 10-K because the Company will file a Definitive Proxy Statement with the Securities and Exchange Commission within 120 days after the end of our year ended December 31, 2018.

**Item 10. *Directors, Executive Officers and Corporate Governance***

The information required by this item is incorporated herein by reference to the Proxy Statement.

**Item 11. *Executive Compensation***

The information required by this item is incorporated herein by reference to the Proxy Statement.

**Item 12. *Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters***

The information required by this item is incorporated herein by reference to the Proxy Statement.

**Item 13. *Certain Relationships and Related Transactions, and Director Independence***

The information required by this item is incorporated herein by reference to the Proxy Statement.

**Item 14. *Principal Accounting Fees and Services***

The information required by this item is incorporated herein by reference to the Proxy Statement.

**PART IV**

**Item 15. *Exhibits and Financial Statement Schedules***

- (a) (1) The financial statements required by Item 15(a) are filed in Item 8 of this Annual Report on Form 10-K.
- (2) The financial statement schedules required by Item 15(a) are omitted because they are not applicable, not required or the required information is included in the financial statements or notes thereto as filed in Item 8 of this Annual Report on Form 10-K.
- (3) We have filed, or incorporated into this report by reference, the exhibits listed on the accompanying Index to Exhibits immediately preceding the signature page of this Annual Report on Form 10-K.



None.

**INDEX TO EXHIBITS**

<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Incorporated by Reference</u>		
		<u>Form</u>	<u>Date</u>	<u>Number</u>
3.1	<a href="#">Amended and Restated Certificate of Incorporation.</a>	8-K	11/13/2014	3.1
3.2	<a href="#">Amended and Restated Bylaws.</a>	8-K	11/13/2014	3.2
4.1	Reference is made to exhibits <a href="#">3.1</a> and <a href="#">3.2</a> .			
4.2	<a href="#">Registration Rights Agreement, dated as of September 10, 2015, by and between Baxalta GmbH and Coherus BioSciences, Inc.</a>	8-K	9/14/2015	4.1
4.3	<a href="#">Form of Common Stock Certificate.</a>	S-1/A	10/24/2014	4.2
4.4	<a href="#">Third Amended and Restated Investor Rights Agreement, dated as of May 9, 2014 by and among Coherus BioSciences, Inc. and certain investors named therein.</a>	S-1	9/25/2014	4.3
4.5	<a href="#">Registration Rights Agreement, dated as of August 21, 2017, by and between V-Sciences Investments Pte Ltd and Coherus BioSciences, Inc.</a>	8K	8/22/2017	4.1
4.6	<a href="#">Registration Rights Agreement, dated as of November 30, 2017, by and between KBI Biopharma, Inc. and Coherus BioSciences, Inc.</a>	8K	12/5/2017	4.1
10.1†	<a href="#">License Agreement, effective January 23, 2012, by and between Daiichi Sankyo Company, Limited and BioGenerics, Inc.</a>	S-1/A	10/20/2014	10.1
10.2†	<a href="#">Distribution Agreement, effective December 26, 2012, by and between Orox Pharmaceuticals B.V. and Coherus BioSciences, Inc.</a>	S-1	9/25/2014	10.3
10.3†	<a href="#">Commercial License Agreement, effective April 8, 2011, by and between Selexis SA and BioGenerics, Inc.</a>	S-1	9/25/2014	10.5
10.4†	<a href="#">Commercial License Agreement, effective June 25, 2012, by and between Selexis SA and Coherus BioSciences, Inc.</a>	S-1	9/25/2014	10.6
10.5	<a href="#">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.</a>	S-1	9/25/2014	10.7
10.6(a)	<a href="#">Standard Industrial/Commercial Multi-tenant Lease-Gross, effective December 5, 2011, by and between Howard California Property Camarillo 5 and BioGenerics, Inc.</a>	S-1	9/25/2014	10.9(a)
10.6(b)	<a href="#">First Amendment to Lease, effective December 21, 2013, by and between Howard California Property Camarillo 5 and Coherus BioSciences, Inc.</a>	S-1	9/25/2014	10.9(b)
10.7(a)#	<a href="#">BioGenerics, Inc. 2010 Equity Incentive Plan, as amended.</a>	S-1	9/25/2014	10.10(a)
10.7(b)#	<a href="#">Form of Stock Option Grant Notice and Stock Option Agreement under the 2010 Equity Incentive Plan, as amended.</a>	S-1	9/25/2014	10.10(b)
10.8(a)#	<a href="#">Coherus BioSciences, Inc. 2014 Equity Incentive Award Plan.</a>	S-1/A	10/24/2014	10.11
10.8(b)#	<a href="#">Form of Stock Option Grant Notice and Stock Option Agreement under the 2014 Equity Incentive Award Plan.</a>	S-1/A	11/4/2014	10.11(b)
10.8(c)#	<a href="#">Form of Restricted Stock Award Grant Notice and Restricted Stock Award Agreement under the 2014 Equity Incentive Award Plan.</a>	S-1/A	11/4/2014	10.11(c)
10.8(d)#	<a href="#">Form of Restricted Stock Unit Award Grant Notice and Restricted Stock Unit Award Agreement under the 2014 Equity Incentive Award Plan.</a>	S-1/A	11/4/2014	10.11(d)
10.9#	<a href="#">Coherus BioSciences, Inc. 2014 Employee Stock Purchase Plan.</a>	S-1/A	10/24/2014	10.12

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
10.10#	<a href="#">Form of Indemnification Agreement between Coherus BioSciences, Inc. and each of its directors, officers and certain employees.</a>	S-1/A	10/24/2014	10.13	
10.11†	<a href="#">Master Services Agreement, effective January 23, 2012, by and between Medpace, Inc. and BioGenerics, Inc.</a>	S-1	9/25/2014	10.15	
10.12(a)†	<a href="#">Task Order Number 13, effective October 18, 2013, by and between Medpace, Inc. and Coherus BioSciences, Inc.</a>	S-1	9/25/2014	10.16(a)	
10.12(b)†	<a href="#">Amendment Number 1 to Task Order Number 13, effective April 23, 2014, by and between Medpace, Inc. and Coherus BioSciences, Inc.</a>	S-1	9/25/2014	10.16(b)	
10.12(c)†	<a href="#">Amendment Number 2 to Task Order Number 13, effective May 21, 2014, by and between Medpace, Inc. and Coherus BioSciences, Inc.</a>	S-1	9/25/2014	10.16(c)	
10.12(d)†	<a href="#">Amendment Number 3 to Task Order Number 13, effective May 30, 2014, by and between Medpace, Inc. and Coherus BioSciences, Inc.</a>	S-1	9/25/2014	10.16(d)	
10.12(e)†	<a href="#">Amendment Number 4 to Task Order Number 13, effective August 19, 2014, by and between Medpace, Inc. and Coherus BioSciences, Inc.</a>	S-1	9/25/2014	10.16(e)	
10.13(a)†	<a href="#">Task Order Number 20, effective November 8, 2013, by and between Medpace, Inc. and Coherus BioSciences, Inc.</a>	S-1/A	10/24/2014	10.17(a)	
10.13(b)†	<a href="#">Amendment Number 1 to Task Order Number 20, effective April 23, 2014, by and between Medpace, Inc. and Coherus BioSciences, Inc.</a>	S-1/A	10/24/2014	10.17(b)	
10.13(c)†	<a href="#">Amendment Number 2 to Task Order Number 20, effective June 27, 2014, by and between Medpace, Inc. and Coherus BioSciences, Inc.</a>	S-1/A	10/24/2014	10.17(c)	
10.13(d)†	<a href="#">Amendment Number 3 to Task Order Number 20, effective September 5, 2014, by and between Medpace, Inc. and Coherus BioSciences, Inc.</a>	S-1/A	10/24/2014	10.17(d)	
10.14(a)†	<a href="#">Master Services Agreement, effective February 27, 2015, by and between a contract research organization and Coherus BioSciences, Inc.</a>	10-Q	5/11/2015	10.2(a)	
10.14(b)†	<a href="#">Work Order #1, effective March 31, 2015, by and between a contract research organization and Coherus BioSciences, Inc.</a>	10-Q	5/11/2015	10.2(b)	
10.15	<a href="#">Task Order Number 23, effective November 12, 2014, by and between Medpace, Inc. and Coherus BioSciences, Inc.</a>	10-Q	8/10/2015	10.1	
10.16	<a href="#">New Office Lease, effective July 6, 2015, by and between Hudson 333 Twin Dolphin Plaza, LLC and Coherus BioSciences, Inc.</a>	10-Q	8/10/2015	10.3	
10.17	<a href="#">First Amendment, effective August 10, 2015, by and between Hudson 333 Twin Dolphin Plaza, LLC and Coherus BioSciences, Inc.</a>	10-Q	8/10/2015	10.4	
10.18	<a href="#">Convertible Note Purchase Agreement, dated as of February 29, 2016, among Coherus Biosciences, Inc., as Issuer, HealthCare Royalty Partners III, L.P., MX II Associates LLC, KMG Capital Partners, LLC and KKR Biosimilar L.P., each as an Investor, and the Guarantors party thereto (including the form of Note attached thereto as Exhibit A).</a>	8-K	2/29/2016	10.1	
10.19	<a href="#">Amendment to Convertible Note Purchase Agreement, dated as of March 25, 2016, among Coherus Biosciences, Inc., the Guarantors party thereto and HealthCare Royalty Partners III, L.P.</a>	10-Q	5/9/2016	10.2	
10.20(a)	<a href="#">Coherus BioSciences, Inc. 2016 Employment Commencement Incentive Plan.</a>	10-Q	8/9/2016	10.1(a)	
10.20(b)	<a href="#">Form of Stock Option Grant Notice and Stock Option Agreement under the Coherus BioSciences, Inc. 2016 Employment Commencement Incentive Plan.</a>	10-Q	8/9/2016	10.1(b)	

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
10.20(c)	<a href="#">Form of Restricted Stock Unit Award Grant Notice and Restricted Stock Unit Award Agreement under the Coherus BioSciences, Inc. 2016 Employment Commencement Incentive Plan.</a>	10-Q	8/9/2016	10.1(c)	
10.20(d)	<a href="#">Form of Restricted Stock Award Grant Notice and Restricted Stock Award Agreement under the Coherus BioSciences, Inc. 2016 Employment Commencement Incentive Plan.</a>	10-Q	8/9/2016	10.1(d)	
10.21	<a href="#">Second Amendment, dated September 21, 2016, by and between Hudson 333 Twin Dolphin Plaza, LLC and Coherus BioSciences, Inc.</a>	8-K	9/26/2016	10.1	
10.22	<a href="#">Stock Purchase Agreement, dated as of August 21, 2017, by and between Coherus BioSciences, Inc. and V-Sciences Investments Pte Ltd.</a>	8-K	8/22/2017	10.1	
10.23	<a href="#">Stock Purchase Agreement, dated as of November 30, 2017, by and between Coherus BioSciences, Inc. and KBI Biopharma, Inc.</a>	8-K	12/5/2017	10.1	
10.24	<a href="#">Letter Agreement to Master Service Agreement, dated as of September 6, 2017, by and between Medpace, Inc. and Coherus BioSciences, Inc.</a>	10Q	11/06/2017	10.2	
10.25	<a href="#">Credit Agreement, dated as of January 7, 2019, by and between Coherus Biosciences, Inc. and affiliates of Healthcare Royalty Partners</a>	8-K	1/11/2019	10.1	
23.1	<a href="#">Consent of Independent Registered Public Accounting Firm</a>				X
24.1	<a href="#">Power of Attorney (included in the signature page to this Form 10-K)</a>				X
31.1	<a href="#">Certification of Principal Executive Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.</a>				X
31.2	<a href="#">Certification of Principal Financial Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.</a>				X
32.1	<a href="#">Certification of Principal Executive Officer and Principal Financial Officer Required Under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. §1350.</a>				X
101.INS*	XBRL Instance Document				X
101.SCH*	XBRL Taxonomy Extension Schema Document				X
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document				X
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document				X
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document				X
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document				X

† Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment and this exhibit has been filed separately with the SEC.

# Indicates management contract or compensatory plan.

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

COHERUS BIOSCIENCES, INC.

Date: February 28, 2019

By: /s/ Dennis M. Lanfear  
Name: Dennis M. Lanfear  
Title: President and Chief Executive Officer  
(Principal Executive Officer)

## POWER OF ATTORNEY

KNOW ALL MEN AND WOMEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Dennis M. Lanfear and Jean-Frédéric Viret, his attorneys-in-fact, for him or her in any and all capacities, to sign any amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the U.S. Securities and Exchange Commission, hereby ratifying and confirming all that said attorney-in-fact, or his substitute, may do or cause to be done by virtue thereof.

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

<u>/s/ Dennis M. Lanfear</u> Dennis M. Lanfear	Chairman, President and Chief Executive Officer <i>(Principal Executive Officer)</i>	February 28, 2019
<u>/s/ Jean-Frédéric Viret, Ph.D.</u> Jean-Frédéric Viret, Ph.D.	Chief Financial Officer <i>(Principal Financial and Accounting Officer)</i>	February 28, 2019
<u>/s/ James I. Healy, M.D., Ph.D.</u> James I. Healy, M.D., Ph.D.	Director	February 28, 2019
<u>/s/ V. Bryan Lawlis, Ph.D.</u> V. Bryan Lawlis, Ph.D.	Director	February 28, 2019
<u>/s/ Samuel R. Nussbaum</u> Samuel R. Nussbaum, M.D.	Director	February 28, 2019
<u>/s/ Christos Richards</u> Christos Richards	Director	February 28, 2019
<u>/s/ Ali J. Satvat</u> Ali J. Satvat	Director	February 28, 2019
<u>/s/ Mats Wahlström</u> Mats Wahlström	Director	February 28, 2019
<u>/s/ Mary T. Szela</u> Mary T. Szela	Director	February 28, 2019

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We consent to the incorporation by reference in the Registration Statements (Form S-3 No. 333-220590); (Form S-3 No. 333-222698); of Coherus BioSciences, Inc.; Registration Statements (Form S-8 Nos. 333-200593, 333-203356, 333-209936, 333-216679, and 333-222700, and 333-229480 ) pertaining to the BioGenerics, Inc. 2010 Equity Incentive Plan, as amended, the Coherus BioSciences, Inc. 2014 Equity Incentive Award Plan, and the Coherus BioSciences, Inc. 2014 Employee Stock Purchase Plan; Registration Statement (Form S-8 No. 333-213077, and 333-225616, 333-228274, 333-229479) pertaining to the 2016 Employment Commencement Incentive Plan; of Coherus BioSciences, Inc. of our reports dated February 28, 2019, with respect to the consolidated financial statements of Coherus BioSciences, Inc., and the effectiveness of internal control over financial reporting of Coherus BioSciences, Inc., included in this Annual Report (Form 10-K) for the year ended December 31, 2018.

/s/ Ernst & Young LLP

Redwood City, California  
February 28, 2019

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER  
PURSUANT TO  
SECTION 13(a) OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
AS ADOPTED PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Dennis M. Lanfear, certify that:

1. I have reviewed this Annual Report on Form 10-K of Coherus BioSciences, Inc. (the "registrant");
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 28, 2019

/s/ Dennis M. Lanfear

Dennis M. Lanfear

President and Chief Executive Officer



**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER  
PURSUANT TO  
SECTION 13(a) OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
AS ADOPTED PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Jean-Frédéric Viret, certify that:

1. I have reviewed this Annual Report on Form 10-K of Coherus BioSciences, Inc. (the "registrant");
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 28, 2019

/s/ Jean-Frédéric Viret  
Jean-Frédéric Viret, Ph.D.  
Chief Financial Officer

**CERTIFICATIONS OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER  
PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officers of Coherus BioSciences, Inc. (the “Registrant”) certify that the Registrant’s Annual Report on Form 10-K for the year ended December 31, 2018 (the “Report”) fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended, and the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

Date: February 28, 2019

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

Date: February 28, 2019

By: /s/ Jean-Frédéric Viret  
Name: Jean-Frédéric Viret  
Title: Chief Financial Officer

*A signed original of this written statement required by Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350 has been provided to the Registrant and will be retained by the Registrant and furnished to the Securities and Exchange Commission or its staff upon request.*

*This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.*