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, 2019

OR

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

For the transition period from _____ to _____
Commission File Number: 001-36721

Coherus BioSciences, Inc.
(Exact name of registrant as specified in its charter)

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

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	CHRS	The Nasdaq Global Market

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 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, 2019 (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 $1.4 billion. For purposes of this disclosure, shares of common stock held by each officer and director have been excluded in that such persons may be deemed to be "affiliates" as that term is defined under the Rules and Regulations of the Securities Exchange Act of 1934. This determination of affiliate status is not necessarily conclusive.

The number of shares of registrant's common stock issued and outstanding as of January 31, 2020 was 70,624,365.

DOCUMENTS INCORPORATED BY REFERENCE

Part III incorporates by reference certain information from the registrant's definitive proxy statement for the 2020 Annual Meeting of Stockholders.

COHERUS BIOSCIENCES, INC.
ANNUAL REPORT ON FORM 10-K
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This Annual Report on Form 10-K contains forward-looking statements regarding future events and our future results that are subject to the safe harbors created under the Securities Act of 1933, as amended (the "Securities Act"), and the Securities Exchange Act of 1934, as amended (the "Exchange Act"). 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 variations of such words and similar expressions, are intended to identify such forward-looking statements. In addition, any statements other than statements of historical fact are forward-looking statements, including statements regarding overall trends, operating cost and revenue trends, liquidity and capital needs and other statements of expectations, beliefs, future plans and strategies, anticipated events or trends and similar expressions.*

We have based these *forward-looking statements on our current expectations about future events. These statements are not guarantees of future performance and involve risks, uncertainties and assumptions that are difficult to predict. Our actual results may differ materially from those suggested by these forward-looking statements for various reasons, including those identified in Part I, Item 1A of this Annual Report on Form 10-K under the heading "Risk Factors." Given these risks and uncertainties, you are cautioned not to place undue reliance on forward-looking statements. The forward-looking statements included in this report are made only as of the date hereof. Except as required under federal securities laws and the rules and regulations of the Securities and Exchange Commission ("SEC"), we do not undertake, and specifically decline, any obligation to update any of these statements or to publicly announce the results of any revisions to any forward-looking statements after the distribution of this report, whether as a result of new information, future events, changes in assumptions or otherwise.*

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

PART I

Item 1. *Business*

Overview

We are a 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.

Oncology Biosimilars

UDENYCA®

UDENYCA® (pegfilgrastim-cbqv) is a biosimilar to Neulasta®. In October 2016, we filed a marketing authorization application ("MAA") with the European Medicines Agency ("EMA") for UDENYCA® (formerly CHS-1701), which was approved by the European Commission ("EC") in September 2018. In the United States, the U.S. Food and Drug Administration ("FDA") approved the biologics license application ("BLA") for UDENYCA® in November 2018. We initiated U.S. sales of UDENYCA® in January 2019.

Bevacizumab (Avastin®) Biosimilar and Option to License Rituximab (Rituxan®) Biosimilar

On January 13, 2020, we entered into a license agreement with Innovent Biologics (Suzhou) Co., Ltd. ("Innovent", and with respect to the license agreement with Innovent, the "Innovent Agreement") for the development and commercialization of a biosimilar version of bevacizumab (Avastin®) in any dosage form and presentations ("bevacizumab Licensed Product") in the United States and Canada (the "Territory"). Under the Innovent Agreement, Innovent granted us an exclusive, royalty-bearing license to develop and commercialize the bevacizumab Licensed Product in the field of treatment, prevention or amelioration of any human diseases and conditions as included in the label of Avastin®. We also acquired an option for twelve months to develop and commercialize Innovent's biosimilar version of rituximab (Rituxan®) in any dosage form and presentations (the "rituximab Licensed Product" and together with the bevacizumab Licensed Product, the "Licensed Products") in the Territory.

We anticipate performing a three-way pharmacokinetic ("PK") study using Avastin drug articles from the U.S., China and Innovent's biosimilar to bevacizumab, as well additional analytical similarity exercises prior to submitting a BLA for a biosimilar product candidate, or a 351(k) BLA, with the FDA in late 2020 or early 2021.

Ophthalmology Biosimilars

Ranibizumab (Lucentis®) Biosimilar

On November 4, 2019, we entered into a license agreement with Bioeq IP AG (now Bioeq AG or "Bioeq", and with respect to the license agreement, the "Bioeq Agreement") for the commercialization of a biosimilar version of ranibizumab (Lucentis) in certain dosage forms in both a vial and pre-filled syringe presentation (the "Bioeq Licensed Products"). Under this agreement, Bioeq granted to us an exclusive, royalty-bearing license to commercialize the Bioeq Licensed Products in the field of ophthalmology (and any other approved labelled indication) in the United States.

The Bioeq ranibizumab biosimilar candidate demonstrated similar binding and bioactivity as Lucentis® (ranibizumab) and met its primary endpoint in a wet age-related macular degeneration ("wet AMD") Phase 3 study. At the request of a national European health authority addressed to Bioeq's drug substance contract manufacturer, the manufacturer moved a piece of processing equipment to a different location within the same site after the production of the Bioeq ranibizumab biosimilar candidate qualification batches was completed. The FDA has requested additional manufacturing data for the equipment in its new location in the context of its review of the 351(k) BLA. We believe that it will take approximately four months to generate this additional data to comply with the FDA's request. As a result, Bioeq has decided to withdraw its 351(k) BLA for this candidate, provide the requested data and resubmit the application thereafter. We anticipate that such withdrawal and resubmission may delay the potential approval of a BLA for the Bioeq ranibizumab biosimilar candidate.

We believe the Bioeq Agreement will help us avoid the time and cost to develop our own ranibizumab (Lucentis) biosimilar (formerly CHS-3351), and will allow us to leverage the commercial infrastructure and relationships deployed for UDENYCA® and establish a new commercial therapeutic franchise with CHS-2020, thereby diversifying our sources of revenue.

Aflibercept (Eylea®) Biosimilar

CHS-2020, our aflibercept (Eylea) biosimilar candidate, is in preclinical development. We have evaluated the amino acid sequence of CHS-2020 and observed that it was identical to the protein in the reference product, Eylea. We completed certain preclinical activities for CHS-2020, such as process development and biosimilarity exercises and initiated the manufacturing scale-up to produce drug substance and drug product for clinical trial supply. We anticipate initiating a Phase 3 study for CHS-2020 in 2021, and if this study meets its primary endpoint and the FDA approves CHS-2020, we project a U.S. commercial launch of CHS-2020 in 2025.

Inflammation Biosimilars

Adalimumab (Humira®) Biosimilar

Our first inflammation biosimilar product candidate, CHS-1420, is an adalimumab (Humira) biosimilar candidate. We completed a Phase 3 clinical 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.

We anticipate submitting a 351(k) BLA for CHS-1420 in 2020. If approved, we anticipate we would be able to launch CHS-1420 in the United States on or after July 1, 2023, in accordance with settlement and license agreements with AbbVie Inc. ("AbbVie") that grants us global, non-exclusive license rights under AbbVie's intellectual property to commercialize CHS-1420.

Etanercept (Enbrel®) Biosimilar

Our second inflammation biosimilar product candidate, CHS-0214, is an etanercept (Enbrel) biosimilar candidate. We completed two Phase 3 clinical studies with CHS-0214 in rheumatoid arthritis and psoriasis, which met their primary clinical endpoints in November 2015 and January 2016, respectively.

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 United States prior to their expiration.

Market Opportunity for Biosimilars

According to Evaluate Pharma, total U.S. annual revenues from our six late stage biosimilar candidates (pegfilgrastim, bevacizumab, rituximab, ranibizumab, aflibercept and adalimumab) are expected to reach approximately $32.0 billion in 2019. We intend to pursue a branded biosimilar strategy to address this potential commercial opportunity, emphasizing a high level of similarity of our biosimilar products to the originators, while offering significantly more value to the U.S. 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. Second, regulatory agencies around the world have responded to these upcoming patent expirations by establishing biosimilar approval pathways. We believe regulatory agencies 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 U.S., the largest market for biologics, 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 address successfully the complexities underlying these challenges. We have also assembled a distinguished scientific advisory board of leading scientists who are acknowledged experts in their respective fields. With the approval and successful commercial launch of UDENYCA®, we believe

we have demonstrated our core capabilities and expertise in product development in the United States and EU, and commercialization in the United States.

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"), based in Boulder, Colorado, for long-term commercial manufacturing of UDENYCA®. 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. We also seek to become a partner of choice to maximize the U.S. commercial biosimilar opportunity, as exemplified by our recent licensing agreements with Bioeq and Innovent.

Oncology Franchise Opportunity

The total 2019 U.S. sales for pegfilgrastim, bevacizumab and rituximab products altogether reached an estimated to reach $10.8 billion according to Evaluate Pharma.

UDENYCA® (pegfilgrastim-cbqv)

UDENYCA® (pegfilgrastim-cbqv) is a biosimilar to Neulasta®, a long-acting granulocyte stimulating colony factor. The production of granulocytes (a type of white blood cell, which includes leukocytes) promotes the body's ability to fight infections. UDENYCA® is a leukocyte growth factor indicated 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.

We initiated U.S. sales of UDENYCA® in January 2019. According to Evaluate Pharma, the 2019 U.S. sales for all pegfilgrastim products represent an estimated $3.2 billion. As of December 31, 2019, IQVIA estimates that UDENYCA® unit market share of all pegfilgrastim units sold is 20.5% based on collected end demand sales information.

Innovent's Bevacizumab (Avastin) Biosimilar Opportunity

Avastin is a recombinant humanized monoclonal antibody that selectively binds circulating VEGF, thereby inhibiting the binding of VEGF to its cell surface receptors. This inhibition leads to a reduction in microvascular growth of tumor blood vessels and thus limits the blood supply to various types of tumor tissues. Avastin was first approved in 2004 by the FDA for combination use with standard chemotherapy for metastatic colon cancer for the treatment of metastatic colorectal cancer, non-small cell lung cancer, metastatic kidney cancer, advanced cervical cancer, platinum-resistant ovarian cancer, and recurrent glioblastoma.

Evaluate Pharma estimated that the 2019 U.S. sales for Avastin in 2019 were $3.2 billion. In January 2020, we acquired the right to commercialize Innovent's Avastin biosimilar candidate in the U.S. and Canada.

Innovent's Rituximab (Rituxan) Biosimilar Opportunity – Option to License

Rituxan is a chimeric (human-mouse) monoclonal antibody against the protein CD20, which is primarily found on the surface of immune system B cells. Rituxan triggers cell death by binding to CD20. The FDA approved Rituxan to treat certain blood cancers, such as non-Hodgkin's lymphoma and chronic lymphocytic leukemia, and to treat rheumatoid arthritis, as well as certain other illnesses mediated by B cells.

Evaluate Pharma estimated that the 2019 U.S. sales for Rituxan in 2019 were approximately $4.4 billion. In January 2020, as part of the Innovent Agreement, we have the option to license the commercial rights to Innovent's Rituxan biosimilar candidate in the U.S. and Canada.

Ophthalmology Franchise Opportunity

Both Lucentis and Eylea are approved for indications such as wet AMD, macular edema following retinal vein occlusion, and diabetic retinopathy. In 2019, Lucentis and Eylea represented an estimated $6.4 billion U.S. market opportunity according to Evaluate Pharma.

Bioeq's 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 blocks angiogenesis by inhibiting vascular endothelial growth factor A.

According to Evaluate Pharma, Lucentis achieved approximately $1.8 billion in U.S. sales in 2019. In November 2019, we in-licensed U.S. commercial rights to Bioeq's ranibizumab (Lucentis) biosimilar.

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. Similarly to Avastin, Eylea blocks angiogenesis by inhibiting VEGF.

According to Evaluate Pharma, Eylea achieved approximately $4.6 billion in U.S. sales in 2019.

Inflammation Product Opportunity

Both biosimilar candidates, CHS-1420 (adalimumab (Humira) biosimilar) and CHS-0214 (etanercept (Enbrel) biosimilar) bind to tumor necrosis factor ("TNF"), which 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.

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

Humira, which is the reference product for CHS-1420, is a monoclonal antibody that can bind to 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.

Evaluate Pharma estimated that 2019 U.S. sales of Humira reached approximately $14.8 billion in 2019. Our settlement and license agreements with AbbVie grant us global, non-exclusive worldwide rights under AbbVie's intellectual property to manufacture and commercialize CHS-1420 starting on July 1, 2023. We believe that a targeted commercial strategy against certain anti-TNF segments may enable us to achieve topline sales between $500 million to $1.0 billion for CHS-1420 in the United States, if approved.

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

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-α" and "TNF-ß," respectively), and inhibits TNF-α and TNF-ß from binding to cell surface proteins that recognize them.

Evaluate Pharma estimates that 2019 U.S. sales of Enbrel will reach approximately $5.0 billion. We developed CHS-0214 for the U.S., Europe and Japan. Our plans are to commercialize all of our biosimilars in the United States. 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. We do not plan to continue to advance the development of CHS-0214 unless the 2028 and 2029 U.S. patents are invalidated.

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 ("PPARγ") which is part of a family of nuclear receptors that are expressed in a broad range of tissues and regulate multiple metabolic processes. PPARγ 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 PPARγ drives adiponectin expression and insulin sensitization, addressing a core issue that underpins the NASH disease process. PPARγ 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, completed in September 2009, 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.

During 2019, we conducted a Phase 1 pharmacokinetic and safety clinical trial for CHS-131 in high body-mass index, but otherwise healthy volunteers.

Sales and Marketing

Our strategy is to retain or acquire commercial rights to biosimilar products in the United States.

The sales call points to oncologists in the United States are highly concentrated and addressable by our relatively small commercial organization. Similarly, for our ophthalmology franchise products, we anticipate that the number of accounts to drive 90% of sales volume is approximately four- to five-fold smaller than that for the oncology support of care market. As a result, we anticipate a relatively small incremental investment in additional sales force will be needed to address the ophthalmology marketplace. For a discussion of risks related to sales and marketing, please see "Risk Factors—Risks Related to Launch and Commercialization of UDENYCA® and our Other Product Candidates."

Manufacturing

We have entered into agreements with several contract manufacturing organizations ("CMOs") for the manufacture and clinical drug supply of our commercial and products candidates. We continue to screen other contract manufacturers to meet our clinical, commercial and regulatory supply requirements on a product-by-product basis. For a discussion of risks related to our sources and availability of supplies, please see "Risk Factors—Risks Related to Our Ability to Hire and Retain Highly Qualified Personnel and Risks Related to Manufacturing and Supply Chain."

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® (pegfilgrastim-cbqv) faces competition from Amgen (which holds rights to Neulasta), and Mylan N.V. ("Mylan")(Fulphila® (pegfilgrastim-jmdb)), Sandoz International GmbH ("Sandoz") (Ziextenzo (pegfilgrastim-bmez)), and may face competition from Pfizer Inc. ("Pfizer"), Amneal Pharmaceuticals, Inc. ("Amneal", through a partnership with Kashiv BioSciences, Inc.) and Fresenius Kabi AG ("Fresenius").

Innovent's bevacizumab (Avastin) may face competition in the U.S. from Genentech, Inc. ("Genentech", the holder of rights to Avastin), as well as Amgen (Mvasi™ (bevacizumab-awwb)) and Pfizer (Zirabev™ (bevacizumab-bvzr)) as well as Merck, Inc. ("Merck", in partnership with Samsung Bioepis), AstraZeneca PLC ("AstraZeneca", in joint venture with Fujifilm Kyowa Kirin Biologics Co. Ltd. "Fujifilm") and Amneal (with partner mAbxience).

Bioeq's ranibizumab (Lucentis) biosimilar candidate may face competition from Genentech (the holder of rights to Lucentis), as well as Samsung Bioepis with U.S. commercialization partner Biogen, Inc.), and Xbrane Biopharma AB (in collaboration with STADA Arzneimittel AG), companies that have each disclosed development plans for a Lucentis biosimilar candidate.

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

CHS-1420, our adalimumab (Humira) biosimilar candidate, may face competition in the U.S. from AbbVie (the holder of rights to Humira), Amgen (Amjevita™ (adalimumab-atto)), Sandoz (Hyrimoz™ (adalimumab-adaz)), Samsung Bioepis Co Ltd. ("Samsung Bioepis") (Hadlima™ (adalimumab-bwwb)), Pfizer (Abrilada™ (adalimumab-afzd)), Boehringer Ingelheim GmbH ("Boehringer Ingelheim") (Cyltezo™ (adalimumab-adbm)) as well as Fujifilm and Fresenius, companies that have each disclosed development plans for a Humira biosimilar candidate.

CHS-0214, our etanercept (Enbrel) biosimilar candidate, may face competition in the U.S. from Amgen (the holder of rights to Enbrel), Sandoz (Erelzi™ (etanercept-szzs)) and Samsung Bioepis (Eticovo™ (etanercept-ykro)).

We expect any products that we develop and commercialize directly or with partners to compete on the basis of, among other things, price and the availability of reimbursement from government and other third-party payers. 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. For a discussion of risks related to our competition, please see "Risk Factors — Risks Related to Competitive Activity."

Collaboration and License Agreements

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 our internally developed biosimilars. Under this agreement, we granted to Orox an exclusive license to commercialize UDENYCA® in Latin America, except Brazil and Argentina, and CHS-1420, CHS-0214, CHS-2020 in Latin America, except Brazil. 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 July 1, 2023.

Settlement and License Agreements with Pfizer, Inc.

In October 2019, we entered into a license and settlement agreement with Pfizer relating to Coherus' patents and applications for patents directed to Humira® (adalimumab) formulations.

License Agreement with Bioeq AG

On November 4, 2019, we entered into a license agreement with Bioeq for the commercialization of a biosimilar version of ranibizumab (Lucentis) in certain dosage forms in both a vial and pre-filled syringe presentation (the "Bioeq Licensed Products"). Under this agreement, Bioeq granted to us an exclusive, royalty-bearing license to commercialize the Bioeq Licensed Products in the field of ophthalmology (and any other approved labelled indication) in the United States. Bioeq will supply to us the Bioeq Licensed Products in accordance with terms and conditions specified in the agreement and a manufacturing and supply agreement to be executed by the parties in accordance therewith.

Under the Bioeq Agreement, Bioeq must use commercially reasonable efforts to develop and obtain regulatory approval of the Bioeq Licensed Products in the United States in accordance with a development and manufacturing plan, and we must use commercially reasonable efforts to commercialize the Bioeq Licensed Products in accordance with a commercialization plan. Additionally, we must commit certain pre-launch and post-launch resources to the commercialization of the Bioeq Licensed Products for a limited time as specified in the agreement. The development, manufacturing, and commercialization of the Bioeq Licensed Products in the United States is governed by a governance committee as described in more detail in the agreement.

We paid Bioeq an upfront payment of €5.0 million and a milestone payment of €5.0 million. Additionally, we are obligated to pay Bioeq in the future an aggregate of up to €25.0 million in milestone payments in connection with the achievement of certain development and regulatory milestones with respect to the Bioeq Licensed Products in the United States. We will share a percentage of gross profits on sales of Bioeq Licensed Products in the United States with Bioeq in the low to mid fifty percent range.

The Bioeq Agreement's initial term continues in effect for ten years after the first commercial sale of a Bioeq Licensed Product in the United States, and thereafter renews for an unlimited period of time unless otherwise terminated in accordance with its

terms. Either party may terminate the Bioeq Agreement for the other party's material breach which is not cured within a specified time period or for the other party's bankruptcy or insolvency-related events. Bioeq may terminate the Bioeq Agreement in certain limited circumstances for failure to obtain specified minimum market share requirements during certain windows of time, if we conduct certain commercial or advanced pre-commercial activities with respect to certain competitive products, if we challenge the validity or enforceability of the patent rights licensed to us under the Bioeq Agreement, or if we undergo a change of control with a competitor of Bioeq and do not divest certain competitive products in connection therewith. We may terminate the Bioeq Agreement for convenience with 18 months advance written notice (provided that such termination shall not become effective prior to 12 months after the first commercial sale of the first Bioeq Licensed Product in the United States). We may also terminate the Bioeq Agreement in certain circumstances of delays, or anticipated delays, in the achievement of regulatory approval of the first Bioeq Licensed Product in the United States, or if Bioeq receives certain adverse regulatory feedback from the FDA for the Bioeq Licensed Products.

The Bioeq ranibizumab biosimilar candidate demonstrated similar binding and bioactivity as ranibizumab (Lucentis) and met its primary endpoint in a wet AMD Phase 3 study. At the request of a national European health authority addressed to Bioeq's drug substance contract manufacturer, the manufacturer moved a piece of processing equipment to a different location within the same site after the production of the Bioeq ranibizumab biosimilar candidate qualification batches was completed. The FDA has requested additional manufacturing data for the equipment in its new location in the context of its review of the 351(k) BLA. We believe that it will take approximately four months to generate this additional data to comply with the FDA's request. As a result, Bioeq has decided to withdraw its 351(k) BLA for this candidate, provide the requested data and resubmit the application thereafter. We anticipate that such withdrawal and resubmission may delay the potential approval of a 351(k) BLA for the Bioeq ranibizumab biosimilar candidate.

License Agreement with Innovent Biologics (Suzhou) Co., Ltd.

On January 13, 2020, we entered into a license agreement with Innovent for the development and commercialization of a biosimilar version of bevacizumab (Avastin®) in any dosage form and presentations (the "bevacizumab Licensed Product") in the United States and Canada (the "Territory"). Under the Innovent Agreement, Innovent granted us an exclusive, royalty-bearing license to develop and commercialize the bevacizumab Licensed Product in the field of treatment, prevention or amelioration of any human diseases and conditions as included in the label of Avastin®. We also acquired an option for twelve months to develop and commercialize Innovent's biosimilar version of rituximab (Rituxan®) in any dosage form and presentations (the "rituximab Licensed Product" and together with the bevacizumab Licensed Product, the "Innovent Licensed Products") in the Territory. Subject to the terms of the Innovent Agreement, we may exercise our option within 12 months of receiving certain regulatory materials from Innovent. Following our option exercise, Innovent's biosimilar version of rituximab would be deemed an Innovent Licensed Product and Innovent would grant us an exclusive, royalty-bearing license to develop and commercialize Innovent's biosimilar version of rituximab in the field of treatment, prevention or amelioration of any human diseases and conditions as included in the label of Rituxan®.

Innovent will supply the Innovent Licensed Products to us in accordance with a manufacturing and supply agreement to be executed by the parties. Under the Innovent Agreement, we acquired the right to require Innovent to perform technology transfer for the manufacturing of the Innovent Licensed Products in the Territory and, upon completion of such technology transfer, we will have the exclusive right to manufacture the Innovent Licensed Products in the Territory.

We paid Innovent an upfront payment of $5.0 million. Additionally, we are obligated to pay Innovent an aggregate of up to $40.0 million in milestone payments in connection with the achievement of certain development, regulatory and sales milestones with respect to the bevacizumab Licensed Product and, if we exercise our option to license Innovent's rituximab biosimilar, an aggregate of up to $40.0 million in milestone payments in connection with the achievement of certain development, regulatory and sales milestones with respect to the rituximab Licensed Product. We will share a percentage of net sales of Innovent Licensed Products with Innovent in the mid-teens to low twenty percent range. If we exercise our option, we would be required to pay an option exercise fee of $5.0 million. Subject to the terms of the Innovent Agreement, if we request Innovent to perform technology transfer for the manufacturing of the Innovent Licensed Products, we would be required to pay up to $10.0 million for fees related thereto.

For the bevacizumab Licensed Product, the initial term continues in effect for ten years after the effective date of the Innovent Agreement, and thereafter renews for successive two-year periods upon mutual agreement by the parties, unless otherwise terminated in accordance with its terms. For the rituximab Licensed Product, the initial term would continue in effect for ten years after the effective date of the option effective date and thereafter would renew for successive two-year periods upon mutual agreement by the parties, unless otherwise terminated in accordance with its terms. Either party may terminate the Innovent

Agreement for the other party's material breach that is not cured within a specified time period or for the other party's bankruptcy or insolvency-related events. Innovent may terminate the Innovent Agreement if we undergo a change of control with a competitor of Innovent and does not assign the Innovent Agreement to a third party within a certain period of time. On an Innovent Licensed Product-by-Licensed Product basis, we may terminate the Innovent Agreement based on certain market conditions beginning 12 months after the first commercial sale of such Innovent Licensed Product with 18 months advance written notice. Also on an Innovent Licensed Product-by-Licensed Product basis, we may terminate the Innovent Agreement in certain circumstances of delays, or anticipated delays, in the achievement of regulatory approval of such Innovent Licensed Product in the United States, if we receive certain adverse regulatory feedback from the FDA for such Innovent Licensed Product, or if we receive written FDA meeting minutes indicating that the FDA recommends an additional Phase 3 clinical trial efficacy comparability study to support the regulatory approval of such Innovent Licensed Product in the United States. The bevacizumab Licensed Product demonstrated PK bioequivalence and showed equivalent clinical efficacy to Avastin® (bevacizumab) in a non-small cell lung carcinoma Phase 3 study.

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 25 patent families related to our biosimilar product candidates, including CHS-1420, CHS-0214 and CHS-2020. Each patent family 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, methods of manufacturing biological proteins, 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 and some include foreign counterparts to certain of the U.S. patents. The licensed patent portfolio includes issued claims directed to PPAR-γ 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 23 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, nonalcoholic steatohepatitis, 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 a Hatch-Waxman patent term extension of CHS-131 related patents. A Hatch-Waxman patent term extension can only be applied to a patent that is not expired at the time of FDA approval. Additionally, 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."

Government Regulation

Our operations and activities are subject to extensive regulation by numerous government authorities in the U.S., the European Union and other countries, including laws and regulations governing the testing, manufacture, safety, efficacy, labeling, storage, record keeping, approval, advertising and promotion of our products. As a result of these regulations, product development and product approval processes are very expensive and time consuming. The regulatory requirements applicable to drug development and approval are subject to change. Any legal and regulatory changes may impact our operations in the future. A country's regulatory agency, such as the FDA in the United States and the EMA or the European Commission for the European Union, must approve a drug before it can be sold in the respective country or countries. The general process for biosimilar approval in the United States is summarized below. Many other countries, including countries in the European Union, have similar regulatory structures.

FDA Approval Process for Drugs and Biologics

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 a pending BLAs or New Drug Applications ("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 PHSA 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 cGCP. 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 PHSA 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, 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 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, a person or entity does not need to have actual knowledge of the statutes or specific intent to violate it in order to have committed a violation. 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. 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 federal False Claims Act. 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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the "ACA"), among other things, imposed 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 significant civil monetary penalties for any payments, transfers of value or ownership or investment interests that are not timely, accurately and completely reported in an annual submission, and additional penalties for "knowing failures." 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. By way of example, the California Consumer Privacy Act, or the CCPA, effective January 1, 2020, gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability.

Some states also 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. A violation of any of such laws or any other applicable governmental regulations may result in 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 the government requires a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and/or imprisonment.

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, the ACA was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers in the United States, and significantly affected the pharmaceutical industry. The ACA contained a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement adjustments and fraud and abuse changes. Additionally, the ACA subjected biologic products to potential competition by lower-cost biosimilars; increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1%; imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell "branded prescription drugs" to specified federal government programs; and addressed 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 ACA. 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 ACA, 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." On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court's decision that the individual mandate was unconstitutional but remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. It is unclear how these decisions, subsequent appeals, if any, or any other efforts to challenge, repeal or replace the ACA will impact the law.

Other legislative changes have been proposed and adopted since the ACA 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.

Environment

We are subject to a number of laws and regulations that require compliance with federal, state, and local regulations for the protection of the environment. The regulatory landscape continues to evolve, and we anticipate additional regulations in the near future. Laws and regulations are implemented and under consideration to mitigate the effects of climate change mainly caused by

greenhouse gas emissions. Our business is not energy intensive. Therefore, we do not anticipate being subject to a cap and trade system or other mitigation measure that would materially impact our capital expenditures, operations or competitive position.

Employees

As of December 31, 2019, we had 291 employees. We believe we have good relations with our employees.

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. 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 a limited operating history in an emerging regulatory environment on which to assess our business and we have incurred significant losses since our inception.

We are a biopharmaceutical company with a limited operating history in an emerging regulatory environment. We have incurred net losses in each year since our inception in September 2010, including net losses of $209.4 million and $238.3 million for the years ended December 31, 2018 and 2017, respectively. However, for the year ended December 31, 2019, we had net income of $89.8 million. As of December 31, 2019, we had an accumulated deficit of $895.0 million. The losses and accumulated deficit were primarily due to the substantial investments we made to identify, develop or license 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 or net income will depend, in part, on the rate of our future product sales, offset by the rate of future expenditures. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We completed several clinical studies with all our lead products, UDENYCA® (pegfilgrastim-cbqv), CHS-1420 (our adalimumab (Humira) biosimilar candidate) and CHS-0214 (our etanercept (Enbrel) biosimilar candidate). 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. We anticipate that we will submit a BLA for CHS-1420 to the FDA in 2020. We have not yet initiated clinical trials for CHS-2020. We anticipate we will incur certain development and pre-commercial expenses for the Lucentis biosimilar candidate, which we licensed from Bioeq in November 2019, and for the Avastin biosimilar candidate, which we licensed from Innovent in January 2020.

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 which include all product candidates for which we obtained commercial rights, in those markets. However, even additional product candidates beyond UDENYCA® gain regulatory approval and are commercialized, we may not remain profitable.

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;
- make upfront, milestone, royalty or other payments under any license agreements;
- 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;
- seek to create, maintain, protect and expand our intellectual property portfolio;
- engage legal counsel and technical experts to help us evaluate and avoid infringing any valid and enforceable intellectual property rights of third parties;
- engage in litigation including patent litigation and Inter Partes Review (“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 or net income 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 may be unable to maintain or increase profitability.

Although we reported net income of $89.8 million for the year ended December 31, 2019, we may not be able to maintain or increase profitability, and we are unable to predict the extent of our long-range future profits or losses. The amount of net profits or losses will depend, in part, on the level of sales of UDENYCA® in the U.S. and the level of our expenses as we expand our product pipeline. To offset these expenses, we will need to generate substantial revenue. If expenses exceed our expectations, or if we fail to achieve expected revenue targets, the market value of our common stock may decline.

We continue to 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, 2019, our cash and cash equivalents were $177.7 million. We expect that our existing cash, cash equivalents and cash collected from our UDENYCA® sales will be sufficient to fund our current operations for the foreseeable future and beyond the next 12 months. We have financed our operations primarily through the sale of equity securities, convertible notes, credit facilities, license agreements and to a lesser extent, through recent product sales of UDENYCA®.

However, our operating or investing 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 continue to successfully commercialize UDENYCA®, and to compete against new pegfilgrastim biosimilar commercial entrants;
- 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 licensing or other arrangements to acquire intellectual property rights that we may establish, including any milestone and royalty payments thereunder;
- the timing of conversion in common shares or repayment in cash of our convertible debt, or the timing of repayment in cash, whether due or not, of our credit facilities; and
- the cost, timing and outcomes of any litigation that we may file against third parties 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, stay profitable or increase our net profits, 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.

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 as we attained 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 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 U.S. and E.U., and we have no products approved in any other territories. The 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 EC, through the EMA, approved UDENYCA® on September 20, 2018 for substantially the same indication as approved by the FDA.

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

Our ability to generate meaningful revenue and remain profitable 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:

- Bioeq's ranibizumab (Lucentis) biosimilar candidate;
- Innovent's bevacizumab (Avastin) biosimilar candidate;
- CHS-1420 (our adalimumab (Humira) biosimilar candidate);
- CHS-2020 (our aflibercept (Eylea) biosimilar candidate); and
- CHS-131 (our NASH small molecule drug candidate).

We may not be able to continue to generate meaningful revenue from product sales, as this depends heavily on our success in many areas, including but not limited to:

- our ability to continue to successfully commercialize UDENYCA® ;

- competing against current and future pegfilgrastim products;
- healthcare providers, payers, and patients adopting our product candidates once approved and launched;
- our ability to procure and commercialize our in-licensed biosimilar candidates;
- 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 of 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.

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 continue to be sufficient to recover our development and manufacturing costs, and as a result, we may not be profitable in the future. 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, or become unavaible, 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.

Effective January 2019, 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 a large majority of payers have adopted the Q-Code assigned by CMS for UDENYCA®, there remains uncertainty as to whether such payers will continue to cover and pay providers for the administration and use of the product with each patient or may favor a competing product. 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 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: Sandoz International GmbH (“Sandoz”), Amgen Inc. (“Amgen”), Pfizer Inc., 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), ranibizumab (Lucentis), bevacizumab (Avastin), adalimumab (Humira), aflibercept (Eylea) and etanercept (Enbrel).

UDENYCA® faces competion in the U.S. from Amgen, Mylan (with partner Biocon Ltd.), Sandoz, and may face completion from Pfizer, Amneal and Fresenius, companies that announced the development of a pegfilgrastim biosimilar.

Our ranibizumab (Lucentis) biosimilar candidate licensed from Bioeq may face competition in the U.S. from Genentech (the manufacturer of Lucentis). Samsung Bioepis and Xbrane Biopharma AB (in collaboration with STADA Arzneimittel AG have each disclosed the development for a Lucentis biosimilar candidate.

Our bevacizumab (Avastin) biosimilar candidate licensed from Innovent may face competition in the U.S. from Genentech (the manufacturer of Avastin) as well as Amgen and Pfzer, each of which have initiated the commercial launch of an Avatin biosimilar.

Similarly, CHS-1420, our adalimumab (Humira) biosimilar may face competition from Abbvie (the manufacturer of Humira) as well as manufacturers of Humira biosimilars such as Pfizer, Boehringer Ingelheim, Amgen, Sandoz and Samsung Bioepis. There are five adalimumab biosimilar products FDA-approved in the U.S. and Fujifilm and Fresenius are companies that have each disclosed development plans for a Humira biosimilar candidate. As a result of number of potential adalimimub (Humira) biosimilar competitors, we may not be able to achieve topline sales between $500 million to $1.0 billion for CHS-1420 in the United States, if approved.

CHS-2020 may face competition in the U.S. from Regeneron Pharmaceuticals, Inc. (the manufacturer of Eylea), as well as Momenta (in collaboration with Mylan) and Santo Holding GmbH (in collaboration with Formycon AG), each of which has disclosed development plans for an Eylea biosimilar candidate.

Our etanercept (Enbrel) biosimilar may face competition in the U.S. from Amgen (the manufacturer of Enbrel) and from Samsung Bioepis and Sandoz, each of which have a biosimilar to Enbrel approved in the United States.

These companies may 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.

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.

Competitors in the biosimilar market have the ability to 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.

If other biosimilars of bevacizumab (Avastin), ranibizumab (Lucentis), aflibercept (Eylea), adalimumab (Humira) or etanercept (Enbrel), are approved and successfully commercialized before our product candidates for these originator products, our business would suffer.

We expect other companies to seek approval to manufacture and market biosimilar versions of Avastin, Lucentis, Eylea, Humira or Enbrel. If other biosimilars of of these branded biologics are approved and successfully commercialized before our biosimilar candidates, 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 September 2018, the EC granted marketing authorization to UDENYCA® and to a pegfilgrastim biosimilar candidate from Intas. In November and December 2018, the EC granted marketing authorizations to three additional pegfilgrastim biosimilar candidates from Sandoz, Mylan and Cinfa. In June 2019, the E.U. granted marketing authorization to a pegfilgrastim biosimilar candidate from USV Biologics.

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.

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, 2019, we had 291 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 Bioeq, Innovent and 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.

We have an exclusive license from Bioeq to commercialize Bioeq's ranibizumab (Lucentis) biosimilar in the United States. We have an exclusive license from Innovent to develop and commercialize Innovent's bevacizumab (Avastin) biosimilar in the United States and Canada. Our licensors are responsible for supplying us with drug substance and final drug products as well as, in the case of Innovent, the necessary regulatory data to submit a 351(k) BLA for Innovent's bevacizumab candidate in the United States and Canada.

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 licenses with Bioeq, Innovent, 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 collaboration partners may fail to provide sufficient amounts of commercial products or they may be ineffective in doing so;
- our existing and potential collaboration partners may fail regulatory inspections which may preclude or delay the delivery of commercial products;
- our existing and potential 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.

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 our product candidates, we currently engage a distinct vendor or service provider for each of the principal activities supporting our manufacture and development of these 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 engaged a limited number of 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 351(k) BLA, original 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. 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 product candidates, including our in-lincensed biosimilar candidates, 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 filed briefs in this matter and oral argument was held on May 8, 2019. On July 29, 2019, the Federal Circuit issued a precedential opinion affirming the District Court's judgment in the Company's favor. The Federal Circuit held that the doctrine of prosecution history estoppel barred Amgen from succeeding on its infringement claim and affirmed the District Court's dismissal. In a Joint Status Report, dated September 20, 2019, Amgen stated that it does not intend to further appeal the Federal Circuit's

decision. On October 11, 2019, the Company filed a Motion for Attorneys' Fees with the District Court. Amgen filed its Answering Brief in Opposition on November 8, 2019. On November 22, 2019, the Company filed its Reply brief. This case is currently pending in the District Court.

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 July 1, 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.

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. 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, which was amended, alleged 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. The complaint, as amended, sought injunctive relief and monetary damages. On May 2, 2019, we and Amgen settled the trade secret action brought by Amgen. The details of the settlement are confidential but the Company will continue to market UDENYCA® and began paying a mid-single digit royalty to Amgen for five years starting on July 1, 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 our biosimilar product candidates. 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.

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., or may result in us incurring substantial legal settlement costs.

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-2020 and the Innovent's bevacizumab (Avastin) biosimilar. 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. 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. For example, Innovent's bevacizumab (Avastin) biosimlar product candidate has been developed principally in China, and the FDA may not agree that Innovent's clinical development plan, even if successfully completed, will support submission of a 351(k) BLA. 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. For example, during FDA's review of Bioeq's 351(k) BLA for its ranibizumab (Lucentis) biosimiar, the FDA requested that Bioeq submit additional manufacturing data for the equipment in its new location, leading Bioeq to withdraw its 351(k) BLA for this candidate in order to provide the requested data and resubmit the application thereafter. 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 our collaborators or 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 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.

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

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 BPCIA, enacted on March 23, 2010, as part of the ACA. The BPCIA established this abbreviated pathway under section 351(k) of the PHSA. Subsequent to the enactment of the BPCIA, the FDA issued guidance documents 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.

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), bevacizumab (Avastin), ranibizumab (Lucentis), aflibercept (Eylea), adalimumab (Humira) or etanercept (Enbrel), are determined to be interchangeable and our biosimilar candidates for these originator products are not, our business would suffer.

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

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

The labelling 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 U.S., 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.

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 "ACA"), was passed, which substantially changed the way health care is financed by both governmental and private insurers and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things, addressed 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, increased 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, added 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 promoted 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 inseverable 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 ACA 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 2029 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 E.U., 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 E.U. or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the E.U., including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than E.U., 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 E.U. member states

have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing E.U. 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 U.S. and E.U., 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 and physician payment transparency 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;
- federal civil and criminal false claims laws, including the False Claims Act, 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. 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 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;
- 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 ACA, 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, as defined in the statute, including their immediate family members, certain other healthcare professionals as of 2022, and teaching hospitals and ownership and investment interests held by such physicians and their immediate family members and applicable GPOs; 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; and 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.

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 now 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 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 CCPA (defined below), 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 the U.S., we may 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 for Economic and Clinical Health Act, or HITECH, and their respective implementing regulations, impose specified requirements relating to the privacy, security and transmission of individually identifiable health information held by covered entities and their business associates. Among other things, HITECH made HIPAAs 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, although we believe that we would not be considered a “business associate” in the normal course of our business. 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. Even when HIPAA does not apply, according to the Federal Trade Commission or the FTC, failing to take appropriate steps to keep consumers’ personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, or the FTCA, 15 U.S.C § 45(a). The FTC expects a company’s data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. The FTC’s guidance for appropriately securing consumers’ personal information is similar to what is required by the HIPAA security regulations.

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 and may not have the same requirements, thus complicating compliance efforts. By way of example, California enacted the California Consumer Privacy Act (the "CCPA") on June 28, 2018, which went into effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability, and many similar laws have been proposed at the federal level and in other states.

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. Additionally, following the United Kingdom's withdrawal from the European Union, we will have to comply with the GDPR and the United Kingdom GDPR, each regime having the ability to fine up to the greater of €20 million/ £17.5 million or 4% of global turnover. The relationship between the United Kingdom and the European Union in relation to certain aspects of data protection law remains unclear, for example around how data can lawfully be transferred between each jurisdiction, which exposes us to further compliance risk.

Although we work to comply with applicable laws, regulations and standards, our contractual obligations and other legal obligations, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another, and may conflict with one another or other legal obligations with which we must comply. Any failure or perceived failure by us or our employees, representatives, contractors, consultants or other third parties to comply with such requirements or adequately address privacy and security concerns, even if unfounded, could result in additional cost and liability to us, damage our reputation, and have a material adverse effect on our business, financial condition and results of operations.

The international aspects of our business expose us to business, regulatory, political, operational, financial and economic risks associated with doing business outside of the 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;
- expose us to sanctions, such as the sanctions levied by U.S., E.U. and Russian regulatory bodies in connection with Russia's military intervention in the Ukraine in March 2014; 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.

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 20, 2020 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, 2019, our executive officers, directors, five percent stockholders and their affiliates beneficially owned approximately 26% 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, 2019, there were 70,366,661 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 are currently freely tradable, without restriction (except as otherwise applicable), in the public market.

In addition, as of December 31, 2019, approximately 20.9 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 that 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, 2019, we reserved for future issuance under the 2016 Plan a total of 3,950,000 share of common stock for new employees. In January 2020, we increased the reserve for future issuance under the 2016 Plan to 4,950,000 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 September 2024 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 entered into a new laboratory lease in a new location of Camarillo, California, which commences in April 2020 and terminates in May 2027, and contains a one-time option to extend the lease term for five years.

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 March 3, 2017, Amgen Inc. and Amgen USA Inc. (collectively "Amgen") filed an action against us and other defendants in the Superior Court of the State of California, County of Ventura. The complaint, which was amended, alleged 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. The complaint, as amended, sought injunctive relief and monetary damages. On May 2, 2019, we and Amgen settled the trade secret action brought by Amgen. The details of the settlement are confidential but the Company continued to market UDENYCA® and began to pay a mid-single digit royalty to Amgen for five years starting on July 1, 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 filed briefs in this matter and oral argument was held on May 8, 2019. On July 29, 2019, the Federal Circuit issued a precedential opinion affirming the District Court's judgment in the Company's favor. The Federal Circuit held that the doctrine of prosecution history estoppel barred Amgen from succeeding on its infringement claim and affirmed the District Court's dismissal. In a Joint Status Report, dated September 20, 2019, Amgen stated that it does not intend to further appeal the Federal Circuit's decision. On October 11, 2019, the Company filed a Motion for Attorneys' Fees. Amgen filed its Answering Brief in Opposition on November 8, 2019. On November 22, 2019, the Company filed its Reply brief. This case is currently pending in District Court.

On January 24, 2019, we filed suit against Amgen in the U.S. District Court of Delaware alleging that the manufacture of 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. On March 5, 2019, we filed an amended complaint asserting an additional patent, U.S. patent 10,207,000. On April 18, 2019, Amgen filed its answer and counterclaims. On June 24, 2019, we filed our answer to Amgen's counterclaims. On November 25, 2019, the parties filed a Stipulation of Dismissal, dismissing all claims set forth in Coherus' amended complaint with prejudice, and all counterclaims and affirmative defenses set forth in Amgen's answer, affirmative defenses, and counterclaims as moot. On November 26, 2019, the Court granted the Stipulation of Dismissal. On December 9, 2019, Amgen filed a Motion for a Determination of Exceptional Case and an Award of Fees. On January 7, 2020, the Company filed its Answering Brief in Opposition to Amgen's motion. On January 21, 2020, Amgen filed its Reply Brief. The case is currently pending.

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, 2018 through December 31, 2019.

	Price Range	
Year ended December 31, 2019	**High**	**Low**
1st Quarter	$ 15.62	$ 8.32
2nd Quarter	22.17	12.95
3rd Quarter	23.91	16.16
4th Quarter	22.08	15.50
Year ended December 31, 2018		
1st Quarter	$ 14.50	$ 8.55
2nd Quarter	17.80	9.85
3rd Quarter	20.66	14.00
4th Quarter	17.25	8.39

On February 21, 2020, the closing sale price of our common stock was $22.53.

Common Stockholders

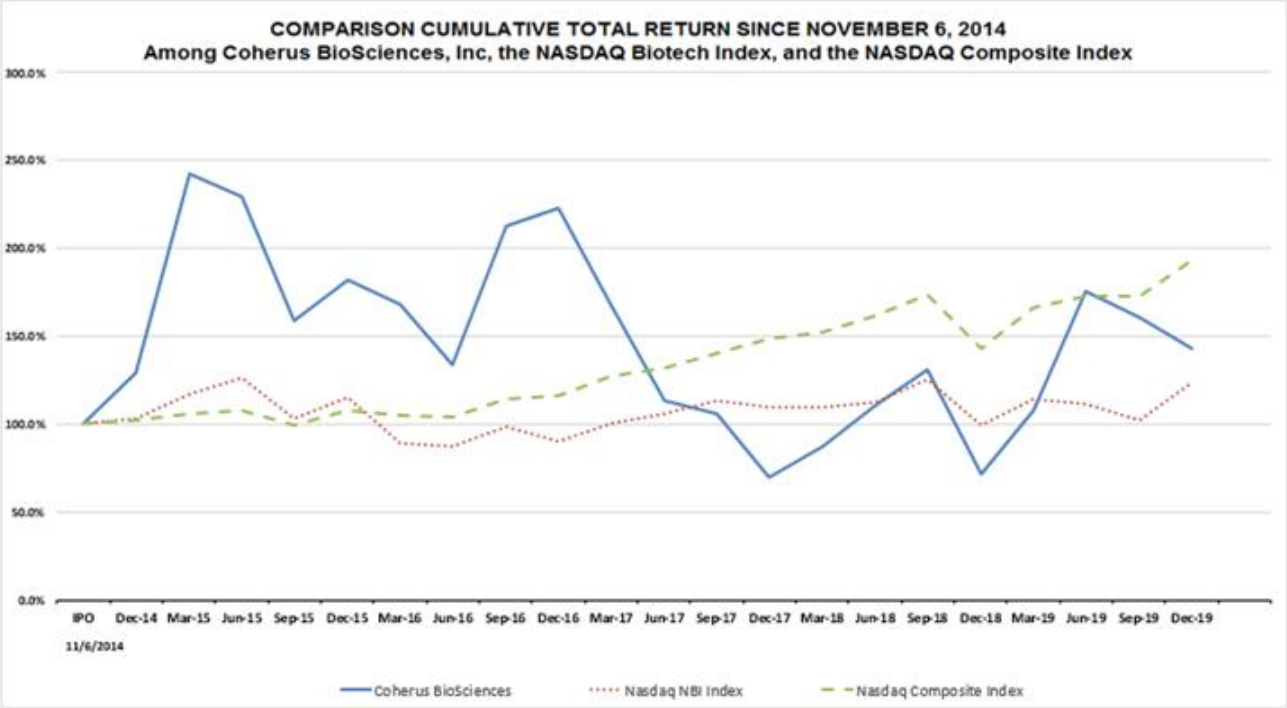
As of January 31, 2020, there were approximately 29 stockholders of record of our common stock. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. 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, 2019 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, 2019 through December 31, 2019, 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, 2019.

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, 2019, 2018 and 2017, and the consolidated balance sheet data as of December 31, 2019 and 2018 are derived from our audited consolidated financial statements included elsewhere in this Form 10-K. The selected consolidated statement of operations data for the years ended December 31, 2016 and 2015, and the consolidated balance sheet data as of December 31, 2017, 2016 and 2015 are derived from our audited financial statements, which are not included in this Annual Report on Form 10-K.

Consolidated Statement of Operations Data:

	Year Ended December 31,				
(in thousands, except share and per share data)	**2019**	**2018**	**2017**	**2016**	**2015**
Revenue:					
Net product revenue	$ 356,071	$ —	$ —	$ —	$ —
Collaboration and license revenue	—	—	1,556	189,476	30,041
Other revenue	—	—	—	630	—
Total revenue	356,071	—	1,556	190,106	30,041
Operating expenses:					
Cost of goods sold (1)	17,078	—	—	—	—
Research and development (1)	94,188	110,239	162,389	254,440	213,062
Selling, general and administrative (1)	137,037	94,177	71,303	51,597	36,046
Total operating expenses	248,303	204,416	233,692	306,037	249,108
Income (loss) from operations	107,768	(204,416)	(232,136)	(115,931)	(219,067)
Interest expense	(17,601)	(9,684)	(9,552)	(7,980)	(33)
Other income (expense), net	2,608	4,691	3,402	(3,877)	(4,838)
Net income (loss) before income taxes	92,775	(209,409)	(238,286)	(127,788)	(223,938)
Income tax provision	2,942	—	—	—	—
Net income (loss)	89,833	(209,409)	(238,286)	(127,788)	(223,938)
Net loss attributable to non-controlling interest	—	70	116	451	678
Net income (loss) attributable to Coherus	$ 89,833	$ (209,339)	$ (238,170)	$ (127,337)	$ (223,260)
Net Income (loss) per share attributable to Coherus:					
Basic (2)	$ 1.29	$ (3.22)	$ (4.48)	$ (3.04)	$ (6.01)
Diluted (2)	$ 1.23	$ (3.22)	$ (4.48)	$ (3.04)	$ (6.01)
Weighted-average number of shares used in computing net income (loss) per share attributable to Coherus:					
Basic (2)	69,679,916	65,034,827	53,133,620	41,912,300	37,122,008
Diluted (2)	73,185,943	65,034,827	53,133,620	41,912,300	37,122,008

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

	Year Ended December 31,				
(in thousands)	**2019**	**2018**	**2017**	**2016**	**2015**
Cost of goods sold	$ 108	$ —	$ —	$ —	$ —
Research and development	12,912	15,339	15,104	13,592	8,038
Selling, general and administrative	20,571	19,458	18,293	13,829	8,683
Total stock-based compensation	$ 33,591	$ 34,797	$ 33,397	$ 27,421	$ 16,721

(2) See Note 15 to our audited consolidated financial statements for an explanation of the method used to calculate basic and diluted net income (loss) per share attributable to Coherus and the weighted-average shares outstanding used to calculate the per share amounts.

Consolidated Balance Sheet Data:

	December 31,				
(in thousands)	**2019**	**2018**	**2017**	**2016**	**2015**
Cash and cash equivalents	$ 177,668	$ 72,356	$ 126,911	$ 124,947	$ 158,226
Working capital	228,040	51,172	117,082	105,110	91,368
Total assets	408,927	99,467	162,611	178,485	212,384
Convertible notes	78,542	77,319	76,206	75,192	—
Convertible notes - related party	26,181	25,773	25,402	25,064	—
Term loan	73,663	—	—	—	—
Accumulated deficit	(894,998)	(984,831)	(775,492)	(537,322)	(409,985)
Total stockholder's equity (deficit)	105,214	(38,591)	30,535	19,354	(6,929)

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.

Our commercial product is UDENYCA® (pegfilgrastim-cbqv), a biosimilar to Neulasta.

Our pre-commercial pipeline includes the following product candidates:

- A bevacizumab (Avastin) biosimilar candidate in collaboration with Innovent;
- A ranibizumab (Lucentis) biosimilar candidate in collaboration with Bioeq;
- CHS-2020 (our aflibercept (Eylea) biosimilar candidate);
- CHS-1420 (our adalimumab (Humira) biosimilar candidate);
- CHS-0214 (our etanercept (Enbrel) biosimilar candidate); and
- CHS-131, our oral, small-molecule drug candidate, which 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.

On January 3, 2019, we initiated the U.S. sales of UDENYCA®, our first commercial product. While we have incurred significant losses historically, we were profitable for the year ended December 31, 2019 as a result of increasing sales of UDENYCA® since January 3, 2019. We anticipate that we will remain profitable on an annual basis, if we are able to grow net sales and maintain operating expenses below net sales. Our net income was $89.8 million for the year ended December 31, 2019 and our net losses were $209.4 million and $238.3 million for the years ended December 31, 2018 and 2017, respectively. As of December 31, 2019, we had an accumulated deficit of $895.0 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 offered and sold 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 January 2019, we issued and sold an aggregate of 761,130 shares of common stock at a weighted average price of $11.17 per share under the ATM Offering Program for aggregate net proceeds of $8.2 million. As of January 19, 2019, our Shelf Registration Statement expired and accordingly the ATM Offering Program expired.

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). The consolidated net sales (customarily defined) for UDENYCA® for the fiscal year ending December 31, 2019, exceeded $250.0 million, which will result in an interest rate reduction to 6.75% per annum plus LIBOR, effective January 1, 2020. 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

Our first FDA approved product, UDENYCA®, was approved in November 2018, and we initiated U.S. sales of UDENYCA® on January 3, 2019. We recorded net product revenue of $356.1 million for the year ended December 31, 2019. Historically, our revenue has been generated from license and collaboration agreements, under which we received license fees, milestone payments and other contingent payments.

Cost of Goods Sold

Cost of goods sold consists primarily of third-party manufacturing, distribution, and overhead costs associated with UDENYCA®. A portion of the costs of producing UDENYCA® sold to date was expensed as research and development prior to the FDA approval of UDENYCA® and therefore it is not reflected in the cost of goods sold.

On May 2, 2019, we settled a trade secret action brought by Amgen Inc. and Amgen USA Inc. (collectively "Amgen"). As a result, the cost of goods sold reflects a mid-single digit royalty on net product revenue, which began on July 1, 2019. The royalty cost will continue for five years per the terms of the settlement agreement.

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;
- costs associated with manufacturing process development activities; and
- certain upfront and milestone payments related to lincesing and collaboration agreements.

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 received regulatory approval for UDENYCA® and as a result, all of our manufacturing costs for this product are capitalized as inventory and subsequently expensed as costs of goods sold when the inventory is sold. We expect our research and development expense in 2020 to be higher than in 2019 as we develop our ophthalmology and oncology pipeline and expect milestone payments related to certain licensing and collaboration agreements.

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 as incurred for product candidates prior to regulatory approval as research and development expense. 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 following table summarizes our research and development expense incurred during the respective periods:

	Phase of Development as of December 31, 2019	Year ended December 31, 2019	2018	2017
			(in thousands)	
External costs incurred by product candidate:				
UDENYCA®	Approved	$ 9,047	$ 42,975	$ 31,247
CHS-1420	Completed	9,039	5,989	52,275
CHS-131	Phase 2	4,789	1,181	2,052
CHS-0214 (1)	Completed	330	4,243	17,596
Licensing and collaboration related expenses		11,075	—	—
Other research and development expenses (2)		8,348	3,774	4,878
Internal costs		51,560	52,077	54,341
Total research and development expenses (1)		$ 94,188	$ 110,239	$ 162,389

(1) Our research and development expense for the year ended December 31, 2017 has been reduced by reimbursements of certain research and development expense pursuant to the cost-sharing provision of our licensing agreement with Daiichi Sankyo.

(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 our selling, general and administrative expense in 2020 to be slightly higher than in 2019 as we build out our commercial capabilities for our ophthalmology therapeutic area.

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, 2019, 2018 and 2017.

Other Income, Net

Other income, net for the years ended December 31, 2019, 2018 and 2017, consists 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.

Leases

We adopted ASU 2016-02, *Leases* on January 1, 2019. We determine if an arrangement is a lease at inception. Operating leases are included in operating lease right-of-use assets, other liabilities, and lease liabilities, non-current in the consolidated balance sheets. Right-of-use assets represent our right to use an underlying asset for the lease term and lease liabilities represent our obligation to make lease payments arising from the lease. Operating lease right-of-use assets and liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. In determining the present value of lease payments, we use the incremental borrowing rate based on the information available at the lease commencement date. Lease terms may include options to extend or terminate the lease when it is reasonably certain that we will exercise any such options. Lease expense is recognized on a straight-line basis over the expected lease term**.**

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 active revenue arragements upon adoption of the New Revenue Standards since the collaboration and licensing agreement with Daiichi Sankyo was terminated in July 2017 (See Note 7), therefore, no adjustment to its retained earnings was required.

Topic 606 supersedes all previous revenue recognition requirements in accordance with generally accepted accounting principles. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration to which the entity is entitled to in exchange for those goods or services. To determine revenue recognition for arrangements that we determine are within the scope of Topic 606, we perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the performance obligation is satisfied. We apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services transferred to the customer.

Net Product Revenue

We account for sales of UDENYCA® under Topic *606 Revenue from Contracts with Customers* in 2019. We sell UDENYCA® to wholesalers and distributors, (collectively, "Customers"). Our Customers resell UDENYCA® to hospitals and clinics (collectively, "Healthcare Providers") under set contracts with us. In addition to distribution agreements with Customers and contracts with Healthcare Providers, we enter into arrangements with group purchasing organizations ("GPOs") that provide for government-mandated or privately-negotiated rebates, chargebacks and discounts with respect to the purchase of UDENYCA®. We also enter into rebate arrangements with payers, which consist primarily of commercial insurance companies, to cover the reimbursement of UDENYCA® to Healthcare Providers. We provide co-payment assistance to patients who have commercial insurance and meet certain eligibility requirements. Revenue from product sales is recognized when a Customer controls the product, which occurs upon delivery of UDENYCA® to and acceptance by that Customer.

Product Sales Discounts and Allowances

Revenue from product sales is recorded at the net sales price ("transaction price"), which includes estimates of variable consideration for which reserves are established and that result from discounts, chargebacks, rebates, co-pay assistance, returns and other allowances that are offered within contracts between us and our Customers, Healthcare Providers, payers and GPOs relating to the sales of UDENYCA®. These reserves are based on the amounts earned or to be claimed on the related sales and are classified as reductions in trade receivables (if the amounts are payable to the customer) or current liabilities (if the amounts are payable to a party other than a customer). Where appropriate, these estimates take into consideration a range of possible outcomes that are probability-weighted for relevant factors such as historical experience, current contractual and statutory requirements, specifically known market events and trends, industry data and forecasted customer buying and payment patterns. Overall, these reserves reflect the best estimates of the amount of consideration to which we are entitled based on the term of our contracts. The amount of variable consideration that is included in the transaction price may be constrained, and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future

period. The actual amount of consideration ultimately received may differ from our estimates. If actual results in the future vary from our estimates, the estimates will be adjusted, which will affect net product revenue in the period that such variances become known.

Chargebacks: Chargebacks are discounts that occur when Healthcare Providers purchase directly from a Customer. Healthcare Providers, which belong to Public Health Service institutions, non-profit clinics, government entities, GPOs, and health maintenance organizations, generally purchase the product at a discounted price. The Customer, in turn, charges back to us the difference between the price initially paid by the Customer and the discounted price paid by the Healthcare Providers to the Customer. The allowance for chargebacks is based on an estimate of sales to contracted Customers.

Discounts for Prompt Payment: We provide prompt payment discounts to our Customers, which are recorded as a reduction in revenue in the same period that the related product revenue is recognized.

Rebates: Allowances for rebates include mandated discounts under the Medicaid Drug Rebate Program, other government programs and commercial contracts. Rebate amounts owed after the final dispensing of the product to a benefit plan participant are based upon contractual agreements or legal requirements with public sector benefit providers, such as Medicaid. Certain rebate amounts commensurate with share utilization of UDENYCA® related to other pegfilgrastim products. The allowance for rebates is based on statutory or contractual discount rates and expected utilization. Our estimates for the expected utilization of rebates are based on customer and payer data received from the pharmacies and distributors and historical utilization rates. Rebates are generally invoiced by the payer and paid in arrears, such that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter's shipments to our Customers, plus an accrual balance for known prior quarters' unpaid rebates. If actual future rebates vary from estimates, we may need to adjust our accruals, which would affect net product revenue in the period of adjustment.

Co-payment Assistance: Patients who have commercial insurance and meet certain eligibility requirements may receive co-payment assistance. The calculation of the accrual for co-pay assistance is based on an estimate of claims and the cost per claim that we expect to receive associated with product that has been recognized as revenue.

Product Returns: We offer our Customers a limited product return right, which is principally based upon whether the product is damaged or defective, or the product's expiration date. Product return allowance is estimated and recorded at the time of sale.

Other Allowances: We pay fees to Customers for account management, data management and other administrative services. To the extent that the services received are distinct from the sale of products to the customer, these payments are classified in selling, general and administrative expense in our consolidated statements of operations, otherwise they are included as a reduction in product revenue.

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, certain upfront and milestone payments under the licensing and collaboration agreements 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.

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.

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.

On January 1, 2019, we adopted the ASU No. 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting*, 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. Prior to the adoption of ASU No. 2018-07, we accounted for stock-based compensation arrangements with non-employees using a fair value approach. The fair value of these options was 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 was assumed to be the remaining contractual life of the option. The fair value of the unvested options under these arrangements was subject to remeasurement over the vested terms as earned.

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, as we have limited historical information to develop expectations about future exercise patterns and post-vesting employment termination behavior.
- *Expected volatility.* The expected volatility for the year ended December 31, 2019 is based on our historical stock price volatility. The expected volatility for the years ended December 31, 2018 and 2017 is based on an average historical stock price volatility of industry peers as we did not have sufficient trading history for our common stock in those reporting periods.
- *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 recorded non-cash stock-based compensation expense related to equity awards granted to employees and non-employees of $33.5 million, $34.8 million and $33.4 million for the years ended December 31, 2019, 2018 and 2017, respectively.

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.

As of December 31, 2019, our total net deferred tax assets, net of gross deferred tax liabilities, were $223.7 million. Due to the weight of the negative evidence, which is primarily our history of losses, outweighing other positive evidence, the federal net deferred tax assets and state net deferred tax assets have been fully offset by a valuation allowance. The deferred tax assets were primarily comprised of net operating losses, tax credit carryforwards and stock-based compensation expenses. 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 2019:

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 sheets 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. In July 2018, FASB issued additional authoritative guidance, ASU 2018-11, providing companies with an optional prospective transition method. We adopted the new standards on January 1, 2019 using the optional prospective transition method and recognized right-of-use assets of $7.2 million and lease liabilities of $9.2 million on the adoption date on our consolidated balance sheets, comprised of facility lease agreements for our corporate headquarters and laboratory facilities in California. We elected 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. Accordingly, the results for the twelve months ended December 31, 2019 are presented under Topic 842, and the results for the twelve months ended December 31, 2018 and other prior period amounts were not adjusted and continue to be reported in accordance with the historical accounting under prior lease guidance, ASC Topic 840: *Leases* ("Topic 840")." We also elected an accounting policy that does not recognize right-of-use assets and lease liabilities related to short-term leases. We did not elect to apply the hindsight expedient.

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. We adopted ASU 2018-07 on January 1, 2019 and the adoption did not have a material impact 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 presented the analysis of changes in stockholders' equity in our interim financial statements beginning with our March 31, 2019 Form 10-Q. We adopted the Securities Act Release No. 33-10532 on January 1, 2019 and the adoption did not have a material effect on our financial position, results of operations, cash flows or stockholders' equity.

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

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments—Credit Losses (Topic 326) (ASU 2016-13).* ASU 2016-13 implements an impairment model, known as the current expected credit loss model that is based on expected losses rather than incurred losses. Under the new guidance, an entity will recognize as an allowance its estimate of expected credit losses. ASU 2016-13 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 do not expect the adoption of this standard to have a material impact on our consolidated financial statements.

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 do not expect the adoption of this standard to have a material impact on our consolidated financial statements.

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 do not expect the adoption of this standard to have a material impact on our consolidated financial statements.

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, 2019, 2018 and 2017

Revenue

	Year Ended December 31,				
	2019	2018	2017	2019 vs 2018 Change	2018 vs 2017 Change
	(in thousands)			*(in thousands)*	
Revenue:					
Net product revenue	$ 356,071	$ —	$ —	$ 356,071	$ —
Collaboration and license revenue	—	—	1,556	—	(1,556)
Total revenue	$ 356,071	$ —	$ 1,556	$ 356,071	$ (1,556)

Net product revenue for the year ended December 31, 2019 was $356.1 million due to the U.S. sales of UDENYCA®, which commenced in January 2019. There were no product sales during the year ended December 31, 2018 and 2017.

We recognized collaboration and license revenue of $1.6 million for the year ended December 31, 2017, a decrease of $1.6 million compared to the same period in 2018. The decrease was due to the recognition of the remaining deferred revenue of Daiichi Sanko as a result of its decision to opt-out of the development of CHS-0214 in Japan in the second quarter of 2017.

Cost of Goods Sold

	Year Ended December 31,				
	2019	2018	2017	2019 vs 2018 Change	2018 vs 2017 Change
	(in thousands)			*(in thousands)*	
Cost of goods sold	$ 17,078	$ —	$ —	$ 17,078	$ —
Gross margin	95%	0%	0%	95%	0%

The cost of goods sold was $17.1 million and $0 for the years ended December 31, 2019 and 2018, respectively. Cost of goods sold consists primarily of third-party manufacturing, distribution, overhead costs associated with the sale of UDENYCA® and a mid-single digit royalty cost on net product revenue payable to Amgen, which began on July 1, 2019 and will continue for five years. A portion of the manufacturing costs for inventory were incurred prior to the regulatory approval of UDENYCA® and, therefore, were expensed as research and development costs when incurred. The costs associated with this inventory were approximately $24.9 million and $47.0 million at December 31, 2019 and 2018, respectively, with estimated associated sales value of approximately $527.3 million and $882.9 million, respectively, based on our current average net selling price for the year ended December 31, 2019. During the year ended December 31, 2019, the cost basis of product sold that was expensed prior to approval, was approximately $17.0 million. Had such inventories been valued at acquisition cost, it would have resulted in a corresponding increase in cost of goods sold and a corresponding decrease in gross margin during such period. We expect utilizing the inventory expensed prior to approval by the first quarter of 2021. Subsequent to using our entire zero cost inventory, we estimate cost of goods sold as a percentage of net product revenue will be in the range of a high single digit to low double digit percentage, including the mid-single digit royalty cost on net product revenue.

We expect our gross margin to moderately decrease over time as a result of decreasing revenue per units sold in response to competitive pressure.

Research and Development Expense

	Year Ended December 31,			2019 vs 2018 Change	2018 vs 2017 Change
	2019	2018	2017		
	(in thousands)			*(in thousands)*	
Research and development	$ 94,188	$ 110,239	$ 162,389	$ (16,051)	$ (52,150)

Research and development expense for the year ended December 31, 2019 was $94.2 million compared to $110.2 million for the same period in 2018, a decrease of $16.1 million. The decrease in research and development expense was primarily due to:

- a decrease of $33.9 million in UDENYCA® manufacturing costs as we began capitalizing these costs as inventory after receiving FDA approval for UDENYCA® in November 2018, which was partially offset by an increase in development expense associated with an on-body device for UDENYCA®;
- a decrease of $4.5 million in facilities, supplies and materials and other infrastructure primarily due to the impairment loss of $3.9 million in the third quarter of 2018 for a machine and equipment used within research and development;
- a decrease of $3.9 million for CHS-0214 development costs due to close-out activities for our Phase 3 open-label extension study, which was completed in the first quarter 2018; and
- a decrease of $2.4 million in stock-based compensation expense primarily due to company-wide options granted in April 2015 with a higher exercise price that have been fully expensed and the capitalization of certain stock-based compensation expense as inventory after receiving FDA approval for UDENYCA® in November 2018. The decrease was partially offset by additional stock options and awards granted in 2019.

The decrease in research and development expense for the year ended December 31, 2019 was partially offset by the following:

- an increase of $15.6 million in costs primarily attributable to $11.1 million of upfront and milestone payments to Bioeq and increases related to the development of our other biosimilar product candidates as we continued to advance our pipeline;
- an increase of $6.4 million in personnel, consulting and other related costs as a result of hiring personnel in research and development to advance our programs;
- an increase of $3.6 million in costs related to CHS-131 in connection with opening an initial new drug (“IND”) application with the FDA and conducting a clinical trial; and
- an increase of $3.0 million in costs for CHS-1420 related to the preparation of our BLA.

We expect our research and development expense in 2020 to be higher than in 2019 as we develop product candidates in our ophthalmology and oncology pipeline and expect to incur milestone payments related to certain licensing and collaboration agreements.

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.

Selling, General and Administrative Expense

	Year Ended December 31,			2019 vs 2018 Change	2018 vs 2017 Change
	2019	2018	2017		
	(in thousands)			*(in thousands)*	
Selling, general and administrative	$ 137,037	$ 94,177	$ 71,303	$ 42,860	$ 22,874

Selling, general and administrative expense for the year ended December 31, 2019 was $137.0 million compared to $94.2 million for the same period in 2018, an increase of $42.9 million. The increase in selling, general and administrative expense was primarily due to:

- an increase of $35.6 million for personnel, consulting and other related expenses due to an increase in sales force personnel and related commercial functions in connection with the ongoing commercialization of UDENYCA®;
- an increase of $3.6 million for marketing, advertising, recruiting and other professional services to support the ongoing commercialization of UDENYCA®, which was partially offset by a decrease in legal costs as a result of entering into a legal settlement with Amgen in May 2019;
- an increase of $2.5 million in facility and other general and administrative expenses to support our growing commercial infrastructure for UDENYCA®; and
- an increase of $1.1 million in stock-based compensation expense due to an increase in commercial-related headcount and additional stock options and awards granted in 2019. The increase was partially offset by a decrease resulting from the company-wide options granted in April 2015 with a higher exercise price that have been fully expensed.

We expect selling, general and administrative expense in 2020 to be slightly higher than in 2019 as we build out our commercial capabilities for our ophthalmology therapeutic area.

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.

Interest Expense

	Year Ended December 31,			2019 vs 2018 Change	2018 vs 2017 Change
	2019	2018	2017		
	(in thousands)			*(in thousands)*	
Interest expense	$ 17,601	$ 9,684	$ 9,552	$ 7,917	$ 132

Interest expense for the year ended December 31, 2019 was $17.6 million compared to $9.7 million for the same period in 2018, an increase of $7.9 million. The increase in interest expense was primarily attributable to the Term Loan we entered into in January 2019.

Interest expense for the year ended December 31, 2018 was $9.7 million compared to $9.6 during the same period in 2017, an increase of $0.1 million. The increase 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, Net

	Year Ended December 31,			2019 vs 2018 Change	2018 vs 2017 Change
	2019	2018	2017		
	(in thousands)			*(in thousands)*	
Other income, net	$ 2,608	$ 4,691	$ 3,402	$ (2,083)	$ 1,289

Other income, net was higher in 2018 compared to that of 2019 or 2017 because the fair value of our contingent liability related to the Compound Transaction Payment associated with our InteKrin acquisition decreased 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.

Income Tax Provision

	Year Ended December 31,			2019 vs 2018 Change	2018 vs 2017 Change
	2019	2018	2017		
	(in thousands)			*(in thousands)*	
Income tax provision	$ 2,942	$ —	$ —	$ 2,942	$ —

Income tax provision for the year ended December 31, 2019 was $2.9 million compared to $0 for the same period in 2018, an increase of $2.9 million. Income tax provision primarily relates to state taxes in jurisdictions outside of California, for which we have a limited operating history. Our historical losses are sufficient to fully offset any federal taxable income for the year ended December 31, 2019.

There was no income tax provision for the years ended December 31, 2018 and 2017 as we maintained a full valuation allowance against our net deferred tax assets due to our history of losses during these periods.

Liquidity and Capital Resources

Due to our significant research and development expenditures, and although we are profitable for the year ended December 31, 2019, we previously generated significant operating losses since our inception. We funded our operations primarily through the issuance of debt, equity financing, sales of our convertible preferred stock and payments received under our collaboration and license agreements.

In October 2016, we entered into a sales agreement with Cowen, under which we offered and sold 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 January 2019, we issued and sold an aggregate of 761,130 shares of common stock at a weighted average price of $11.17 per share under the ATM Offering Program for aggregate net proceeds of $8.2 million. As of January 19, 2019, our Shelf Registration Statement expired and accordingly the ATM Offering Program was terminated.

On January 7, 2019 (the "Term Loan Closing Date"), we entered into a credit agreement (the "Term Loan") with affiliates of Healthcare Royalty Partners (together, the "Lender"). The Term Loan 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 Borrowings under the Term Loan bear interest through maturity at 7.00% per annum plus LIBOR (customarily defined). The consolidated net sales (customarily defined) for UDENYCA® for the fiscal year ending December 31, 2019, exceeded $250.0 million, which will result in an interest rate reduction to 6.75% per annum plus LIBOR, effective January 1, 2020. 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 Term Loan 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 Term Loan 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 Term Loan, 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 Term Loan, 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 Term Loan 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 Term Loan Closing Date, (ii) with respect to any prepayment paid or required to be paid after the three year anniversary of the Term Loan Closing Date but on or prior to the four year anniversary of the Term Loan 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 Term Loan Closing Date but on or prior to the five year anniversary of the Term Loan 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 Term Loan, we paid a fee to the Lender of approximately $1.1 million at closing in the form of an original issue discount. Upon the prepayment or maturity 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 Term Loan are secured by a lien on substantially all of our and our Guarantors' tangible and intangible property, including intellectual property. The Term Loan 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 Lender under the Term Loan to declare the Borrowings, together with accrued interest and fees, to be immediately due and payable.

In 2019, 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, 2019, we had an accumulated deficit of $895.0 million and cash and cash equivalents of $177.7 million. We had $89.8 million in net income for the year ended December 31, 2019. We believe that our current available cash, cash equivalents and cash collected from UDENYCA® sales 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 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 to us.

Summary Statement of Cash Flows

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

	Year Ended December 31,		
	2019	2018	2017
		(in thousands)	
Net cash provided by (used in) operating activities	$ 28,355	$ (159,266)	$ (200,286)
Net cash used in investing activities	(12,732)	(1,188)	(4,417)
Net cash provided by financing activities	89,370	105,421	206,787
Effect of exchange rate changes in cash, cash equivalents and restricted cash	(276)	468	(120)
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 104,717	$ (54,565)	$ 1,964

Net cash provided by (used in) operating activities

Cash provided by operating activities was $28.4 million for the year ended December 31, 2019, which was primarily due to the following:

- net income of $89.8 million;
- an increase in accrued rebates, fees and reserve of $51.1 million as a result of UDENYCA® sales;
- non-cash charges related to stock-based compensation of $33.6 million, depreciation and amortization of property and equipment of $3.3 million, non-cash interest expense from amortization of debt issuance discounts of $2.3 million, non-cash operating lease expense of $1.8 million and excess and obsolete inventory of $0.4 million;
- upfront and milestone payments related to license and collaboration arrangements of $11.1 million are being reclassified as investing activities to provide better alignment between the cash flows and the underlying nature of those transactions;
- an increase in accrued and other liabilities of $10.4 million primarily due to our accruals for our UDENYCA® manufacturing and royalty expenses;
- an increase in accrued compensation of $10.0 million primarily due to increased compensation and bonus accrual attributable to increase in headcount and as a result of attainment of certain corporate goals during 2019; and
- an increase in accounts payable of $9.9 million due to the timing of receiving and processing invoices.

The cash provided by operating activities was partially offset by the following:

- an increase in trade receivables of $142.0 million due to initiating sales of UDENYCA® on January 3, 2019;
- an increase in inventory of $48.2 million as we began capitalizing inventory in November 2018 upon receiving FDA approval for UDENYCA®;
- an increase in other prepaid and current assets of $2.1 million primarily due to prepaid commercial activities to support UDENYCA® and the timing of vendor invoices;
- an decrease in lease liabilities of $2.0 million due to the lease payments for the twelve months of 2019 and amortization;
- an increase in prepaid manufacturing services of $0.7 million to secure drug production runs scheduled for 2020; and
- an increase in other assets, non-current of $0.3 million primarily due to the security deposit as a result of amending our operating lease agreement in September 2019.

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.

Net cash used in investing activities

Cash used in investing activities of $12.7 million for the year ended December 31, 2019 was due to the purchase of short-term investments in marketable securities of $20.2 million, upfront and milestone payments related to our Bioeq license and collaboration arrangement of $11.1 million and purchases of property and equipment of $1.8 million. The cash used in investing activities was partially offset by proceeds from maturities of investments in marketable securities of $20.4 million.

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.

Net cash provided by financing activities

Cash provided by financing activities of $89.4 million for year ended December 31, 2019 was primarily related to $73.0 million in proceeds from our term loan, net of issuance costs, $8.1 million from the issuance of our common stock from our ATM Offering Program, net of underwriting discounts, commissions and offering costs, $5.6 million from the exercise of stock options and $3.5 million in proceeds related to our ESPP. The proceeds were partially offset by payments of $0.8 million for taxes related to the net shares settlement of bonus payout in RSUs.

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.

Funding Requirements

We believe that our current available cash, cash equivalents, and cash collected from UDENYCA® sales will be sufficient to fund our planned expenditures and meet our obligations for the foreseeable future, beyond the 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. 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 research and development activities, and on-going and future licensing and collaboration obligations. Our future funding requirements will depend on many factors, including the following:

- cash proceeds from UDENYCA® sales;
- the costs of manufacturing, distributing and marketing UDENYCA®;
- the cost of manufacturing clinical supplies and any products that we may develop;
- the terms and timing of any other collaborative, licensing and other arrangements that we have established or may establish;
- 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 cost, timing and outcomes of regulatory approvals;
- the cost of preparing, filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and
- the extent to which we acquire or invest in businesses, products or technologies.

If the proceeds from UDENYCA® sales are insufficient or are not collected in a timely manner and or our operating expenses are higher than the proceeds from UDENYCA® sales, 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 may 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, 2019 were as follows:

	Payments Due by Period				
Contractual Obligations:	**Total**	**Less than 1 year**	**1 to 3 years**	**3 to 5 years**	**More than 5 years**
			(in thousands)		
Long-term debt obligations - Convertible notes (1)	$ 127,450	$ 8,200	$ 119,250	$ —	$ —
Long-term debt obligations - Term loan (1)	108,532	7,244	14,448	75,491	11,349
Non-cancelable purchase commitments (2)	64,405	25,011	39,394	—	—
Operating lease obligations (3)(4)	15,133	3,141	6,207	5,785	—
Contingent payments to InteKrin Stockholders	102	—	—	102	—
Total contractual obligations	$ 315,622	$ 43,596	$ 179,299	$ 81,378	$ 11,349

(1) The long-term debt obligation is comprised of future minimum payments related to the Convertible Notes and Term Loan.
(2) These amounts are comprised of non-cancelable purchase commitments to our CMO's.
(3) These amounts are comprised of future minimum rent payment on our facility leases.
(4) As of December 31, 2019, we had an additional operating lease for office space that has not yet commenced. The Commencement Date is expected to be in the first quarter of 2020 when we take possession of the space. The future minimum rental payments for this lease are $1.8 million in the aggregate.

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.

On January 7, 2019, we entered into a Term Loan with affiliates of Healthcare Royalty Partners. The Term Loan 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"). See "Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources."

In September 2019, we amended our headquarters lease to secure additional space of approximately 7,448 rentable square feet, which resulted in the total headquarters leased space of approximately 47,789 rentable square feet, and also extended the total headquarters lease term through September 2024.

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, 2019, we had cash and cash equivalents of $177.7 million. A portion of our cash equivalents, which are in money market funds, may be subject to interest rate risk and could fall in value if market interest rates increase. However, because our cash equivalents are primarily short-term in duration, we believe that our exposure to interest rate risk is not significant and a 1% movement in market interest rates would not have a significant impact on the total value of our portfolio.

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

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

COHERUS BIOSCIENCES, INC.

ANNUAL REPORT ON FORM 10-K

INDEX TO AUDITED CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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, 2019 and 2018, the related consolidated statements of operations, comprehensive income (loss), stockholders' equity (deficit), and cash flows, for each of the three years in the period ended December 31, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019, 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, 2019, 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 27, 2020 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.

Critical Audit Matters

This critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Estimate of Reserves for Chargeback and Rebates

Description of the Matter

As described in Note 2 to the consolidated financial statements, the Company recognizes revenues from product sales at the net sales price, which includes estimates of reserves for chargebacks and rebates it provides to hospitals, clinics, and payers under commercial and government programs. These reserves are recorded in the period when sales occur and are based on the amounts to be claimed on the related sales which may not be known at the point of sale. Chargebacks and rebates are estimated based on expected channel and payer mix, and contracted discount rates, adjusted for current period assumptions. Estimated chargebacks are recorded as a reduction of trade receivables on the consolidated balance sheet and totaled $29.9 million at December 31, 2019. Estimated rebates are presented within accrued rebates, fees and reserves on the consolidated balance sheet and totaled $27.1 million at December 31, 2019.

Auditing the estimates for chargebacks and rebates was complex due to the judgmental nature of the assumptions used. In particular for product that remains in the distribution channel at December 31, 2019, management is required to estimate the portion of product that is expected to be subject to a chargeback and rebate as well as the applicable discount rate.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design and tested the operating effectiveness of internal controls over the Company's estimates of chargebacks and rebates, which are accounted as reductions to revenue. This included controls over management's review of significant assumptions used in the estimates such as expected channel and payer mix and contractual discount rate.

To test the Company's estimated reserves for chargebacks and rebates, our audit procedures included, among others, testing the accuracy and completeness of the underlying data used in the Company's analyses and evaluating the significant assumptions stated above. Specifically, for estimated chargebacks and rebates, we obtained third-party channel inventory reports and reviewed the remaining inventory in the distribution channel, tested historical channel and payer mix data, and compared applicable contractual chargeback or rebate percentages applied against executed chargeback and rebate agreements. We also assessed the completeness and accuracy of current and historical channel and payer mix and discount rate data used in management's estimates and performed sensitivity analyses to determine the effect of changes in assumptions, where appropriate.

/s/ Ernst & Young LLP

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

Redwood City, California

February 27, 2020

Coherus BioSciences, Inc.

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

	December 31,	
	2019	**2018**
Assets		
Current assets:		
Cash and cash equivalents	$ 177,668	$ 72,356
Restricted cash	—	50
Trade receivables, net	141,992	—
Inventory	9,807	1,659
Prepaid manufacturing	8,578	7,906
Other prepaid and other assets	4,964	2,462
Total current assets	343,009	84,433
Property and equipment, net	5,840	6,660
Inventory, non-current	45,264	4,012
Operating lease right-of-use assets	10,649	—
Intangible assets	2,620	2,620
Goodwill	943	943
Restricted cash, non-current	240	785
Other assets, non-current	362	14
Total assets	$ 408,927	$ 99,467
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 25,985	$ 15,294
Accrued rebates, fees and reserve	51,120	—
Accrued compensation	18,410	10,540
Accrued liabilities	17,258	7,008
Other current liabilities	2,196	419
Total current liabilities	114,969	33,261
Contingent consideration, non-current	102	60
Convertible notes	78,542	77,319
Convertible notes - related parties	26,181	25,773
Term loan	73,663	—
Lease liabilities, non-current	10,256	—
Other liabilities, non-current	—	1,645
Total liabilities	303,713	138,058
Commitments and contingencies (Note 8)		
Stockholders' equity (deficit):		
Common stock, $0.0001 par value; Shares authorized: 300,000,000; Shares issued and outstanding: 70,366,661 and 68,302,681 at December 31, 2019 and 2018, respectively	7	7
Additional paid-in capital	1,000,763	946,515
Accumulated other comprehensive loss	(558)	(282)
Accumulated deficit	(894,998)	(984,831)
Total stockholders' equity (deficit)	105,214	(38,591)
Total liabilities and stockholders' equity (deficit)	$ 408,927	$ 99,467

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,		
	2019	2018	2017
Revenue:			
Net product revenue	$ 356,071	$ —	$ —
Collaboration and license revenue	—	—	1,556
Total revenue	356,071	—	1,556
Operating expenses:			
Cost of goods sold	17,078	—	—
Research and development (includes related party of $52, $1,609 and $8,199 for the years ended December 31, 2019, 2018 and 2017, respectively)	94,188	110,239	162,389
Selling, general and administrative (includes related party of $1, $181 and $62 for the years ended December 31, 2019, 2018 and 2017, respectively)	137,037	94,177	71,303
Total operating expenses	248,303	204,416	233,692
Income (loss) from operations	107,768	(204,416)	(232,136)
Interest expense (includes related party of $2,457, $2,421 and $2,388 for the years ended December 31, 2019, 2018 and 2017, respectively)	(17,601)	(9,684)	(9,552)
Other income, net	2,608	4,691	3,402
Net income (loss) before income taxes	92,775	(209,409)	(238,286)
Income tax provision	2,942	—	—
Net income (loss)	89,833	(209,409)	(238,286)
Net loss attributable to non-controlling interest	—	70	116
Net income (loss) attributable to Coherus	$ 89,833	$ (209,339)	$ (238,170)
Net income (loss) per share attributable to Coherus:			
Basic	$ 1.29	$ (3.22)	$ (4.48)
Diluted	$ 1.23	$ (3.22)	$ (4.48)
Weighted-average number of shares used in computing net income (loss) per share attributable to Coherus:			
Basic	69,679,916	65,034,827	53,133,620
Diluted	73,185,943	65,034,827	53,133,620

See accompanying notes to consolidated financial statements.

Coherus BioSciences, Inc.

Consolidated Statements of Comprehensive Income (Loss)
(in thousands)

	Year Ended December 31,		
	2019	2018	2017
Net income (loss)	$ 89,833	$ (209,409)	$ (238,286)
Other comprehensive income (loss):			
Foreign currency translation adjustments, net of tax	(276)	468	(120)
Comprehensive income (loss)	89,557	(208,941)	(238,406)
Comprehensive loss attributable to non-controlling interest	—	70	116
Comprehensive income (loss) attributable to Coherus	$ 89,557	$ (208,871)	$ (238,290)

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 Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Coherus Stockholders' Equity (Deficit)	Non-controlling Interest	Total Stockholders' Equity (Deficit)
	Shares	Amount						
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 of underwriters discounts, commissions and offering costs	6,220,901	—	131,849	—	—	131,849	—	131,849
Issuance of common stock in connection with private placements, net of underwriters discounts, commissions and offering costs	7,332,220	1	81,190	—	—	81,191	—	81,191
Issuance of common stock upon exercise of stock options	162,978	—	482	—	—	482	—	482
Issuance of common stock upon vesting of restricted stock units ("RSUs")	14,750	—	—	—	—	—	—	—
Issuance of common stock upon 2017 bonus payout	301,455	—	2,668	—	—	2,668	—	2,668
Stock-based compensation expense	—	—	33,397	—	—	33,397	—	33,397
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 of underwriters discounts, commissions and offering costs	7,747,778	1	101,787	—	—	101,788	—	101,788
Issuance of common stock upon exercise of stock options	477,019	—	2,153	—	—	2,153	—	2,153
Issuance of common stock upon vesting of restricted stock units ("RSUs")	61,804	—	—	—	—	—	—	—
Issuance of common stock under the employee stock purchase plan ("ESPP")	175,613	—	1,591			1,591		1,591
Stock-based compensation expense	—	—	34,984	—	—	34,984	—	34,984
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)
Issuance of common stock in connection with common stock offerings, net of underwriters discounts, commissions and offering costs	761,130	—	8,228	—	—	8,228	—	8,228
Issuance of common stock upon exercise of stock options	863,940	—	5,934	—	—	5,934	—	5,934
Issuance of common stock upon vesting of restricted stock units ("RSUs")	39,765	—	—	—	—	—	—	—
Issuance of common stock under the employee stock purchase plan ("ESPP")	289,977	—	3,518	—	—	3,518	—	3,518
Issuance of common stock upon 2018 bonus payout in RSUs	175,054	—	2,165	—	—	2,165	—	2,165

Taxes paid related to net share settlement of bonus payout in RSUs	(65,886)	—	(815)	—	—	(815)	—	(815)
Stock-based compensation expense	—	—	35,218			35,218		35,218
Cumulative translation adjustment	—	—	—	(276)	—	(276)	—	(276)
Net income attributable to Coherus	—	—	—	—	89,833	89,833	—	89,833
Balances at December 31, 2019	70,366,661	$ 7	$ 1,000,763	$ (558)	$ (894,998)	$ 105,214	$ —	$ 105,214

See accompanying notes to consolidated financial statements.

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

	Years Ended December 31,		
	2019	2018	2017
Operating activities			
Net income (loss)	$ 89,833	$ (209,409)	$ (238,286)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Depreciation and amortization	3,259	3,235	3,398
Remeasurement of fair-value contingent consideration	42	(3,230)	(2,260)
Stock-based compensation expense	33,591	34,797	33,397
Non-cash accretion of discount on marketable securities	(165)	(301)	(156)
Non-cash interest expense from amortization of debt discount	2,339	1,484	1,352
Impairment of property and equipment	110	3,861	558
Excess and obsolete inventory	410	—	—
Loss (gain) on disposal of property and equipment	—	—	51
Non-cash bonus payment settled in common stock	—	—	2,668
Non-cash manufacturing postponement fee settled in common stock	—	—	4,125
Non-cash operating lease expense	1,789	—	—
Upfront and milestone expense related to license and collaboration arrangements	11,075	—	—
Changes in operating assets and liabilities:			
Trade receivables, net	(141,992)	—	—
Receivables from collaboration and license agreement	—	—	1,859
Inventory	(48,184)	(5,484)	—
Prepaid manufacturing	(672)	7,063	7,788
Other prepaid and current assets	(2,126)	1,146	11,014
Other assets, non-current	(348)	(1)	—
Accounts payable	9,893	(301)	(3,810)
Accounts payable - related parties	—	(233)	(644)
Accrued rebates, fees and reserve	51,120	—	—
Accrued compensation	10,035	8,466	(4,871)
Accrued and other liabilities	10,386	69	(14,079)
Lease liabilities	(2,010)	—	—
Deferred revenue	—	—	(1,562)
Advance payments under license agreements	—	—	(1,070)
Other liabilities, non-current	(30)	(428)	242
Net cash provided by (used in) operating activities	28,355	(159,266)	(200,286)
Investing activities			
Purchases of property and equipment	(1,822)	(789)	(4,573)
Purchases of investments in marketable securities	(20,235)	(42,869)	(74,344)
Proceeds from maturities of investments in marketable securities	20,400	43,170	74,500
Upfront and milestone payments related to license and collaboration arrangements	(11,075)	—	—
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	(12,732)	(1,188)	(4,417)
Financing activities			
Proceeds from common stock offering, net of underwriters discounts, commissions and offering costs	8,153	101,748	131,305
Proceeds from private placement	—	—	75,000
Proceeds from term loan, net of issuance costs	72,955	—	—
Proceeds from issuances of common stock upon exercise of stock options	5,558	2,082	482
Proceeds from purchase under the employee stock puchase plan	3,519	1,591	—
Taxes paid related to net share settlement of bonus payout in RSUs	(815)	—	—
Net cash provided by financing activities	89,370	105,421	206,787
Effect of exchange rate changes in cash, cash equivalents and restricted cash	(276)	468	(120)
Net increase (decrease) in cash, cash equivalents and restricted cash	104,717	(54,565)	1,964
Cash, cash equivalents and restricted cash at beginning of period	73,191	127,756	125,792
Cash, cash equivalents and restricted cash at end of period	$ 177,908	$ 73,191	$ 127,756
Supplemental disclosure of cash flow information			
Cash paid for interest	$ 15,263	$ 8,200	$ 8,200
Cash paid for income taxes	1,732	—	—

Supplemental disclosures of non-cash investing and financing activities			
Purchase of property and equipment in accounts payable and accrued liabilities	999	272	77
Non-cash non-controlling interest reflected in additional paid in capital	—	1,359	—
Right-of-use assets obtained in exchange for lease obligations	5,267	—	—
Non-cash employee bonuses settled in common stock	1,350	—	2,668
Common stock offering costs in accounts payable and accrued liabilities	—	75	115
Manufacturing services settled in common stock	—	—	6,810

See accompanying notes to consolidated financial statements.

1. Organization and Operations

Description of the Business

Coherus BioSciences, Inc. (the "Company" or "Coherus") is 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. 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.

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, 2019: Coherus Intermediate Corp, InteKrin Therapeutics Inc. ("InteKrin") and InteKrin's wholly-owned subsidiary, InteKrin Russia. Unless otherwise specified, references to the Company are references to Coherus and its consolidated subsidiaries. All intercompany transactions and balances have been eliminated upon consolidation.

Liquidity

As of December 31, 2019, the Company had an accumulated deficit of $895.0 million and cash and cash equivalents of $177.7 million. The Company had $89.8 million in net income for the year ended December 31, 2019. The Company believes that its current available cash, cash equivalents 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.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make judgements, estimates and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses, and related disclosures reported in the financial statements. Management uses significant judgment when making estimates including, but not limited to: those related to revenue recognition, including determining the nature and timing of satisfaction of performance obligations, and determing the standalone selling price of performance obligations, and variable consideration such as rebates, chargebacks, sales returns and sale allowances, as well as milestones included in collaboration and license arrangements; 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, 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.

For the years ended December 31, 2019, 2018 and 2017, the foreign exchange gains and losses recorded in other income (expense), net in the consolidated statements of operations were a net gain of $239,000, a net loss of $571,000 and a net gain of $52,000, respectively.

Segment Reporting and Revenue by Geographic Region

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,		
	2019	2018	2017
United States	$ 356,071	$ —	$ —
Rest of the world	—	—	1,556
Total revenue	$ 356,071	$ —	$ 1,556

Cash, Cash Equivalents and Restricted Cash

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 (in thousands):

	Year Ended December 31,		
	2019	2018	2017
Cash and cash equivalents	$ 177,668	$ 72,356	$ 126,911
Restricted cash	—	50	60
Restricted cash - non-current	240	785	785
Total cash, cash equivalents and restricted cash	$ 177,908	$ 73,191	$ 127,756

Restricted cash – non-current consists of deposits for a letter of credit that the Company has provided to secure its obligations under certain facility leases.

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.

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, 2019, 2018 and 2017 interest income from marketable securities was $1.6 million, $1.4 million and $0.8 million, respectively.

Trade Receivables

Trade receivables are recorded net of allowances for chargebacks, chargeback prepayments, and cash discounts for prompt payment. The Company's estimate of the allowance for doubtful accounts is based on an evaluation of the aging of its receivables. Trade receivable balances are written off against the allowance when it is probable that the receivable will not be collected. To date, the Company has determined that an allowance for doubtful accounts is not required.

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 is subject to credit risk from trade receivables related to the product sales in the United States. To date, the Company has not experienced significant losses with respect to the collection of trade receivables. The Company believes that its allowance for doubtful accounts was adequate at December 31, 2019.

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 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 goods sold 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, 2019, 2018 and 2017, the Company recorded an impairment of property and equipment of $0.1 million, $3.9 million and $0.6 million, respectively, in research and development within the statement of operations.

The intangible assets of $2.6 million as of December 31, 2019 and 2018 comprise of acquired in-process research and development (“IPR&D”), which 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, 2019, 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, 2019.

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 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 active revenue arragements upon adoption of the New Revenue Standards since the collaboration and licensing agreement with Daiichi Sankyo was terminated in July 2017 (See Note 7), therefore, no adjustment to its retained earnings was required.

Topic 606 supersedes all previous revenue recognition requirements in accordance with generally accepted accounting principles. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration to which the entity is entitled to in exchange for those goods or services. To determine revenue recognition for arrangements that the Company determines is within the scope of Topic 606, it performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the performance obligation is satisfied. The Company only applies the five-step model to contracts when it is probable that it will collect the consideration it is entitled to in exchange for the goods or services it transferred to the customer.

Net Product Revenue

The Company accounts for sales of UDENYCA® under Topic *606 Revenue from Contracts with Customers* in 2019. The Company sells UDENYCA® to wholesalers and distributors, (collectively, "Customers"). The Customers then resell UDENYCA® to hospitals and clinics (collectively, "Healthcare Providers") pursuant to contracts with the Company. In addition to distribution agreements with Customers and contracts with Healthcare Providers, the Company enters into arrangements with group purchasing organizations ("GPOs") that provide for U.S. government-mandated or privately-negotiated rebates, chargebacks and discounts with respect to the purchase of UDENYCA®. The Company also enters into rebate arrangements with payers, which consist primarily of commercial insurance companies and government entities, to cover the reimbursement of UDENYCA® to Healthcare Providers. The Company provides co-payment assistance to patients who have commercial insurance and meet certain eligibility requirements. Revenue from product sales is recognized when a Customer controls the product, which occurs upon delivery of UDENYCA® to and acceptance by that Customer.

Product Sales Discounts and Allowances

Revenue from product sales is recorded at the net sales price ("transaction price"), which includes estimates of variable consideration for which reserves are established and that result from chargebacks, rebates, co-pay assistance, prompt-payment discounts, returns and other allowances that are offered within contracts between the Company and its Customers, Healthcare Providers, payers and GPOs relating to the sales of UDENYCA®. These reserves are based on the amounts earned or to be claimed on the related sales and are classified as reductions in trade receivables (if the amounts are payable to a Customer) or current liabilities (if the amounts are payable to a party other than a Customer). Where appropriate, these estimates take into consideration a range of possible outcomes that are probability-weighted for relevant factors such as historical experience, current contractual and statutory requirements, specifically known market events and trends, industry data and forecasted Customer buying and payment patterns. Overall, these reserves reflect the best estimates of the amount of consideration to which the Company is entitled based on the terms of its contracts. The amount of variable consideration that is included in the transaction price may be constrained, and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. The actual amount of consideration ultimately received may differ. If actual results in the future vary from the Company's estimates, the estimates will be adjusted, which will affect the net product revenue in the period that such variances become known.

Chargebacks: Chargebacks are discounts that occur when Healthcare Providers purchase directly from a Customer. Healthcare Providers, which belong to Public Health Service institutions, non-profit clinics, government entities, GPOs, and health maintenance organizations, generally purchase the product at a discounted price. The Customer, in turn, charges back to the Company the difference between the price initially paid by the Customer and the discounted price paid by the Healthcare Providers to the Customer. The allowance for chargebacks is based on an estimate of sales through to Healthcare Providers from the Customer.

Discounts for Prompt Payment: The Company provides for prompt payment discounts to its Customers, which are recorded as a reduction in revenue in the same period that the related product revenue is recognized.

Rebates: Rebates include mandated discounts under the Medicaid Drug Rebate Program, other government programs and commercial contracts. Rebate amounts owed after the final dispensing of the product to a benefit plan participant are based upon contractual agreements or legal requirements with these public sector benefit providers. Certain rebate amounts commensurate

with share utilization of UDENYCA® relative to other pegfilgrastim products. The accrual for rebates is based on statutory or contractual discount rates and expected utilization. The estimates for the expected utilization of rebates are based on Customer and commercially available payer data, as well as data collected from the Healthcare Providers, Customers, GPOs, and historical utilization rates. Rebates invoiced by payers, Healthcare Providers and GPOs are paid in arrears. If actual future rebates vary from estimates, the Company may need to adjust its accruals, which would affect net product revenue in the period of adjustment.

Co-payment Assistance: Patients who have commercial insurance and meet certain eligibility requirements may receive co-payment assistance. The calculation of the accrual for co-pay assistance is based on an estimate of claims and the cost per claim that the Company expects to receive associated with product that has been recognized as revenue.

Product Returns: The Company offers its Customers a limited product return right, which is principally based upon whether the product is damaged or defective, or the product's expiration date. Product return allowance is estimated and recorded at the time of sale.

Other Allowances: The Company pays fees to Customers and GPOs for account management, data management and other administrative services. To the extent that the services received are distinct from the sale of products to the customer, these payments are classified in selling, general and administrative expense in the Company's consolidated statements of operations, otherwise they are included as a reduction in product revenue.

Collaboration and License Revenue

Prior to the adoption of the New Revenue Standard, the Company recognized revenue in accordance with Accounting Standards Codification Topic 605, revenue was recognized 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. As such, prior period amounts related to the collaboration and license agreement with Daiichi Sankyo, which terminated in July 2017 (see Note 7), reflects revenue in accordance with the historical accounting under Topic 605.

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.

Cost of Goods Sold

Cost of goods sold consists primarily of third-party manufacturing, distribution, and overhead costs associated with UDENYCA®. A portion of the costs of producing UDENYCA® sold to date was expensed as research and development prior to the FDA approval of UDENYCA® and, therefore, it is not reflected in the cost of goods sold.

On May 2, 2019, the Company and Amgen Inc. and Amgen USA Inc. (collectively "Amgen") settled a trade secret action brought by Amgen. As a result, cost of goods sold reflects a mid-single digit royalty on net product revenue, which began on July 1, 2019. The royalty cost will continue for five years pursuant to the settlement.

Cost of goods sold for the year ended December 31, 2019, included write-off of prepaid manufacturing costs of $1.3 million due to the cancellation of certain manufacturing reservations, and $0.4 million due to the write-off of excess and obsolete inventory.

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, certain upfront and milestone payments under the licensing and collaboration agreements 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 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.

License Agreements

The Company has entered and may continue to enter into license agreements to access and utilize certain technology. To determine whether the licensing transactions should be accounted for as a business combination or as an asset acquisition, the Company makes certain judgments, which include assessing whether the acquired set of activities and assets would meet the definition of a business under the relevant accounting rules.

If the acquired set of activities and assets does not meet the definition of a business, the transaction is recorded as an acquisition of assets and, therefore, any acquired IPR&D that does not have an alternative future use is charged to expense at the acquisition date. To date none of the Company's license agreements have been considered to be the acquisition of a business.

Selling, General and Administrative Expense

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 $4.5 million, $2.8 million, and $0 for the years ended December 31, 2019, 2018 and 2017, respectively.

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 ("RSU"). The Company accounts for forfeitures as they occur.

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.

On January 1, 2019, the Company adopted the ASU No. 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting*, 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. Prior to the adoption of ASU No. 2018-07, the Company accounted for equity instruments issued to non-employees using the fair value approach. These equity instruments consisted of stock options, which were valued using the Black-Scholes option-pricing model. Stock-based compensation expense was recognized as the equity instruments were earned. The measurement of stock-based compensation was subject to periodic adjustments as the underlying equity instruments vested.

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.

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, 2019 and 2018.

Net Income (Loss) per Share Attributable to Coherus

Basic net income (loss) per share attributable to Coherus is calculated by dividing the net income (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. Diluted net income (loss) per share is computed by dividing the net income (loss) by the weighted average number of common shares outstanding for the period plus any diluted potential common shares outstanding for the period determined using the treasury stock method for options, RSUs and ESPP and using the if-converted method for the convertible notes (see Note 15).

Comprehensive Income (Loss)

Comprehensive income (loss) is composed of two components: net income (loss) and other comprehensive income (loss). Other comprehensive income (loss) refers to gains and losses that under U.S. GAAP are recorded as an element of stockholders'

equity (deficit), but are excluded from net income (loss). The Company's other comprehensive income (loss) included unrealized gains and losses from available-for-sale marketable securities and foreign currency translation adjustments for the years ended December 31, 2019, 2018 and 2017.

Recent Accounting Pronouncements

The following are the recent accounting pronouncements adopted by the Company in 2019:

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. In July 2018, FASB issued additional authoritative guidance, ASU 2018-11, providing companies with an optional prospective transition method. The Company adopted the new standards on January 1, 2019 using the optional prospective transition method and recognized a right-of-use assets of $7.2 and lease liabilities of $9.2 million on the adoption date on its consolidated balance sheet, primarily comprised of facility lease agreements for its corporate headquarters and laboratory facilities in California. The Company elected 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. Accordingly, the results for the year ended December 31, 2019 are presented under Topic 842, and the results for the year ended December 31, 2018 and other prior period amounts were not adjusted and continue to be reported in accordance with the historical accounting under prior lease guidance, ASC Topic 840: *Leases* ("Topic 840"). The new standard also provides practical expedients for an entity's ongoing accounting. The Company elected an accounting policy that does not recognize right-of-use assets and lease liabilities related to short-term leases. The Company also elected the practical expedient to not separate lease and non-lease components for its facility leases. The Company did not elect to apply the hindsight expedient.

The impact of the adoption of Topic 842 on the accompanying consolidated balance sheet as of January 1, 2019 was as follows (in thousands):

	December 31, 2018	Adjustments Due to the Adoption of Topic 842	January 1, 2019
Operating lease right-of-use asset	$ —	$ 7,172	$ 7,172
Operating lease liabilities:			
Other current liabilities[1]	$ 419	$ 1,665	$ 2,084
Other lease liabilities, non-current[2]	$ 1,645	$ 5,466	$ 7,111

(1) Includes current portion of deferred rent and current portion of operating lease liabilities.

(2) Non-current portion of deferred rent and operating lease liabilities.

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. The Company's adoption of ASU 2018-07 on January 1, 2019 did not have a material impact 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 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 presented the analysis of changes in stockholders' equity in its interim financial statements beginning in its March 31, 2019 Form 10-Q. The Company adopted the Securities Act Release No. 33-10532 on January 1, 2019 and such adoption did not have a material effect on the Company's financial position, results of operations, cash flows or stockholders' equity.

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

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments—Credit Losses (Topic 326) (ASU 2016-13).* ASU 2016-13 implements an impairment model, known as the current expected credit loss model that is based on expected losses rather than incurred losses. Under the new guidance, an entity will recognize as an allowance its estimate of expected credit losses. ASU 2016-13 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 does not expect the adoption of this standard to have a material impact on its consolidated financial statements.

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 does not expect the adoption of this standard to have a material impact on its consolidated financial statements.

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 does not expect the adoption of this standard to have a material impact on its consolidated financial statements.

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, 2019			
	Total	Level 1	Level 2	Level 3
Assets:				
Money market funds	$ 155,523	$ 155,523	$ —	$ —
Restricted cash (money market funds)	240	240	—	—
Total financial assets	$ 155,763	$ 155,763	$ —	$ —
Liabilities:				
Contingent consideration	$ 102	$ —	$ —	$ 102

	Fair Value Measurements December 31, 2018			
	Total	Level 1	Level 2	Level 3
Assets:				
Money market funds	$ 71,062	$ 71,062	$ —	$ —
Restricted cash (money market funds)	835	835	—	—
Total financial assets	$ 71,897	$ 71,897	$ —	$ —
Liabilities:				
Contingent consideration	$ 60	$ —	$ —	$ 60

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

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 (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 based on significant inputs not observable in the market and thus represents a Level 3 measurement within the fair value hierarchy. The Compound Transaction analysis as of December 31, 2019 applied a 20% 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. The expected cash flow is based on estimates provided by the Company’s management including the timing and probability of occurrence. The value of the consideration is tiered based on the value of a license or similar agreement with a third party and the timing of such agreement. 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, 2019, 2018 and 2017, the Company recognized a loss of $42,000 , a gain of $3.2 million and a gain of $2.3 million in other income, 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, 2017	$ 3,290
Change in fair value of the contingent consideration liability	(3,230)
Balance as of December 31, 2018	$ 60
Change in fair value of the contingent consideration liability	42
Balance as of December 31, 2019	$ 102

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 8) is based on an income approach. The estimated fair value was approximately $117.1 million (par value $100.0 million) as of December 31, 2019 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):

	December 31, 2019	December 31, 2018
Raw materials	$ 5,089	$ 2,851
Work in process	43,446	1,576
Finished goods	6,536	1,244
Total	$ 55,071	$ 5,671

Balance sheet classification (in thousands):

	December 31, 2019	December 31, 2018
Inventory	$ 9,807	$ 1,659
Inventory, non-current	45,264	4,012
Total	$ 55,071	$ 5,671

Inventory expected to be sold in periods more than twelve months from the balance sheet is classified as inventory, non-current on the consolidated balance sheets. As of December 31, 2019 and 2018, the non-current portion of inventory consisted of raw materials and a portion of work in process.

Prepaid manufacturing of $8.6 million and $7.9 million on the consolidated balance sheets as of December 31, 2019 and 2018, respectively, includes prepayments of $7.2 million and $6.6 million as of December 31, 2019 and 2018, respectively, made to a contract manufacturing organization ("CMO") for manufacturing services for UDENYCA®, 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, 2019	December 31, 2018
Machinery and equipment	$ 12,611	$ 11,505
Computer equipment and software	2,923	1,651
Furniture and fixtures	714	714
Leasehold improvements	4,388	4,364
Construction in progress	1,500	1,463
Total property and equipment	22,136	19,697
Accumulated depreciation and amortization	(16,296)	(13,037)
Property and equipment, net	$ 5,840	$ 6,660

Depreciation and amortization expense was $3.3 million, $3.2 million and $3.4 million for the years ended December 31, 2019, 2018 and 2017, 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 $0.1 million, $3.9 million and $0.6 million for the years ended December 31, 2019, 2018 and 2017, respectively.

Accrued Liabilities

Accrued liabilities are as follows (in thousands):

	December 31, 2019	December 31, 2018
Accrued clinical and manufacturing	$ 7,106	$ 3,950
Accrued other	10,152	3,058
Accrued liabilities	$ 17,258	$ 7,008

6. Revenue

The Company initiated U.S. sales of UDENYCA® on January 3, 2019. The Company recorded net product revenue of $356.1 million during the year ended December 31, 2019. There was no product revenue during the years ended December 31, 2018 or 2017.

Revenue by significant Customer was distributed as follows:

	Year Ended December 31, 2019 Percent of Total
McKesson	42%
AmeriSource-Bergen Corp	33%
Cardinal	23%
Others	2%
Total revenue	100%

Product Sales Discounts and Allowances

The activities and ending reserve balances for each significant category of discounts and allowances, which constitute variable consideration, were as follows (in thousands):

	Chargebacks and Discounts for Prompt Payment	Rebates	Other Fees, Co-pay Assistance and Returns	Total
Balance at December 31, 2018	$ —	$ —	$ —	$ —
Activity related to 2019 sales	226,901	46,810	70,775	344,486
Payments and customer credits issued	(191,742)	(19,316)	(46,281)	(257,339)
Balance at December 31, 2019	$ 35,159	$ 27,494	$ 24,494	$ 87,147

Chargebacks and discounts for prompt payment are recorded as a reduction in trade receivables, and the remaining reserve balances are classified as current liabilities in the accompanying consolidated balance sheets.

7. Collaboration and License Agreements

Bioeq AG

On November 4, 2019, the Company entered into a license agreement with Bioeq IP AG (now Bioeq AG, or "Bioeq") for the commercialization of a biosimilar version of ranibizumab (Lucentis) in certain dosage forms in both a vial and pre-filled syringe presentation (the "Licensed Products"). Under this agreement, Bioeq granted to the Company an exclusive, royalty-bearing license to commercialize the Licensed Products in the field of ophthalmology (and any other approved labelled indication) in the United States. Bioeq will supply to the Company the Licensed Products in accordance with terms and conditions specified in the agreement and a manufacturing and supply agreement to be executed by the parties in accordance therewith. The agreement's initial term continues in effect for ten years after the first commercial sale of a Licensed Product in the United States, and thereafter renews for an unlimited period of time unless otherwise terminated in accordance with its terms.

Under the agreement, Bioeq must use commercially reasonable efforts to develop and obtain regulatory approval of the Licensed Products in the U.S. in accordance with a development and manufacturing plan, and the Company must use commercially reasonable efforts to commercialize the Licensed Products in accordance with a commercialization plan. Additionally, the Company must commit certain pre-launch and post-launch resources to the commercialization of the Licensed Products for a limited time as specified in the agreement.

The Company treated the licensing transaction as an asset acquisition under the relevant accounting rules. The Company paid Bioeq an upfront and a milestone payment aggregating to €10 million ($11.1 million), which was recorded as research and development expense in the Company's consolidated statement of operations for the year ended December 31, 2019. The Company is obligated to pay Bioeq an aggregate of up to €25 million in additional milestone payments in connection with the achievement of certain development and regulatory milestones with respect to the Licensed Products in the United States. The Company will share a percentage of gross profits on sales of Licensed Products in the United States with Bioeq in the low to mid fifty percent range. The additional milestone payments and royalties are contingent upon future events and, therefore, will be recorded when it is probable that a milestone will be achieved or when royalties are due.

Daiichi Sankyo

The Company recognized revenue related to the collaboration and license agreement of $1.6 million from Daiichi Sankyo for the year ended December 31, 2017.

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, which was recorded as deferred revenue and amortized over the remaining estimated performance period under the agreement using the straight-line method. 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 June 2015, the Company and Daiichi Sankyo entered into the Memorandum of Understanding No. 3 (the "MOU 3") in which both parties agreed to cooperate further on a global Phase 3 clinical trial 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 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 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.

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 only recognized MOU cost reimbursement of $4.2 million for the year ended December 31, 2017 as a reduction of research and development expense in its consolidated statements of operations.

8. 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, 2019, 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, 2019 and 2018 (in thousands):

	December 31, 2019	December 31, 2018
Principal amount of the Convertible Notes	$ 81,750	$ 81,750
Unamortized debt discount and debt issuance costs	(3,208)	(4,431)
Convertible Notes	$ 78,542	$ 77,319
Principal amount of the Convertible Notes - related parties	$ 27,250	$ 27,250
Unamortized debt discount and debt issuance costs - related parties	(1,069)	(1,477)
Convertible Notes - related parties	$ 26,181	$ 25,773
Total Convertible Notes	$ 104,723	$ 103,092

If the Convertible Notes were converted on December 31, 2019, the holders of the Convertible Notes would receive common shares with an aggregate value of $80.5 million based on the Company's closing stock price of $18.00.

The following table presents the components of interest expense of the Convertible Notes for the years ended December 31, 2019, 2018 and 2017 (in thousands):

	Year Ended December 31,		
	2019	2018	2017
Stated coupon interest	$ 6,150	$ 6,150	$ 6,150
Accretion of debt discount and debt issuance costs	1,223	1,113	1,014
Interest expense	$ 7,373	$ 7,263	$ 7,164
Stated coupon interest - related parties	$ 2,050	$ 2,050	$ 2,050
Accretion of debt discount and debt issuance costs - related parties	407	371	338
Interest expense - related parties	$ 2,457	$ 2,421	$ 2,388
Total interest expense	$ 9,830	$ 9,684	$ 9,552

The remaining unamortized debt discount and debt offering costs related to the Company's Convertible Notes of approximately $4.3 million as of December 31, 2019, will be amortized using the effective interest rate over the remaining term of the Convertible Notes of 2.25 years. The annual effective interest rate is 9.48% for the Convertible Notes.

Future payments on the Convertible Notes as of December 31, 2019 are as follows (in thousands):

Year ending December 31,	
2020	$ 8,200
2021	8,200
2022	111,050
Total minimum payments	127,450
Less amount representing interest	(18,450)
Convertible Notes, principal amount	109,000
Less debt discount and debt issuance costs on Convertible Notes	(4,277)
Net carrying amount of Convertible Notes	$ 104,723

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 Borrowings under the Credit Agreement bear interest through maturity at 7.00% per annum plus three month LIBOR ("LIBOR"). The consolidated net sales for UDENYCA® for the fiscal year ending December 31, 2019, exceeded $250.0 million, which will result in an interest rate reduction to 6.75% per annum plus LIBOR effective January 1, 2020. Interest is payable quarterly in arrears and varies with LIBOR. The Company adopted the prospective method to account for future cash payments. Under the prospective method, the effective interest rate is not constant, and any change in the expected cash flows is recognized prospectively as an adjustment to the effective yield. As of December 31, 2019, the effective interest rate is 10.7%.

The Company is 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.

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.

The following table summarizes information about the components of the Term Loan (in thousands):

	December 31, 2019
Principal amount of the Term Loan	$ 75,000
Unamortized debt discount and debt issuance costs	(1,337)
Term Loan	$ 73,663

The following table presents the components of interest expense:

	Year Ended Decemeber 31, 2019
Stated coupon interest	$ 7,063
Accretion of debt discount and debt issuance costs	709
Interest expense	$ 7,772

The remaining unamortized debt discount and debt offering costs related to the Term Loan of approximately $4.3 million as of December 31, 2019, will be amortized using the effective rate over the remaining term of the Term Loan of 5.0 years.

Future payments on the Term Loan as of December 31, 2019 are as follows (in thousands):

Year ending December 31,		
2020	$	7,244
2021		7,224
2022		7,224
2023		39,346
2024 and beyond		47,494
Total minimum payments		108,532
Less amount representing interest		(30,532)
Term Loan, gross		78,000
Less debt discount and debt issuance costs on Term Loan		(4,337)
Net carrying amount of Term Loan	$	73,663

9. Commitments and Contingencies

Purchase Commitments

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

As of December 31, 2019, the Company's non-cancellable purchase commitment was as follows (in thousands):

Year ending December 31,		
2020	$	25,011
2021		30,991
2022		8,403
Total obligations	$	64,405

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.

Contingencies

On March 3, 2017, 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. On May 2, 2019, the Company and Amgen settled the trade secret action brought by Amgen. The details of the settlement are confidential but the Company will continue to market UDENYCA® and began paying a mid-single digit royalty to Amgen for five years starting on July 1, 2019 (see Note 2 – Cost of Goods Sold).

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.

10. Leases

In July 2015, the Company entered into the office space for its corporate headquarters in Redwood City, California under an operating lease agreement, which has been subject to amendments to secure additional space such that the total headquarters leased space is approximately 40,341 square feet. The lease agreement (as amended, the "Lease Agreement") provides for aggregate tenant improvement allowance of $1.4 million, which was amortized as a reduction to rent expense on a straight-line basis over the lease term prior to the adoption of Topic 842 (see Note 2). Additionally, the Lease Agreement, provides for certain limited rent abatement and contains annual scheduled rent increases over the lease term. The lease terminates in November 2022 and contains a one-time option to extend the lease term for five years.

The Company also leases two 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 facilities.

Effective upon the adoption of Topic 842, the Company evaluated the above facility leases and determined that they were all operating leases. In determining the present value of the lease payments, the Company used the incremental borrowing rate based on the information available at the adoption date. The lease option to extend the lease term for five years was not included as part of the right-of-use asset or lease liability as the Company was not reasonably certain it would exercise this option. The Company also performed an evaluation of its other contracts with Customers and suppliers in accordance with Topic 842 and determined that, except for the facility leases described above, none of its contracts contain a lease.

Certain of the Company's lease agreements contain lease components (for example, fixed payments such as rent) and non-lease components such as common-area maintenance costs. Both of these types of provisions are accounted for as a single lease component. For such arrangements, there may be variability in future lease payments as the amount of the non-lease components is typically revised from one period to the next. These variable lease payments, which are primarily comprised of common-area maintenance, utilities, and real estate taxes that are passed on from the lessor in proportion to the space leased by the Company within the entire building or building complex, are recognized in the period in which the obligation for those payments is incurred.

In September 2019, the Company amended the Lease Agreement to secure additional space of approximately 7,448 rentable square feet, which resulted in the total headquarters leased space of approximately 47,789 rentable square feet, and also extended the total headquarters lease term through September 2024. The Lease Agreement amendment contains a one-time option to extend its term for five years. The Company evaluated the above Lease Agreement amendment under Topic 842 and determined that the lease modification did not result in two separate contracts and the lease continues to be an operating lease. Additionally, in determining the present value of the new lease payments, the Company used the incremental borrowing rate based on the information available at lease modification date of September 2019. The lease option to extend the lease term for five years was not included as part of the right-of-use asset or lease liability as the Company was not reasonably certain it would exercise this option.

In October 2019, the Company entered into a new laboratory facility lease ("New Camarillo Lease") of approximately 25,017 square feet in a new location of Camarillo, California as the current Camarillo lease terminates in June 2020 and December 2020. The New Camarillo Lease provides for certain limited rent abatement and annual scheduled rent increases over the lease term. The lease commences in April 2020 and terminates in May 2027, and contains a one-time option to extend the lease term for five years. The future minimum rental payments for this lease are $1.8 million. The Company has not obtained control over the leased facility as of December 31, 2019, as a result, the right-of-use asset and lease liability related to the new Camarillo lease was not reflected in the consolidated financial statements of the Company as of December 31, 2019.

The balance sheet classification of the lease liabilities was as follows (in thousands):

	December 31, 2019
Operating lease liabilities	
Other current liabilities	$ 2,196
Lease liabilities, non-current	10,256
Total operating lease liabilities	$ 12,452

Cash paid for amounts included in the measurement of the lease liabilities for the year ended December 31, 2019 was $2.7 million, and was included in net cash provided by operating activities in the consolidated statements of cash flows.

As of December 31, 2019, the maturities of the operating lease liabilities were as follows (in thousands):

Years ending December 31,	Operating leases
2020	$ 3,141
2021	3,173
2022	3,034
2023	3,171
2024	2,614
Total lease payments	15,133
Less imputed interest	(2,681)
Operating lease liabilities	$ 12,452

As of December 31, 2019, the weighted average remaining lease term was 4.7 years and the weighted average operating discount rate used to determine the operating lease liabilities was 8.2%. Rent expense was $2.4 million, $2.2 million and $2.3 million for the years ended December 31, 2019, 2018 and 2017, respectively.

The following table summarizes minimum future rental commitments related to noncancelable operating leases under the prior lease guidance as of December 31, 2018 (in thousands):

Years ending December 31,	
2019	$ 2,660
2020	2,695
2021	2,672
2022	2,518
Total minimum lease payments	$ 10,545

11. 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 acted as its sales agent (the "ATM Offering Program"). Cowen was 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 had no obligation to sell any shares under the Sales Agreement, and could at any time suspend solicitation and offers under the Sales Agreement. The shares were 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 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. 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 gross proceeds of $8.5 million. After deducting commission of $0.3 million, the net proceeds were $8.2 million. As of January 18, 2019, the Company's Shelf Registration Statement expired and accordingly the ATM Offering Program was terminated.

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.

12. 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, 2019, the Company had 420,581 shares of common stock available for future issuance.

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. As of December 31, 2019, the Company had 230,795 shares of common stock available for future issuance for new employees. The 2016 Plan does not provide for any annual increases in the number of shares available.

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 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, 2018	14,674,553	$ 14.202
Granted - at fair value	5,328,500	15.137
Exercised	(863,940)	6.869
Forfeited/Cancelled	(1,327,442)	17.630
Balances at December 31, 2019	17,811,671	$ 14.582

Additional information related to the status of options as of December 31, 2019 is summarized as follows:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Contractual Terms (Years)	Aggregate Intrinsic Value (in thousands)
Options outstanding	17,811,671	$ 14.582	6.64	$ 93,797
Options vested and exercisable	10,699,012	$ 14.456	5.64	$ 65,412

During the years ended December 31, 2019, 2018 and 2017, the estimated weighted-average grant-date fair value of options granted was $9.52, $7.77 and $11.70 per share, respectively, and the aggregate intrinsic value of options exercised was $10.3 million, $4.9 million and $2.1 million, respectively.

The Company recognized stock-based compensation expenses of $30.0 million, $31.4 million and $29.0 million for the years ended December 31, 2019, 2018 and 2017, respectively, related to employee stock options. As of December 31, 2019, total unrecognized stock-based compensation expenses related to unvested employee stock options was $56.4 million, which is expected to be recognized on a straight-line basis over a weighted-average period of approximately 2.9 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 over two to three years from the applicable grant date, 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.

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, 2018	44,387	$ 12.700
RSUs granted	282,804	15.114
RSUs vested	(214,819)	12.457
RSUs cancelled	(7,622)	15.798
Balances at December 31, 2019	104,750	$ 19.544

The total fair value of RSUs vested was $2.7 million and $1.0 million during the years ended December 31, 2019 and 2018, respectively. The total fair value of RSUs vested during the year ended December 31, 2017 was $2.9 million, which included a $2.7 million bonus payout settled in RSUs. The total estimated grant date fair value of RSUs was $4.3 million and $78,000 during the years ended December 31, 2019 and 2018, respectively. The total estimated grant date fair value of RSUs during the year ended December 31, 2017 was $6.4 million, which included a $4.3 million bonus payout settled in RSUs. The estimated weighted-average grant-date fair value per share of RSUs granted during the years ended December 31, 2019, 2018 and 2017 was $15.11, $15.60 and $10.43, respectively.

The Company recognized stock-based compensation expenses related to RSUs of $0.8 million, $0.7 million and $0.6 million for the years ended December 31, 2019, 2018 and 2017, respectively. As of December 31, 2019, total unrecognized stock-based compensation expenses related to unvested RSUs was $1.3 million, which is expected to be recognized on a straight-line basis over a weighted-average period of approximately 1.2 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 UDENYCA®. The Company recognized stock-based compensation expense of $0.8 million and $0.5 million, and $0 for the years ended December 31, 2019, 2018 and 2017, respectively, related to PSOs.

Nonemployees Stock-Based Compensation

The Company granted 10,000 shares of RSUs and no stock options to purchase shares of common stock to nonemployees during the year ended December 31, 2019. The Company granted 147,500 and 60,000 stock options to purchase shares of common stock to nonemployees during the years ended December 31, 2018 and 2017, respectively. The weighted-average exercise price of the options granted in 2018 and 2017 was $14.32 and $13.47 per share, respectively. For the years ended December 31, 2019, 2018 and 2017, the Company recorded stock-based compensation expense related to options and RSUs granted to nonemployees of $0.7 million, $1.6 million and $1.9 million, respectively. On January 1, 2019, the Company adopted the ASU No. 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting*, 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. Prior to the adoption of ASU No. 2018-07, 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 or a number of shares as determined by the Company's board of directors. The ESPP had 2,316,555 shares of common stock available for future issuance as of December 31, 2019. 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 $1.3 million, $0.8 million and $80,000 for the years ended December 31, 2019, 2018 and 2017, respectively. As of December 31, 2019, there was $0.8 million of unrecognized compensation expense associated with the ESPP, which is expected to be recognized over an estimated weighted-average period of 4.5 months.

Stock-Based Compensation

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

	Year Ended December 31,		
	2019	2018	2017
Cost of goods sold (1)	$ 108	$ —	$ —
Research and development	12,912	15,339	15,104
General and administrative	20,571	19,458	18,293
Stock-based compensation expense	$ 33,591	$ 34,797	$ 33,397
Capitalized stock-based compensation expense into inventory	$ 1,735	$ —	$ —

(1) Stock-based compensation capitalized into inventory is recognized as cost of sales when the related product is sold.

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, 2019, 2018 and 2017:

	Year Ended December 31,		
	2019	2018	2017
Expected term (years)			
Stock options	6.00	6.00	6.00
ESPP	0.50	0.50	0.50
Expected volatility			
Stock options	69%	71%	76%
ESPP	61%	71%	68%
Risk-free interest rate			
Stock options	2.29%	2.77%	2.01%
ESPP	1.89%	2.40%	1.42%
Expected dividend yield			
Stock options	0%	0%	0%
ESPP	0%	0%	0%

Expected Term: The expected term represents the period for which the stock-based awards are expected to be outstanding and is based on the options' vesting term 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, as it has limited historical information to develop expectations about future exercise patterns and post-vesting employment termination behavior.

Expected Volatility: The expected volatility for the year ended December 31, 2019 is based on the Company's historical stock price volatility. The expected volatility for the years ended December 31, 2018 and 2017 is based on an average historical stock price volatility of industry peers as the Company did not have sufficient trading history for its common stock in those reporting periods.

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

401(k) Retirement Plan

In 2019, the Company's Compensation Committee approved the Company's matching of the employees 401(k) Plan (the 401(k) Plan) whereby eligible employees may elect to contribute up to the lesser of 99% of their annual compensation or the statutorily prescribed annual limit allowable under Internal Revenue Service regulations. During 2019, the Company made matching contributions of 50% of the first $6,000 of each participant's contributions into the 401(k) Plan. The Company recorded compensation expense related to the match of $0.8 million for the year ended December 31, 2019.

13. 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 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 2017 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 2017 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, 2019 and 2018.

14. Income Taxes

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

	Year Ended December 31,		
	2019	2018	2017
Domestic	$ 92,584	$ (208,843)	$ (222,674)
Foreign	190	(496)	(15,496)
Total	$ 92,774	$ (209,339)	$ (238,170)

Provision for (benefit from) income taxes (in thousands):

	Year Ended December 31,		
	2019	2018	2017
Current			
Federal	$ —	$ —	$ —
State	2,942	—	—
Foreign	—	—	—
Subtotal	$ 2,942	$ —	$ —
Deferred			
Federal	$ —	$ —	$ —
State	—	—	—
Foreign	—	—	—
Subtotal	$ —	$ —	$ —
Provision for income taxes	$ 2,942	$ —	$ —

Income tax provision for the year ended December 31, 2019 of $2.9 million primarily relates to state taxes in jurisidictions outside of California, for which we have a limited operating history. There was no income tax provision for the years ended December 31, 2018 and 2017 due to the Company's history of losses and valuation of allowances against the 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,		
	2019	2018	2017
Percent of pre-tax income:			
U.S. federal statutory income tax rate	21.00%	21.00%	34.00%
State taxes, net of federal benefit	1.51	0.16	0.80
Foreign rate differences	(0.04)	(0.05)	(2.21)
Permanent items	(0.64)	0.15	(0.19)
Research and development credit	(4.77)	2.61	2.10
Effect in NOLs due to adoption of ASU 2016-09	—	—	4.55
U.S. Tax Reform tax rate change	—	—	(36.90)
Other	0.55	2.23	(0.21)
Change in valuation allowance	(14.44)	(26.10)	(1.94)
Effective income tax rate	3.17%	—%	—%

Significant components of the Company's net deferred tax assets as of December 31, 2019 and 2018 consist of the following (in thousands):

	December 31,	
	2019	2018
Net operating loss carryforwards	$ 138,663	$ 168,753
Research and development credits	43,879	39,891
Depreciation and amortization	7,230	7,901
Stock-based compensation	22,807	17,123
Sales related accruals	7,137	—
Other accruals	6,927	3,942
Gross deferred tax assets	226,643	237,610
Right-of-use asset	(2,396)	—
In-process research and development	(589)	(552)
Gross deferred tax liabilities	(2,985)	(552)
Total net deferred tax asset	223,658	237,058
Less valuation allowance	(223,658)	(237,058)
Net deferred tax assets	$ —	$ —

ASC Topic 740 (“ASC 740”) requires that the tax benefit of net operating losses, temporary differences and credit carry forwards be recorded as an asset to the extent that management assesses that realization is "more likely than not." Realization of the future tax benefits is dependent on our ability to generate sufficient taxable income within the carry forward period. Because of our recent history of operating losses, management believes that recognition of the deferred tax assets arising from the above-mentioned future tax benefits is currently not likely (as defined in ASC 740) to be realized and, accordingly, has provided a valuation allowance. The valuation allowance decreased by $13.4 million during the year ended December 31, 2019 and increased by $54.6 million and $4.6 million during the years ended December 31, 2018 and 2017, respectively.

As of December 31, 2019, the Company had federal net operating loss carryforwards of approximately $642.2 million, which will start to expire beginning in 2035, and various state net operating loss carryforwards of approximately $46.3 million, which have various expiration dates beginning in 2031.

As of December 31, 2019, the Company had federal research and development credit carryforwards for federal income tax purposes of approximately $42.9 million, which will start to expire in 2031, and state research and development credit carryforwards of approximately $15.1 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 weight of the negative evidence, which is primarily its history of losses outweighing other positive evidence, the Company has determined that it is more likely than not that its federal net deferred tax assets and certain state net deferred tax assets will not be realized, and therefore, the federal and certain state net deferred tax assets are fully offset by a valuation allowance at December 31, 2019 and 2018. The deferred tax assets were primarily comprised of net operating losses, tax credit carryforwards and stock-based compensation. 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.

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, 2019, 2018 and 2017 is as follows (in thousands):

	Year Ended December 31,		
	2019	2018	2017
Balance at beginning of year	$ 18,115	$ 15,682	$ 18,682
Additions based on tax positions related to current year	1,206	1,276	3,387
Additions (reductions) for tax positions of prior years	(7,718)	1,157	(6,387)
Balance at end of year	$ 11,603	$ 18,115	$ 15,682

As of December 31, 2019, 2018 and 2017, the Company had approximately $11.6 million, $18.1 million, and $15.7 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, 2019, 2018 and 2017, 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 that impacts the rate for tax positions of prior years.

15. Net Income (Loss) Per Share Attributable to Coherus

The following table sets forth the computation of the basic and diluted net income (loss) per share attributable to the Company (in thousands, except share and per share data):

	Years Ended December 31,		
	2019	2018	2017
Basic net income (loss) per share			
Numerator:			
Net income (loss) attributable to Coherus	$ 89,833	$ (209,339)	$ (238,170)
Denominator:			
Weighted-average common shares outstanding	69,679,916	65,034,827	53,133,620
Basic net income (loss) per share attributable to Coherus	$ 1.29	$ (3.22)	$ (4.48)
Diluted net income (loss) per share			
Numerator:			
Net income (loss) attributable to Coherus	$ 89,833	$ (209,339)	$ (238,170)
Numerator for diluted net income (loss) per share attributable to Coherus	89,833	(209,339)	(238,170)
Denominator:			
Denominator for basic net income (loss) per share attributable to Coherus	69,679,916	65,034,827	53,133,620
Add effect of potential dilutive securities:			
Stock options, including purchases from contributions to ESPP	3,491,272	—	—
Restricted stock units	14,755	—	—
Denominator for diluted net income (loss) per share attributable to Coherus	73,185,943	65,034,827	53,133,620
Diluted net income (loss) per share attributable to Coherus	$ 1.23	$ (3.22)	$ (4.48)

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

	Year Ended December 31,		
	2019	2018	2017
Stock options, including purchases from contributions to ESPP	10,412,471	14,743,547	11,433,069
Restricted stock units	22,068	44,387	120,377
Shares issuable upon conversion of Convertible Notes	4,473,871	4,473,871	4,473,871
Total	14,908,410	19,261,805	16,027,317

16. 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. The Company recognized $1.5 million and $8.2 million during years ended December 31, 2018 and 2017, 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 was a partner of a firm that provided recruiting services to the Company. As such, the recruiting services provided were deemed to be related party transactions. As of December 31, 2019 and 2018, 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, $52,000, $130,000 and $17,000 for the years ended December 31, 2019, 2018 and 2017, respectively, for services rendered by the recruiting company. The Company recorded in selling, general and administrative expense in its consolidated statements of operations, $1,000, $181,000 and $62,000 for the years ended December 31, 2019, 2018 and 2017, 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 8 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.

17. Subsequent Events

On January 13, 2020, Coherus BioSciences, Inc. (the "Company") entered into a license agreement (the "License Agreement") with Innovent Biologics (Suzhou) Co., Ltd. ("Innovent") for the development and commercialization of a biosimilar version of bevacizumab (Avastin®) in any dosage form and presentations ("bevacizumab Licensed Product") in the United States and Canada (the "Territory"). Under the License Agreement, Innovent granted to the Company an exclusive, royalty-bearing license to develop and commercialize the bevacizumab Licensed Product in the field of treatment, prevention or amelioration of any human diseases and conditions as included in the label of Avastin®. Under the License Agreement, the Company also acquired an option to develop

and commercialize Innovent's biosimilar version of rituximab (Rituxan®) in any dosage form and presentations (the "rituximab Licensed Product" and together with the bevacizumab Licensed Product, the "Licensed Products") in the Territory. Subject to the terms of the License Agreement, the Company may exercise its option within 12 months of its receipt of certain regulatory materials from Innovent. Following the Company's option exercise, Innovent's biosimilar version of rituximab would be deemed a Licensed Product for all purposes of the License Agreement and Innovent would grant to the Company an exclusive, royalty-bearing license to develop and commercialize Innovent's biosimilar version of rituximab in the field of treatment, prevention or amelioration of any human diseases and conditions as included in the label of Rituxan®.

Innovent will supply the Licensed Products to the Company in accordance with a manufacturing and supply agreement to be executed by the parties. Under the License Agreement, the Company acquired the right to require Innovent to perform technology transfer for the manufacturing of the Licensed Products in the Territory and, upon completion of such technology transfer, the Company will have the exclusive right to manufacture the Licensed Products in the Territory.

The Company will pay Innovent an upfront payment of $5.0 million. Additionally, the Company is obligated to pay Innovent an aggregate of up to $40.0 million in milestone payments in connection with the achievement of certain development, regulatory and sales milestones with respect to the bevacizumab Licensed Product and, if the Company's option is exercised, an aggregate of up to $40.0 million in milestone payments in connection with the achievement of certain development, regulatory and sales milestones with respect to the rituximab Licensed Product. The Company will share a percentage of net sales of Licensed Products with Innovent in the mid-teens to low twenty percent range. If the Company exercises its option, it would be required to pay an option exercise fee of $5.0 million. Subject to the terms of the License Agreement, if the Company requests Innovent to perform technology transfer for the manufacturing of the Licensed Products, it would be required to pay up to $10.0 million for fees related thereto.

18. Supplementary Data – Quarterly Financial Data (Unaudited)

The following table presents certain unaudited consolidated quarterly financial information for each of the quarters ended December 31, 2019 and 2018:

	2019 Quarter End			
(in thousands, except per share data)	March 31	June 30	September 30	December 31
Total revenue	$ 37,098	$ 83,433	$ 111,684	$ 123,856
Gross profit	34,873	82,832	105,237	116,051
Total operating expenses	53,697	55,940	59,843	78,823
Net income (loss)	(20,004)	23,567	47,043	39,227
Net income (loss) per share attributable to Coherus:				
Basic	(0.29)	0.34	0.67	0.56
Diluted	(0.29)	0.32	0.63	0.53

	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)

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, 2019. 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, 2019, 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, 2019, 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, 2019 and 2018, and the related consolidated statements of operations, comprehensive income (loss), stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2019, and the related notes and our report dated February 27, 2020 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 27, 2020

Changes in Internal Control Over Financial Reporting.

During the year ended December 31, 2019, we implemented certain internal controls in connection with our product launch and our adoption of Topic 842. There were no other 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, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. ***Other Information***

Not applicable.

PART III

Certain information required by Part III is omitted from this Annual Report on From 10-K because the Company will file a Definitive Proxy Statement with the Securities and Exchange Commission within 120 days after the end of our year ended December 31, 2019.

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.

Item 16. ***Form 10-K Summary***

None.

INDEX TO EXHIBITS

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
3.1	Amended and Restated Certificate of Incorporation.	8-K	11/13/2014	3.1	
3.2	Amended and Restated Bylaws.	8-K	11/13/2014	3.2	
4.1	Reference is made to exhibits 3.1 and 3.2.				
4.2	Form of Common Stock Certificate.	S-1/A	10/24/2014	4.2	
4.3	Description of Coherus' Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934.				X
10.1†	License Agreement, effective January 23, 2012, by and between Daiichi Sankyo Company, Limited and BioGenerics, Inc.	S-1/A	10/20/2014	10.1	
10.2†	Distribution Agreement, effective December 26, 2012, by and between Orox Pharmaceuticals B.V. and Coherus BioSciences, Inc.	S-1	9/25/2014	10.3	
10.3†	Commercial License Agreement, effective April 8, 2011, by and between Selexis SA and BioGenerics, Inc.	S-1	9/25/2014	10.5	
10.4†	Commercial License Agreement, effective June 25, 2012, by and between Selexis SA and Coherus BioSciences, Inc.	S-1	9/25/2014	10.6	
10.5	Agreement and Plan of Merger, dated January 8, 2014, by and among Coherus BioSciences, Inc., Coherus Intermediate Corp., Coherus Acquisition Corp., InteKrin Therapeutics Inc., and Fortis Advisors LLC.	S-1	9/25/2014	10.7	
10.6(a)	Standard Industrial/Commercial Multi-tenant Lease-Gross, effective December 5, 2011, by and between Howard California Property Camarillo 5 and BioGenerics, Inc.	S-1	9/25/2014	10.9(a)	
10.6(b)	First Amendment to Lease, effective December 21, 2013, by and between Howard California Property Camarillo 5 and Coherus BioSciences, Inc.	S-1	9/25/2014	10.9(b)	
10.7(a)#	BioGenerics, Inc. 2010 Equity Incentive Plan, as amended.	S-1	9/25/2014	10.10(a)	
10.7(b)#	Form of Stock Option Grant Notice and Stock Option Agreement under the 2010 Equity Incentive Plan, as amended.	S-1	9/25/2014	10.10(b)	
10.8(a)#	Coherus BioSciences, Inc. 2014 Equity Incentive Award Plan.	S-1/A	10/24/2014	10.11	
10.8(b)#	Form of Stock Option Grant Notice and Stock Option Agreement under the 2014 Equity Incentive Award Plan.	S-1/A	11/4/2014	10.11(b)	
10.8(c)#	Form of Restricted Stock Award Grant Notice and Restricted Stock Award Agreement under the 2014 Equity Incentive Award Plan.	S-1/A	11/4/2014	10.11(c)	
10.8(d)#	Form of Restricted Stock Unit Award Grant Notice and Restricted Stock Unit Award Agreement under the 2014 Equity Incentive Award Plan.	S-1/A	11/4/2014	10.11(d)	
10.9#	Coherus BioSciences, Inc. 2014 Employee Stock Purchase Plan.	S-1/A	10/24/2014	10.12	
10.10#	Form of Indemnification Agreement between Coherus BioSciences, Inc. and each of its directors, officers and certain employees.	S-1/A	10/24/2014	10.13	
10.11†	Master Services Agreement, effective January 23, 2012, by and between Medpace, Inc. and BioGenerics, Inc.	S-1	9/25/2014	10.15	

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
10.12(a)†	Task Order Number 13, effective October 18, 2013, by and between Medpace, Inc. and Coherus BioSciences, Inc.	S-1	9/25/2014	10.16(a)	
10.12(b)†	Amendment Number 1 to Task Order Number 13, effective April 23, 2014, by and between Medpace, Inc. and Coherus BioSciences, Inc.	S-1	9/25/2014	10.16(b)	
10.12(c)†	Amendment Number 2 to Task Order Number 13, effective May 21, 2014, by and between Medpace, Inc. and Coherus BioSciences, Inc.	S-1	9/25/2014	10.16(c)	
10.12(d)†	Amendment Number 3 to Task Order Number 13, effective May 30, 2014, by and between Medpace, Inc. and Coherus BioSciences, Inc.	S-1	9/25/2014	10.16(d)	
10.12(e)†	Amendment Number 4 to Task Order Number 13, effective August 19, 2014, by and between Medpace, Inc. and Coherus BioSciences, Inc.	S-1	9/25/2014	10.16(e)	
10.13(a)†	Task Order Number 20, effective November 8, 2013, by and between Medpace, Inc. and Coherus BioSciences, Inc.	S-1/A	10/24/2014	10.17(a)	
10.13(b)†	Amendment Number 1 to Task Order Number 20, effective April 23, 2014, by and between Medpace, Inc. and Coherus BioSciences, Inc.	S-1/A	10/24/2014	10.17(b)	
10.13(c)†	Amendment Number 2 to Task Order Number 20, effective June 27, 2014, by and between Medpace, Inc. and Coherus BioSciences, Inc.	S-1/A	10/24/2014	10.17(c)	
10.13(d)†	Amendment Number 3 to Task Order Number 20, effective September 5, 2014, by and between Medpace, Inc. and Coherus BioSciences, Inc.	S-1/A	10/24/2014	10.17(d)	
10.14(a)†	Master Services Agreement, effective February 27, 2015, by and between a contract research organization and Coherus BioSciences, Inc.	10-Q	5/11/2015	10.2(a)	
10.14(b)†	Work Order #1, effective March 31, 2015, by and between a contract research organization and Coherus BioSciences, Inc.	10-Q	5/11/2015	10.2(b)	
10.15	Task Order Number 23, effective November 12, 2014, by and between Medpace, Inc. and Coherus BioSciences, Inc.	10-Q	8/10/2015	10.1	
10.16	New Office Lease, effective July 6, 2015, by and between Hudson 333 Twin Dolphin Plaza, LLC and Coherus BioSciences, Inc.	10-Q	8/10/2015	10.3	
10.17	First Amendment, effective August 10, 2015, by and between Hudson 333 Twin Dolphin Plaza, LLC and Coherus BioSciences, Inc.	10-Q	8/10/2015	10.4	
10.18	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).	8-K	2/29/2016	10.1	
10.19	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.	10-Q	5/9/2016	10.2	
10.20(a)	Coherus BioSciences, Inc. 2016 Employment Commencement Incentive Plan.	10-Q	8/9/2016	10.1(a)	
10.20(b)	Form of Stock Option Grant Notice and Stock Option Agreement under the Coherus BioSciences, Inc. 2016 Employment Commencement Incentive Plan.	10-Q	8/9/2016	10.1(b)	
10.20(c)	Form of Restricted Stock Unit Award Grant Notice and Restricted Stock Unit Award Agreement under the Coherus BioSciences, Inc. 2016 Employment Commencement Incentive Plan.	10-Q	8/9/2016	10.1(c)	

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
10.20(d)	Form of Restricted Stock Award Grant Notice and Restricted Stock Award Agreement under the Coherus BioSciences, Inc. 2016 Employment Commencement Incentive Plan.	10-Q	8/9/2016	10.1(d)	
10.21	Second Amendment, dated September 21, 2016, by and between Hudson 333 Twin Dolphin Plaza, LLC and Coherus BioSciences, Inc.	8-K	9/26/2016	10.1	
10.22	Stock Purchase Agreement, dated as of August 21, 2017, by and between Coherus BioSciences, Inc. and V-Sciences Investments Pte Ltd.	8-K	8/22/2017	10.1	
10.23	Stock Purchase Agreement, dated as of November 30, 2017, by and between Coherus BioSciences, Inc. and KBI Biopharma, Inc.	8-K	12/5/2017	10.1	
10.24	Letter Agreement to Master Service Agreement, dated as of September 6, 2017, by and between Medpace, Inc. and Coherus BioSciences, Inc.	10Q	11/06/2017	10.2	
10.25	Credit Agreement, dated as of January 7, 2019, by and between Coherus Biosciences, Inc. and affiliates of Healthcare Royalty Partners	8-K	1/11/2019	10.1	
10.26†	Confidential Litigation Settlement Agreement and Release, dated as of April 30, 2019 between Amgen Inc. and Amgen USA Inc. (collectively "Amgen"), and Coherus BioSciences Inc.	10-Q	8/5/2019	10.1	
10.27	Third Amendment, effective May 24, 2019, by and between Hudson 333 Twin Dolphin Plaza, LLC and Coherus BioSciences, Inc.	10-Q	11/8/2019	10.1	
10.28	Fourth Amendment, effective September 4, 2019, by and between Hudson 333 Twin Dolphin Plaza, LLC and Coherus BioSciences, Inc.		11/8/2019	10.2	
10.29††	License Agreement, dated November 4, 2019, by and between Coherus BioSciences, Inc. and Bioeq IP AG				X
10.30††	License Agreement, dated January 13, 2020, by and between Coherus BioSciences, Inc. and Innovent Biologics (Suzhou) Co., Ltd.				X
23.1	Consent of Independent Registered Public Accounting Firm				X
24.1	Power of Attorney (included in the signature page to this Form 10-K)				X
31.1	Certification of Principal Executive Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.				X
31.2	Certification of Principal Financial Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.				X
32.1	Certification of Principal Executive Officer and Principal Financial Officer Required Under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. §1350.				X
101.INS*	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.				X
101.SCH*	Inline XBRL Taxonomy Extension Schema Document				X
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document				X
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document				X
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document				X

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document				X
104	The cover page from the Company's Annual Report on Form 10-K for the year ended December 31, 2019 has been formatted in Inline XBRL.				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.

†† Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment or pursuant to Regulation S-K, Item 601(b)(10). Such omitted information is not material and would likely cause competitive harm to the registrant if publicly disclosed. Additionally, schedules and attachments to this exhibit have been omitted pursuant to Regulation S-K, Item 601(a)(5).

# 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 27, 2020

By: /s/ Dennis M. Lanfear
Name: Dennis M. Lanfear
Title: President and Chief Executive Officer
(Principal Executive Officer)

POWER OF ATTORNEY

KNOW ALL MEN AND WOMEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Dennis M. Lanfear and Jean-Frédéric Viret, his attorneys-in-fact, for him or her in any and all capacities, to sign any amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the U.S. Securities and Exchange Commission, hereby ratifying and confirming all that said attorney-in-fact, or his substitute, may do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

/s/ Dennis M. Lanfear Dennis M. Lanfear	Chairman, President and Chief Executive Officer *(Principal Executive Officer)*	February 27, 2020
/s/ Jean-Frédéric Viret, Ph.D. Jean-Frédéric Viret, Ph.D.	Chief Financial Officer *(Principal Financial and Accounting Officer)*	February 27, 2020
/s/ James I. Healy, M.D., Ph.D. James I. Healy, M.D., Ph.D.	Director	February 27, 2020
/s/ V. Bryan Lawlis, Ph.D. V. Bryan Lawlis, Ph.D.	Director	February 27, 2020
/s/ Samuel R. Nussbaum Samuel R. Nussbaum, M.D.	Director	February 27, 2020
/s/ Christos Richards Christos Richards	Director	February 27, 2020
/s/ Ali J. Satvat Ali J. Satvat	Director	February 27, 2020
/s/ Mary T. Szela Mary T. Szela	Director	February 27, 2020
/s/ Mats Wahlström Mats Wahlström	Director	February 27, 2020

Exhibit 4.3

DESCRIPTION OF COHERUS' SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

As of December 31, 2019, Coherus Biosciences, Inc. ("CHRS") had common stock, $0.0001 par value per share, registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and listed on The Nasdaq Stock Market LLC under the trading symbol "CHRS."

DESCRIPTION OF COMMON STOCK

The following description of CHRS's common stock is a summary. This summary is subject to the General Corporation Law of the State of Delaware (the "**DGCL**") and the complete text of CHRS's amended and restated certificate of incorporation (the "**certificate of incorporation**") and amended and restated bylaws (the "**bylaws**"), filed as Exhibits 3.1 and 3.2, respectively, to CHRS's Annual Report on Form 10-K. We encourage you to read that law and those documents carefully.

Common Stock

General

The certificate of incorporation authorizes 300,000,000 shares of common stock, $0.0001 par value per share.

Voting Rights

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

Dividends

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

Liquidation

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

Rights and Preferences

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

Fully Paid and Nonassessable

All outstanding shares of common stock are fully paid and non-assessable.

Annual Stockholder Meetings

The certificate of incorporation and bylaws provide that annual stockholder meetings will be held at a date, place (if any) and time as designated by resolution of the board of directors from time to time. To the extent permitted under applicable law, we may but are not obligated to conduct meetings by remote communications, including by webcast.

Anti-Takeover Effects of Provisions

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

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

Delaware Anti-Takeover Statute

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

Undesignated Preferred Stock

Under CHRS's amended and restated certificate of incorporation, CHRS's board of directors has the authority, without action by CHRS's stockholders, to designate and issue up to 5,000,000 shares of preferred stock, par value $0.0001 per share, in one or more series and to designate the rights, preferences and privileges of each series, any or all of which may be greater than the rights of CHRS common stock. It is not possible to state the actual effect of the issuance of any shares of preferred stock upon the rights of holders of CHRS common stock until CHRS's board of directors determines the specific rights of the holders of preferred stock. However, the effects might include, among other things, restricting dividends on the common stock, diluting the voting power of the common stock, impairing the liquidation rights of the common stock and delaying or preventing a change in control of CHRS common stock without further action by CHRS's stockholders and may adversely affect the market price of CHRS common stock. As of January 31, 2020, no shares of CHRS's preferred stock were outstanding.

Special Stockholder Meetings

The bylaws provide that a special meeting of stockholders may be called by the secretary of CHRS only at the direction of the board of directors pursuant to a resolution adopted by a majority of the board of directors.

Requirements for Advance Notification of Stockholder Nominations and Proposals

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

Composition of the Board of Directors; Election and Removal of Directors; Filling Vacancies

CHRS's board of directors is divided into three classes. The directors in each class will serve for a three-year term, one class being elected each year by CHRS's stockholders, with staggered three-year terms. Only one class of directors will be elected at each annual meeting of CHRS's stockholders, with the other classes continuing for the

remainder of their respective three-year terms. Furthermore, the size of the board of directors shall be determined from time to time exclusively by the board of directors pursuant to a resolution adopted by the board of directors, provided the board of directors may not consist of fewer than one member. In addition, a vote of not less than sixty-six and two-thirds percent (66 2/3%) of all outstanding shares of CHRS capital stock is required for removal of a director only for cause (and a director may only be removed for cause). Furthermore, any vacancy on the board of directors, including a vacancy resulting from an increase in the size of the board, may be filled only by a majority vote of the board of directors then in office, although less than a quorum, or by a sole remaining director. This system of electing and removing directors and filling vacancies may tend to discourage a third party from making a tender offer or otherwise attempting to obtain control of CHRS, because it generally makes it more difficult for stockholders to replace a majority of the directors.

Amendment of the Certificate of Incorporation and Bylaws

Amendment of any of the above anti-takeover provisions set forth in the certificate of incorporation, except for the the provision making it possible for the board to issue "blank check" preferred stock, would require approval by holders of at least sixty-six and two-thirds percent (66 2/3%) of the voting power of the then outstanding voting stock. Subject to limitations set forth in the bylaws or the certificate of incorporation, the board is expressly empowered to adopt, amend or repeal the bylaws. Stockholders shall have the power to amend the bylaws provided that any such amendment would require approval by holders of at least sixty-six and two-thirds percent (66 2/3%) of the voting power of the then outstanding voting stock.

The provisions of the DGCL, the certificate of incorporation and bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of CHRS common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in the management of CHRS. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

Limitations of Liability and Indemnification Matters

The certificate of incorporation contains provisions that limit the liability of the directors and officers for monetary damages to the fullest extent permitted by Delaware law. Consequently, directors and officers are not personally liable to CHRS or its stockholders for monetary damages for any breach of fiduciary duties as directors, except liability for:

- any breach of the director’s or officer’s duty of loyalty to CHRS or its stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the DGCL; or
- any transaction from which the director or officer derived an improper personal benefit.

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

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

Stock Exchange Listing

Shares of common stock are listed on Nasdaq under the symbol "CHRS."

No Sinking Fund

The shares of common stock have no sinking fund provisions.

Transfer Agent and Registrar

The transfer agent and registrar for CHRS common stock is Equiniti Trust Company Shareowner Services. The transfer agent and registrar's address is Equiniti Trust Company Shareowner Services, P.O. Box 64854, St. Paul, MN 55164-0854.

Exhibit 10.29

Confidential
Execution Version

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and would likely cause competitive harm to the registrant if publicly disclosed.

NOV 02, 2019

BIOEQ IP AG

AND

COHERUS BIOSCIENCES, INC.

LICENSE AND DEVELOPMENT AGREEMENT

CONTENTS

LICENSE AND DEVELOPMENT AGREEMENT

This LICENSE AND DEVELOPMENT AGREEMENT (this ***Agreement***) is entered into effective as of Nov. 02, 2019 (the ***Effective Date***) by and between ***Bioeq IP AG***, having its place of business at [***] (***Bioeq***) and ***Coherus BioSciences, Inc.***, having its principal place of business at 333 Twin Dolphin Drive, Suite 600, Redwood City, CA, 94065, USA (***Licensee***).

Bioeq and Licensee shall also each individually be referred to herein as a ***Party***, and shall be referred to jointly as the ***Parties***.

RECITALS

WHEREAS, Bioeq is a specialized biosimilar company;

WHEREAS, Bioeq is the owner or exclusive licensee of all right, title and interest to certain products which are being developed as biosimilars to pharmaceutical products comprising the monoclonal antibody fragment Ranibizumab and currently marketed in the field of ophthalmology under the brand name Lucentis®;

WHEREAS, Licensee is a company focused on the development and commercialization of biosimilar products; and

WHEREAS, Licensee wishes to obtain an exclusive license from Bioeq for the commercialization of Ranibizumab biosimilar products being developed by Bioeq in the United States of America in consideration for upfront, milestone and royalty payments to Bioeq, and Bioeq is willing to grant such license subject to the terms and conditions of this Agreement.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants set forth below, the Parties hereby agree as follows:

1.DEFINITIONS AND INTERPRETATION

For purposes of this Agreement, the capitalized terms used in this Agreement shall have the respective meanings set forth in this Section 1 below.

1.1 ***Affiliate*** means with respect to any Party, (a) any legal entity of which the securities or other ownership interests representing more than 50% of the equity or more than 50% of the ordinary voting power or more than 50% of the general partnership interest are, at the time such determination is being made, owned, controlled or held, directly or indirectly, by such legal entity; or (b) any legal entity which, at the time such determination is being made, is controlling or under common control with, such Party. As used in this definition, the term “control”, whether used as a noun or verb, refers to the possession, directly or indirectly, of the power to direct, or cause the direction of, the management or policies of a legal entity, whether through the ownership of voting securities, by contract or otherwise.

1.2 ***Agreement*** shall have the meaning ascribed to it in the introductory paragraph above.

1.3 ***Applicable Law*** means any and all applicable federal, state, local and international laws, rules and regulations, including regulations of competent Regulatory Authorities and environmental laws, as amended from time to time, and the regulations promulgated thereunder, as amended from time to time.

1.4 **[***]**

1.5 ***Biologics License Application*** or ***BLA*** means a request for permission to introduce, or deliver for introduction, a biologic product into interstate commerce (21 CFR 601.2) to the FDA, including any supplements, addendums, or amendments thereto. For the avoidance of doubt, the term Biologics License Application or BLA shall include any Abbreviated Biologics License Application.

1.6 ***Biologics License Application Approval*** means issuance of a Department of Health and Human Services U.S. License under 351(k) of the Public Health Services Act controlling the manufacture and sale of biologic products or any successor statutory provisions thereof.

1.7 ***BPCIA*** means the Biologics Price Competition and Innovation Act of 2009, as amended.

1.8 ***CMO*** means contract manufacturing organization.

1.9 ***Commercially Reasonable Efforts*** means, with respect to the efforts to be used by a Party under this Agreement with respect to the Licensed Products, those efforts and resources normally used by a major pharmaceutical or a sufficiently financed biotechnology company for a product owned by it, or to which it has rights, which is of similar market potential at comparable stages of development, taking into account the competitiveness of the marketplace, the proprietary position of the product, the performance of other products that are of similar market potential and the likely timing of other product's entry into the market, the regulatory structure involved, the profitability of the applicable product, relevant Third Party intellectual property necessary to manufacture or Commercialize the Licensed Product and other relevant factors commonly considered in similar circumstances, including technical, legal, scientific or medical factors.

1.10 ***Commercialization*** means the conduct of all activities undertaken before and after Regulatory Approval relating to the promotion, marketing, sale and distribution (including importing, exporting, transporting, customs clearance, warehousing, invoicing, handling and delivering products to customers) of pharmaceutical products, including: (a) sales force efforts, detailing, advertising, medical education, planning, marketing, sales force training and sales and distribution; and (b) scientific and medical affairs. For clarity, Commercialization does not include any Development activities, whether conducted before or after Regulatory Approval. "***Commercialize***" and "***Commercializing***" have correlative meanings.

1.11 ***Competitive Product*** means (i) any product which contains Ranibizumab and is either a Reference Product or a biosimilar to a Reference Product, but excluding in any case the Licensed Products, (ii) [***] (but for clarity [***]) or (iii) [***] (but for clarity [***]).

1.12 ***Competitor*** means any person or entity (other than the Parties and their Affiliates) which has initiated and is then-active in [***] the marketing, selling or distribution of a Competitive Product, [***] in the Territory, as well as any Affiliate of any such person or entity.

1.13 ***Competitor Change of Control*** means any of the following events after the Effective Date:

(a) any Competitor (i) becomes the beneficial owner, directly or indirectly, of shares of capital stock or other interests (including partnership interests) of the Licensee then outstanding and normally entitled (without regard to the occurrence of any contingency) to vote in the election of the directors, managers or similar supervisory positions (***Voting Stock***) of such Party representing more than fifty percent (50%) of the total voting power of all outstanding classes of Voting Stock of the Licensee or (ii) has the power, directly or indirectly, to appoint a majority of the Licensee's managing directors or to elect a majority of the members of the Licensee's board of directors, supervisory board or similar governing body (***Board of Directors***); or

(b) the Licensee enters into a merger, consolidation or similar transaction with a Competitor (whether or not such Party is the surviving entity) and as a result of such merger, consolidation or similar transaction (i) the managing directors or the members of the Board of Directors of the Licensee immediately prior to such transaction constitute less than a majority of the managing directors or the members of the Board of Directors of the Licensee or such surviving person immediately following such transaction or (ii) the persons that beneficially owned, directly or indirectly, the shares of Voting Stock of the Licensee immediately prior to such transaction cease to beneficially own, directly or indirectly, shares of Voting Stock of the Licensee representing a majority of the total voting power of all outstanding classes of Voting Stock of the surviving person in substantially the same proportions as their ownership of Voting Stock of the Licensee immediately prior to such transaction.

1.14 ***Confidential Information*** means, with respect to a Party, all Know-How and all other proprietary information of such Party, including information on the business, affairs, research and development activities, results of non-clinical and clinical trials, national and multinational regulatory proceedings and affairs, finances, plans, contractual relationships and operations of such Party. Furthermore, the terms and conditions of this Agreement shall be considered Confidential Information of both Parties. For the avoidance of doubt, all Know-How and proprietary information relating to the Licensed Products generated by or on behalf of Bioeq and provided to Licensee hereunder shall be considered Confidential Information of Bioeq.

1.15 ***Control*** (whether used as a noun or as a verb) or ***Controlled*** means, with respect to any Intellectual Property Right, Trademark or Know-How, the possession (whether by ownership or license, other than pursuant to this Agreement) by a Party of the ability to grant to the other Party access or a license as provided herein under such Intellectual Property Right, Trademark or Know-How without violating the terms of any agreement or other arrangements with any Third Party.

1.16 ***Damages*** shall have the meaning ascribed to it in Section 9.4.3.

1.17 ***Defend*** or ***Defense*** shall have the meaning ascribed to it in Section 9.4.2.

1.18 ***Development*** means all non-clinical and clinical research and drug development activities as well as Manufacturing process development, upscaling of the Manufacturing process and chemistry, manufacturing and control development work conducted in respect of any pharmaceutical product, including those necessary to obtain Regulatory Approval for such pharmaceutical product. When used as a verb, ***Develop*** means to engage in ***Development***.

1.19 ***Disclosing Party*** shall have the meaning ascribed to it in Section 11.1.

1.20 ***Effective Date*** shall have the meaning ascribed to it in the introductory paragraph above.

1.21 ***Existing Reference Product*** shall have the meaning ascribed to it in Section 1.61.

1.22 ***FDA*** means the United States Food and Drug Administration, and any successor agency thereto.

1.23 ***Field*** means any human use of the Licensed Product in the field of ophthalmology and for any other approved labelled indication of such Licensed Products.

1.24 ***First Commercial Sale*** means, with respect to any Licensed Product in the Territory, the first sale by Licensee or its Affiliates of such Licensed Product to a Third Party for use in the Field in the Territory, after such Licensed Product has been granted Regulatory Approval for use in the Field in the Territory.

1.25 **[***]** means [***]

1.26 **[***]** ***Agreement*** means the license agreement existing between Bioeq and [***] dated as of [***] and attached to this Agreement as Annex 1.

1.27 ***Gross Margin*** means Net Sales for the sale of any Licensed Product less (a) [***] the supply price paid by Licensee or its Affiliates to Bioeq for the supply of such Licensed Product under the Manufacturing and Supply Agreement (including any Sales Tax thereon paid by Licensee to Bioeq and not refunded back to Licensee in accordance with Section 8.1) [***], (b) Damages, and (c) Qualifying IP Clearance Litigation Costs. Gross Margin will be calculated on a Licensed Product-by-Licensed Product and calendar quarter-by-calendar quarter basis in accordance with Section 7.3.3.

1.28 ***Improvement*** means any Invention developed, conceived or reduced to practice by or on behalf of either Party in relation to any Licensed Product during the term of this Agreement, but for clarity excluding any New Products.

1.29 ***Indemnified Party*** shall have the meaning ascribed to it in Section 13.3(a).

1.30 ***Indemnifying Party*** shall have the meaning ascribed to it in Section 13.3(a).

1.31 ***Infringement Claim*** shall have the meaning ascribed to it in Section 9.4.2.

1.32 ***Insolvency Event*** means:

1.32.1 In relation to Licensee: (a) the making by it of a general assignment for the benefit of creditors; (b) the commencement by it of any voluntary petition in bankruptcy or suffering by it of the filing of an involuntary petition of its creditors; (c) the suffering by it of the appointment of a receiver to take possession of all, or substantially all, of its assets; (d) the suffering by it of the attachment or other judicial seizure of all, or substantially all, of its assets; (e) the admission by it in writing of its inability to pay its debts as they come due; or (f) the making by it of an offer of settlement, extension or composition to its creditors generally.

1.32.2 In relation to Bioeq: (a) its over-indebtedness (*Überschuldung*), (b) its inability to make payments as and when they fall due (*Zahlungsunfähigkeit*), (c) it ceasing to make payments on account of debts as and when they fall due (Zahlungseinstellung), (d) the commencement of negotiations with its creditors with a view to rescheduling its indebtedness, (e) the initiation by Bioeq of any proceedings for bankruptcy (*Konkurs*), the postponement of bankruptcy (*Konkursaufschub*) or the grant of a composition moratorium (*Nachlassstundung*), (f) the opening of proceedings for bankruptcy, the postponement of bankruptcy or the grant of a composition moratorium with respect to Bioeq upon request of a Third Party (g) the sequestration (*Arrestierung*), attachment or seizure of, or the appointment of a receiver or administrator with respect to, all or substantially all of its assets or (f) the occurrence of any event which is similar in its effect to (a) through (f) under any Applicable Laws.

1.33 ***Intellectual Property Rights*** means, with respect to any technology, (a) all Patent Rights which claim or cover such technology, and (b) all other existing and future intellectual property rights (but not any Know-How) relating to such technology, including all legally protected trade secrets, copyrights and other intellectual property rights of any kind, but excluding any Trademark.

1.34 ***In-Licensed Licensed Patents*** means all Licensed Patents which are exclusively in-licensed by Bioeq, including those Patent Rights exclusively in-licensed by Bioeq from [***] pursuant to the [***] Agreement ([***]-Licensed Patents).

1.35 ***Invention*** means any invention, technology, improvement, change, modification or enhancement developed, conceived or reduced to practice by or on behalf of either Party during the term of this Agreement.

1.36 ***Know-How*** means all technical, scientific and other information, inventions, discoveries, trade secrets, knowledge, technology, means, methods, processes, practices, formulae, instructions, skills, techniques, procedures, expressed ideas, technical assistance, designs, drawings, assembly procedures, computer programs, apparatuses, specifications, Development information, results, non-clinical, clinical, safety, process and Manufacturing and quality control data and information (including trial designs and protocols), registration dossiers and assay and biological methodology, in each case, solely to the extent confidential and proprietary and in written, electronic or any other form now known or hereafter developed.

1.37 ***Launch Readiness*** means with respect to a Licensed Product, the date on which all of the following requirements are fulfilled: (a) Regulatory Approval for that Licensed Product (*i.e.*, either a Vial Product or a PFS Product) has been obtained in the Territory and (b) the Launch Order (as defined in Annex 2) of that Licensed Product have been released and made available for delivery by Bioeq (unless later rejected for nonconformity) by the agreed upon date of First Delivery (as defined in Annex 2) [***]

1.38 ***Licensed Patents*** means all Patent Rights Controlled by Bioeq during the term of this Agreement that, but for the license granted by Bioeq to Licensee pursuant to Section 2.1 hereunder, would be infringed or misappropriated by Licensee's use, sale, offering for sale or import of the Licensed Products in the Territory in the Field. The Licensed Patents existing as of the Effective Date are listed in Schedule 1.38.

1.39 ***Licensed Product*** means the finished dosage forms (including final packaging) of the biosimilars containing Ranibizumab which have been Developed and/or are being Developed by Bioeq to each of the Existing Reference Products ([***]). For clarity, Licensed Products include without limitation Vial Products and PFS Products, and shall extend to any New Products to the extent this Agreement is amended in accordance with Section 3.4

1.40 ***Licensed Technology*** means all Intellectual Property Rights and Know-How Controlled by Bioeq during the term of this Agreement that, but for the license granted by Bioeq to Licensee pursuant to Section 2.1 hereunder, would be infringed or misappropriated by Licensee's use, sale, offering for sale or import of the Licensed Products in the Territory in the Field. For clarity, the Licensed Technology includes the Licensed Patents.

1.41 ***Licensee Cure Period*** shall have the meaning ascribed to it in Section 15.2.2.

1.42 **[***]** shall [***]

1.43 **[***]** means [***]

1.44 **[***]** means [***] the company engaged by [***] and/or Bioeq for the Development of the Manufacturing process relating to the Licensed Products and related activities.

1.45 ***Losses*** shall have the meaning ascribed to it in Section 13.1.

1.46 ***Manufacture*** or ***Manufacturing*** means to process, prepare, make or have made and analyse one or more pharmaceutical products, including the recombinant production of Ranibizumab and the conversion of Ranibizumab into Licensed Products, and all subsequent packaging and labelling, sterilization, quality control and other testing steps.

1.47 ***Manufacturing and Supply Agreement*** shall have the meaning assigned to it in Section 5.2.

1.48 [***]

1.49 ***Net Sales*** means the actual gross amount invoiced by Licensee or its Affiliates for any sale of any Licensed Product to a Third Party (including for clarity a wholesaler or distributor) in a bona fide arm's length transaction, in the Territory in a given period, less the following deductions to the extent actually allowed or specifically allocated to the Licensed Product by the selling party using GAAP (as defined below):

(a) sales and excise taxes, value added taxes, and duties which fall due and are paid by the purchaser as a direct consequence of such sales and any other governmental charges imposed upon the importation, use or sale of such product, but only to the extent that such taxes and duties are (i) actually included and itemized in the gross amounts invoiced to and specifically paid by the purchaser over and above the usual selling price of such product, (ii) customarily included and itemized in the gross amounts invoiced to and specifically paid by the purchaser over and above the usual selling price of all comparable products in the relevant market and (iii) are not recovered or recoverable;

(b) Third Party distribution fees and trade, quantity and cash discounts including prompt pay discounts, that are customary in the industry in the Territory and that are allowed on and specifically allocated to the Licensed Product;

(c) a reasonable accrual for write-offs for bad debts, not to exceed [***] ([***])% of such gross amounts invoiced by Licensee or its Affiliates in a given calendar quarter (which accrual shall be trued up and reconciled in the ordinary course of business);

(d) allowances or credits to customers on account of rejections, withdrawal, recall (only for the purchase price of such Licensed Product), or returns of Licensed Product or on account of retroactive price reductions, re-procurement charges, price protection and shelf stock adjustments, slotting allowances, allowances, discounts or inventory management fees, to the extent that such allowances, credits or charges are customary in the biosimilar pharmaceutical industry in the United States; affecting such Licensed Product;

(e) rebates and chargebacks specifically related to such product on an accrual basis, which shall be trued up and reconciled in the ordinary course of business, including those granted to government agencies (i.e. payments made under the "Medicare Part D Coverage Gap Discount Program"); and

(f) freight and insurance costs, if they are included in the selling price for the Licensed Product invoiced to Third Parties, to the extent that Licensee or an Affiliate is responsible for payment of such charges in the Territory;

provided, however, where any such deduction (or similar adjustment to Net Sales) is based on sales of a bundled set of products in which a Licensed Product is included, the discount (or similar adjustment to Net Sales) shall be allocated to such Licensed Product on a pro rata basis based upon the sales value (i.e., the unit average selling price of a bundled set of products in which the Licensed Product is included multiplied by the unit volume of such Licensed Product within the bundled set of products) of such Licensed Product relative to the sales value contributed by the other constituent products in the bundled set, with respect to such sale. Net Sales are to be ascertained from books and records maintained by or on behalf of Licensee in accordance with generally accepted accounting principles, as consistently applied by it with respect to sales of all its drug products (GAAP).

1.50 ***New Product*** means any finished dosage form of a biosimilar containing Ranibizumab to a Reference Product which is not an Existing Reference Product and which may in the future become approved (e.g. Reference Products of dosage strengths and presentations which are different from the dosage strengths and presentations comprising the Existing Reference Products) and for which the performance of clinical trials to obtain a Regulatory Approval is required.

1.51 ***Patent Rights*** means any and all right, title, and interest in (a) issued patents, patent applications, and future patents issued from any such patent applications; (b) future patents issued from a patent application filed in any country worldwide which claims priority from a patent or patent application of (a); and (c) reissues, confirmations, renewals, extensions, counterparts, divisions, continuations, continuations-in part, supplemental protection certificates or utility models based on any patent or patent application of (a) or (b).

1.52 ***Parties*** shall have the meaning ascribed to it in the introductory paragraph above.

1.53 ***Paying Party*** shall have the meaning ascribed to it in Section 8.2.

1.54 ***Payment Receiving Party*** shall have the meaning ascribed to it in Section 8.2.

1.55 ***PFS Product*** means Licensed Product in the form of prefilled syringes.

1.56 **[***]** means [***]

1.57 **[***]** shall [***]

1.58 ***Qualifying IP Clearance Litigation Costs*** means all documented out-of-pocket costs and expenses incurred by Licensee and its Affiliates in connection with activities undertaken and controlled by Licensee and its Affiliates in accordance with Section 9.4 [***] but excluding any and all Damages; provided further that the first [***] Euros (€[***]) of such costs and expenses paid or incurred by Licensee and its Affiliates in connection with activities undertaken under Section 9.4.1 and/or activities undertaken with respect to the Defense of an Infringement Claim initiated by the Reference Product sponsor pursuant to the BPCIA shall not be considered Qualifying IP Clearance Litigation Costs and shall instead be borne solely by Licensee.

1.59 ***Ranibizumab*** means the recombinantly produced ranibizumab drug substance.

1.60 ***Receiving Party*** shall have the meaning ascribed to it in Section 11.1.

1.61 ***Reference Product*** means any biologic drug products of the innovator in the Territory, whether currently existing or hereinafter Developed, containing Ranibizumab drug substance and sold under the trademark Lucentis®, including: (a) single use vial for intravitreal injection containing [***] ml, (b) single use vial for intravitreal injection containing [***] ml, (c) prefilled syringe for intravitreal injection containing [***] ml, and (d) prefilled syringe for intravitreal injection containing [***] ((a)-(d) collectively, the ***Existing Reference Products***).

1.62 ***Regulatory Approval*** means, with respect to any country or jurisdiction, the authorizations, approvals or registrations of the competent Regulatory Authorities necessary for the Commercialization of a pharmaceutical product in such country or jurisdiction. For the avoidance of doubt, Regulatory Approval shall include a provisional approval provided and as long as it grants the right to Commercialize a pharmaceutical product in such country or jurisdiction.

1.63 ***Regulatory Authority*** means any national, supra-national, regional, state or local agency, department, bureau, commission, council or other governmental entity having jurisdiction over the manufacture, market approval, sale, distribution, packaging or use of drug product, including Licensed Products. For clarity, the FDA shall be considered a Regulatory Authority in the Territory.

1.64 ***Remedial Action*** means any recall, corrective action or other regulatory action with respect to the Licensed Products taken by virtue of Applicable Law.

1.65 ***Repayment Amount*** shall have the meaning ascribed to it in Section 8.3.

1.66 ***Sales Tax*** means any turnover, consumption, sales, use, goods and services tax, value added tax, import sales tax or similar tax (excluding, for the avoidance of doubt, any capital gains, income or similar tax).

1.67 ***Saving*** shall have the meaning ascribed to it in Section 8.3.

1.68 **[***]** shall [***]

1.69 ***Territory*** shall mean the United States of America, including its territories and protectorates.

1.70 ***Third Party*** shall mean any entity or person other than Bioeq or Licensee or their respective Affiliates.

1.71 ***Third Party Claim*** shall have the meaning ascribed to it in Section 13.3(c).

1.72 ***Trademark*** means any trademark, trade name, trade dress or domain name or any application to any of the above.

1.73 ***Vial Product*** means Licensed Product in the form of single use vials.

1.74 ***Interpretation***. In this Agreement, unless the context otherwise requires:

(a) headings do not affect the interpretation of this Agreement; the singular shall include the plural and vice versa; and references to one gender include all genders;

(b) references to EUR or € are references to the lawful currency from time to time in the Eurozone;

(c) words such as "***herein***," "***hereof***" and "***hereunder***" refer to this Agreement as a whole and not merely to a subdivision in which such words appear;

(d) any phrase introduced by the terms "***including***", "***include***", "***in particular***" or any similar expression shall be construed as illustrative and shall not limit the sense of the words preceding those terms;

(e) except as otherwise expressly provided in this Agreement, any express reference to an enactment (which includes any legislation in any jurisdiction) includes references to (i) that enactment as amended, consolidated or re-enacted by or under any other enactment before or after the date of this Agreement; (ii) any enactment which that enactment re-enacts (with or without modification); and (iii) any subordinate legislation (including regulations) made (before or after the date of this Agreement) under that enactment, as amended, consolidated or re-enacted as described in (i) or (ii) above; and

(f) the Annexes and Schedules comprise annexes and schedules to this Agreement and form part of this Agreement. Unless noted otherwise, capitalized terms used but not defined in the Annexes and Schedules have the meanings ascribed to such terms in this Agreement.

2.LICENSE GRANT

2.1 Technology License.

2.1.1 Exclusive License Grant. Subject to the provisions of this Agreement, Bioeq hereby grants to Licensee an exclusive (even as to Bioeq), milestone- and royalty-bearing, non-transferable license (including the right to grant sublicenses only to the extent permitted by Section 2.1.2) under the Licensed Technology (including the Licensed Patents) to use, sell, have sold, import, have imported or otherwise Commercialize the Licensed Products in the Field in the Territory.

2.1.2 Sublicensing to Affiliates Only. Licensee shall be entitled to grant sublicenses under its license pursuant to Section 2.1 to Affiliates only, provided that any sublicense granted by Licensee under this Section 2.1.2 shall be made through a written agreement in the English language and shall be consistent with the terms of this Agreement. Licensee shall promptly inform Bioeq in writing of any sublicenses granted hereunder and, upon Bioeq's request, shall make a copy of the relevant sublicense agreement available to Bioeq. Licensee may redact the [***] terms and conditions of such sublicense agreement in such copy. Licensee shall monitor compliance with and enforce any sublicense agreements against its sublicensees, and shall be liable for the operations, acts and omissions of any sublicensee as if such operations, acts or omissions were carried out by Licensee itself. For clarity, the Parties acknowledge and agree that Licensee shall be entitled to engage Third Party distributors and/or wholesalers in connection with the Commercialization of the Licensed Products in the Field in the Territory, and that such engagement of Third Party distributors and/or wholesalers is permitted under this Agreement and such arrangements shall not be considered sublicenses for which this Section 2.1.2 applies.

2.2 [***]

2.3 No Further Rights. Except as expressly provided in Sections 2.1 and 2.2, and except as set forth in Annex 2 and the Manufacturing and Supply Agreement, Bioeq will not be deemed to have granted to Licensee (by implication, estoppel or otherwise) any right, title, license or other interest in or with respect to any Patent Rights, Know-How, Trademark or other Intellectual Property Rights Controlled by Bioeq. In particular, the license granted pursuant to Section 2.1 does not include the right of Licensee to Develop or Manufacture any Licensed Product (provided that for clarity Licensee shall have the limited right to Manufacture the Licensed Product as set forth in Annex 2 and the Manufacturing and Supply Agreement [***].

3.DEVELOPMENT

3.1 Development Rights and Obligations. Subject to the terms and conditions of this Agreement, Bioeq shall be solely responsible for the Development of Licensed Products and shall bear all costs and expenses relating thereto.

3.2 Diligence Obligations. Bioeq shall use Commercially Reasonable Efforts to complete the ongoing Development of the Licensed Products in the Field in the Territory until receipt of Regulatory Approval for the Licensed Products in the Field in the Territory in accordance with and as set forth in a Development and Manufacturing plan (the ***Development & Manufacturing Plan***). The initial Development & Manufacturing Plan is attached to this Agreement as Schedule 3.2.

3.3 Information.

3.3.1 [***] within [***] ([***]) [***] days following the end of each calendar quarter, (i) Bioeq [***] shall provide a written report to the Development and Manufacturing Committee setting forth in reasonable detail the status of its then-current Development activities in relation to the Licensed Products in the Field in the Territory and (ii) the Parties, through the Development and Manufacturing Committee, shall review and update the Development & Manufacturing Plan for Bioeq's planned Development activities for the Vial Products in the Field in the Territory.

3.3.2 [***], Bioeq shall conduct the activities set forth in subsections (i) and (ii) of Section 3.3.1 with respect to the Licensed Products but only as and to the extent agreed upon by the Development and Manufacturing Committee.

3.3.3 In addition to the above in Section 3.3.1 and Section 3.3.2, Bioeq [***] shall inform the Development and Manufacturing Committee without undue delay of any material Development results or activities proposed to be undertaken with respect to any Licensed Product including those that may (i) [***] or (ii) [***], and shall respond to the other Party's reasonable questions or requests for information relating thereto.

3.4 **New Products**. During the term of this Agreement, neither Party shall, and shall not permit its Affiliates to, nor grant any rights to any Third Party to, directly or indirectly, Commercialize, or Develop any New Product for Commercialization in the Territory, except as permitted in accordance with this Section 3.4. If Bioeq wishes to Develop a New Product for Commercialization in the Territory, it shall notify Licensee thereof in writing. Upon such notification, the Parties shall discuss in good faith whether and on what terms such New Product shall he Developed be Bioeq under this Agreement and become part of the Licensed Products licensed to Licensee in the Territory hereunder. If the Parties agree that such New Product shall be Developed and become a Licensed Product under this Agreement, the Parties shall amend this Agreement to reflect their agreement in relation to such New Product (including the Parties' respective share of the Development costs for the Development of such New Product), such New Product shall become part of the Licensed Products, and the restrictions in this Section 3.4 shall cease to apply to such New Product.

3.5 [***]

4.REGULATORY ACTIVITIES

4.1 **Regulatory Filings**. Subject to the terms and conditions of this Agreement, including Sections 3.5 and 4.4 herein, Bioeq shall be solely responsible for all regulatory activities necessary to obtain Regulatory Approval of the Licensed Products in the Field in the Territory, including filing Biologics License Applications for the Licensed Products in the Field in the Territory, and shall bear all costs and expenses relating thereto.

4.1.1 **First BLA for a Licensed Product.** Within [***] ([***]) [***] following the Effective Date, Bioeq shall make available to Licensee the complete draft of the Biologics License Application that Bioeq has prepared and intends to file for the first Licensed Product with the FDA. Licensee shall use Commercially Reasonable Efforts to review such draft without delay and to notify Bioeq in writing of any concerns it may identify in relation to such draft within [***] ([***]) days of such draft being made available to Licensee by Bioeq. Subsequently, Licensee may notify Bioeq in writing of any concerns that it identifies in relation to such draft promptly after such identification. For clarity, nothing in this Section 4.1.1 shall restrict Bioeq's right to file the first Biologics License Application for a Licensed Product in the Field in the Territory at its sole discretion.

4.2 Diligence Obligations. Bioeq shall use Commercially Reasonable Efforts to obtain Regulatory Approval for the Licensed Products in the Field in the Territory in accordance with and as set forth in the Development & Manufacturing Plan.

4.3 Coordination of the Parties. Each Party shall reasonably coordinate its regulatory activities relating to the Licensed Products ([***]) with the other Party to the extent such activities relate to the Commercialization of the Licensed Products ([***]) in the Field in the Territory and shall keep the other Party reasonably informed about any material regulatory developments or activities proposed to be conducted with respect to the Licensed Products ([***]), including those (a) [***] or (b) [***] provided, however, that such coordination is [***] Without limiting the foregoing:

4.3.1 Without limiting or modifying Section 4.1.1, each Party shall provide a copy of all Biologics License Applications and all other substantive written correspondence planned to be filed with or submitted to Regulatory Authorities for the Licensed Product ([***]) in the Field in the Territory (collectively, ***Material Regulatory Submissions***) at reasonably in advance of the planned submission date therefor. The other Party shall have the right to review and comment on all such Material Regulatory Submissions and the submitting or filing Party shall take all of the other Party's comments received within a reasonable time period after the other Party receives such copy of such Material Regulatory Submission under good faith consideration. Additionally, each Party shall provide a copy of all written correspondence or feedback received from Regulatory Authorities in the Territory relevant to the Development or Commercialization of the Licensed Products ([***]) to the other Party promptly after receipt thereof, and the Parties shall discuss in good faith the impact of such information on, and potential changes to, the activities contemplated hereunder.

4.3.2 Additionally, Bioeq will promptly, and in any event within [***] ([***]) days of receipt, forward to Licensee a copy of any communications received from Regulatory Authorities outside of the Territory in relation to the Licensed Products which would [***] impact the Development, the receipt or maintenance of Regulatory Approval for, or the Commercialization of the Licensed Products in the Field in the Territory, and the Parties shall discuss in good faith the impact of such information on, and potential changes to, the activities contemplated hereunder.

4.4 Ownership and Transfer of Biologics License Application Approvals in the Territory. The Biologics License Applications for each Licensed Product in the Field in the Territory shall initially be filed and owned by Bioeq. Prior to the First Commercial Sale of any Licensed Product in the Territory, Bioeq shall transfer or cause to be transferred the applicable Regulatory Approvals and Biologics License Applications for such Licensed Product to Licensee, including by preparing and submitting a transfer letter notifying the FDA of the transfer of the applicable Regulatory Approvals and Biologics License Applications for such Licensed Product to Licensee. Following such transfer, Licensee shall have the sole right and shall use Commercially Reasonable Efforts to maintain such Regulatory Approvals for the Licensed Product in the Field in the Territory at Licensee's expense (subject to the remainder of this Section 4.4), and shall have the sole right to communicate and correspond with Regulatory Authorities in the Territory in connection therewith, in each case, in consultation with Bioeq. Licensee shall provide Bioeq with copies of any substantive submissions to any Regulatory Authority without undue delay. Upon request by Licensee, Bioeq shall, and shall use Commercially Reasonable Efforts to cause its Affiliates (including [***]), CMOs, licensors, and other relevant contractors (including, for the avoidance of doubt, [***] and [***],) to provide Licensee with copies of all relevant data and information (i) requested by Regulatory Authorities in the Territory for the Licensed Product in a timely fashion or (ii) which are required to be filed or submitted with such Regulatory Authorities [***] (e.g. [***]), in each case of (i) and (ii), in a timely fashion to allow Licensee to comply with relevant deadlines and Applicable Law. Such assistance as described in the preceding sentence shall be provided [***]. Additionally, upon request by Bioeq, Licensee shall without undue delay (a) [***] and (b) apply to Regulatory Authorities in the Territory for changes in

relation to the Manufacturing of such Licensed Product, in each case (a) and (b), based on the [***]. Bioeq shall, and shall use Commercially Reasonable Efforts to cause its Affiliates (including [***]), CMOs, licensors, and other relevant contractors (including, for the avoidance of doubt, [***], [***], and [***]) to provide Licensee with copies of all relevant data and information to support such applications. Such assistance as described in the preceding sentence shall be provided [***]

4.5 Regulatory Meetings.

4.5.1 Prior to the transfer of Biologics License Applications and Regulatory Approvals for the Licensed Products in the Territory pursuant to Section 4.4, Licensee shall have the right to attend meetings with Regulatory Authorities concerning Licensed Products in the Field in the Territory at its own costs. Without limiting the foregoing, [***]

4.5.2 After transfer of Regulatory Approvals for the Licensed Products in the Field in the Territory pursuant to Section 4.4, (i) Bioeq shall have the right to attend meetings with Regulatory Authorities concerning Licensed Products ([***]) in the Fields in the Territory at its own costs and [***] and (ii) upon written request by Licensee, Bioeq shall be obliged to, and shall use Commercially Reasonable Efforts to cause its Affiliates and their employees, CMOs, licensors, and other relevant contractors, representatives and agents (including, for the avoidance of doubt, [***], [***], and [***]) to attend meetings with Regulatory Authorities concerning Licensed Products in the Field in the Territory upon Licensee's costs.

4.6 Pharmacovigilance. At least [***] ([***]) [***] prior to the First Commercial Sale for any Licensed Product ([***]), the Parties shall define and finalize the actions that the Parties shall employ with respect to such Licensed Product ([***]) to protect patients and promote their well-being in a written pharmacovigilance agreement (***Pharmacovigilance Agreement***), with Bioeq as the global safety database holder. These responsibilities set forth in the Pharmacovigilance Agreement shall include mutually acceptable guidelines and procedures for the receipt, investigation, recordation, communication and exchange (as between the Parties) of adverse event reports and any other information concerning the safety of the Licensed Products ([***]). Such guidelines and procedures shall be in accordance with, and enable the Parties to fulfil, local and national regulatory reporting obligations under Applicable Law and regulations. Each Party hereby agrees to comply with its respective obligations under such Pharmacovigilance Agreement and to cause its Affiliates to comply with such obligations. Bioeq will maintain its global safety databases pursuant to its own policies and as necessary to comply with Applicable Law governing adverse experiences.

4.7 Product Inserts and Labeling; Promotional Materials. Following Regulatory Approval for a Licensed Product ([***]) in the Field in the Territory, Licensee shall be responsible for the text and regulatory compliance of all package labels, product inserts and other labeling used in connection with such Licensed Product ([***]) in the Territory, as well as for the promotional materials, if any, for use in connection with each of the Licensed Products ([***]) in the Territory; provided that any communication with or materials to be provided to a Regulatory Authority in the Territory with respect to a label for a Licensed Product ([***]) shall be subject to [***]

5.MANUFACTURING AND SUPPLY

5.1 Manufacturing. Subject to the terms and conditions of this Agreement (including Section 5.3 and Annex 2) and the Manufacturing and Supply Agreement, Bioeq shall have the sole responsibility for the Manufacturing and supply of the Licensed Products to Licensee for Commercialization in the Field in the Territory.

5.2 **Manufacturing and Supply Agreement**. Within [***] ([***]) [***] following the Effective Date, the Parties shall negotiate in good faith and execute a written manufacturing and supply agreement (the ***Manufacturing and Supply Agreement***) to govern the Manufacturing and supply of the Licensed Products ([***]) from Bioeq (or a CMO selected by Bioeq) to Licensee on the basis of the term sheet attached hereto as Annex 2; The terms of the Manufacturing and Supply Agreement shall be consistent with the terms set forth on Annex 2. Prior to the execution of the Manufacturing and Supply Agreement, the terms and conditions set forth on Annex 2 and Section 3 shall govern the rights and obligations of the Parties in relation to the Manufacture and supply of any Licensed Products. Following the execution of such Manufacturing and Supply Agreement, the terms and conditions of Annex 2 shall be superseded by the Manufacturing and Supply Agreement, and all rights and obligations of the Parties in relation to the Manufacture and supply of any Licensed Products shall be governed by such Manufacturing and Supply Agreement and Section 3.

5.3 [***]

6.COMMERCIALIZATION

6.1 **General**. Subject to the terms and conditions of this Agreement, Licensee shall have the sole right and obligation to conduct the Commercialization of the Licensed Products in the Field in the Territory, including the sole right to conduct the following activities: (a) developing and executing a commercial launch and pre-launch plan; (b) set-up of distribution network in the Territory, negotiation of wholesaler contracts and negotiations with buyer groups (including group purchasing organizations) and key accounts; (c) negotiating with public and private health insurance companies and governmental authorities regarding the price and reimbursement status of the Licensed Products and obtaining and maintaining pricing and reimbursement approvals; (d) marketing, medical affairs, and promotion (including by entertaining a dedicated and sufficiently qualified sales staff, providing for appropriate incentive mechanisms for such sales staff, attending relevant conferences, interacting with key opinion leaders, etc.); (e) set-up of hub services including pre-authorization and reimbursement support and co-pay assist programs; (f) booking of sales and performance of related services; (g) handling all aspects of order processing, invoicing and collection, inventory and receivables; (h) providing customer support, including handling medical queries, and performing other related functions; and (i) dealing with any Remedial Actions in relation to the Licensed Products in the Field in the Territory. As between the Parties, Licensee shall be solely responsible for all costs and expenses in connection with the Commercialization of the Licensed Products in the Field in the Territory, unless otherwise agreed in relation to costs for Remedial Actions in the Territory under Annex 2 and/or the Manufacturing and Supply Agreement.

6.2 **Diligence Obligations**. Licensee shall use Commercially Reasonable Efforts to Commercialize the Licensed Products in the Field in the Territory. In particular, Licensee commits to:

(a) use Commercially Reasonable Efforts to Commercialize each Licensed Product promptly following First Commercial Sale of such Licensed Product in the Field in the Territory;

(b) use Commercially Reasonable Efforts to perform the planned Commercialization activities as set forth in each Commercialization Plan (defined in Section 6.3 below); and

(c) dedicate the minimum pre-launch and post-launch resources specified in Section B of Schedule 6.2(c) to its Commercialization of the Licensed Products in the Territory in accordance with the Commercialization Plan during each year ([***]) after the First Commercial Sale of any Licensed Product in the Field in the Territory until [***] (***Commercialization Commitment Period***); provided that if Licensee [***], then the commercialization commitments as set forth in Section B of Schedule 6.2(c) shall continue to apply except that the [***]. For clarity, after the expiration of the Commercialization Commitment Period, Licensee shall have no further obligation under this Section 6.2(c).

6.3 Commercialization Plan & Reports.

6.3.1 Commercialization Plan. Beginning [***] ([***]) calendar quarters prior to the anticipated First Commercial Sale of a Licensed Product in the Field in the Territory, Licensee shall provide a written plan to the Commercialization Committee for review and approval (the ***Commercialization Plan***) setting forth in reasonable detail the planned Commercialization activities (or preparations for First Commercial Sale, as applicable) in relation to the Licensed Products planned for the four (4) calendar quarters following such quarter. Each Commercialization Plan shall include at least the information as set forth in Schedule 6.3 to this Agreement. Such Commercialization Plan shall be updated, reviewed, and approved by the Commercialization Committee [***] at least on an annual basis.

6.3.2 Commercialization Reports. Beginning [***] ([***]) calendar quarters prior to the anticipated First Commercial Sale of a Licensed Product in the Field in the Territory, and every calendar quarter thereafter, Licensee shall report to Bioeq (a) the Commercialization activities (or preparations for First Commercial Sale, as applicable) performed in relation to the Licensed Products in the preceding four (4) calendar quarters, (b) the planned Commercialization activities (or preparations for First Commercial Sale, as applicable) in relation to the Licensed Products planned for the four (4) calendar quarters following such quarter, and (c) any significant changes in the market or of the competitive landscape. In addition, Licensee shall promptly respond to Bioeq's reasonable questions or requests for information relating to Licensee's and its Affiliates' Commercialization activities with respect to the Licensed Products in the Field in the Territory, including activities performed to prepare for the First Commercial Sale.

6.4 First Commercial Sale. Notwithstanding any other provision of this Agreement, Licensee shall [***].

6.5 Trademarks. Licensee may, at its sole discretion, elect to use any Trademark which it owns or has exclusive rights to (***Licensee-Controlled Trademark***) in connection with its Commercialization of the Licensed Products in the Territory (provided that Licensee discusses the use of such Licensee-Controlled Trademark with Bioeq and takes into account Bioeq's global branding strategy for the Licensed Products).

7.FINANCIAL PROVISIONS

7.1 Upfront Payment. In consideration for entering into this Agreement, activities undertaken with respect to organizing and managing of the product supply chain and the grant of the licenses by Bioeq to Licensee hereunder, Licensee shall pay to Bioeq a one-time, non-refundable, non-creditable upfront payment in the amount of EUR [***] (€ [***]), payable as follows:

7.1.1 EUR five million (€ 5,000,000) within [***] ([***]) days of the Effective Date.

7.1.2 EUR [***] (€ [***]) within [***] ([***]) days after [***].

7.2 Milestone Payments. In addition, in consideration of services performed by Bioeq to achieve the milestone events set forth below, Licensee shall pay to Bioeq the following one-time, non-refundable (except as provided in Section 15.3.6), non-creditable development milestone payments upon the first occurrence of any of the following milestone events; provided, that [***]:

Milestone Event	Payment
1.[***]	EUR [***] (€[***])
2.[***]	EUR [***] (€[***])

Milestone Event	Payment
3.[***]	EUR[***](€[***])
4.[***]	EUR [***]
5.[***]	EUR [***] (€[***])
6.[***]	EUR [***](€[***])
7.[***]	EUR [***] (€[***])
8.[***]	EUR [***] (€[***])
9.[***]	EUR [***] (€[***])
10.[***]	EUR [***] (€[***])

Within [***] ([***]) days of the achievement of any such milestone, Bioeq shall invoice the relevant milestone amount to Licensee and Licensee shall remit payment to Bioeq within [***] ([***]) days upon receipt of Bioeq's invoice relating thereto. For the avoidance of doubt, any milestone payment made hereunder shall only be due once and shall not be due for any second or subsequent occurrence of the same milestone for the same or any other Licensed Product in the Field in the Territory. Additionally, for the avoidance of doubt, (X) [***], (Y) in no event will the total milestone payments to be paid to Bioeq hereunder exceed EUR [***] (€[***]) ([***]), and (Z) [***].

7.3 Royalties on Gross Margins.

7.3.1 Royalty Rate. In addition, Licensee shall pay to Bioeq the following royalties on Licensee's and its Affiliates' Gross Margins (calculated in accordance with Section 7.3.3) generated through the sale of Licensed Products in the Field in the Territory:

(a) Prior to [***], Licensee shall pay to Bioeq royalties in the amount of [***] percent ([***]%) on Licensee's and its Affiliates' Gross Margins (calculated in accordance with Section 7.3.3) generated through the sale of Licensed Products in the Field in the Territory, payable on a Licensed Product-by-Licensed Product basis, and subject to Section 7.3.1(c) hereunder.

(b) Starting [***], Licensee shall pay to Bioeq royalties in the amount of [***] percent ([***]%) on the Licensee's and its Affiliates' Gross Margins generated through the sale of Licensed Products in the Field in the Territory, payable on a Licensed Product-by-Licensed Product basis, and subject to Section 7.3.1(c) hereunder.

(c) To the extent that the Gross Margin achieved for a given Licensed Product in a given calendar quarter is a negative amount, Licensee shall owe no royalty to Bioeq on Net Sales of such Licensed Product in such calendar quarter, and Licensee shall instead be entitled to carry forward such negative amount and deduct such amount (i) first from the calculation of Gross Margin with respect to Net Sales of any other Licensed Products sold in the Territory in such calendar quarter and (ii) if there are no other Licensed Products sold in the Territory in such calendar quarter, in calculating the Gross Margin with respect to Net Sales of such Licensed Product in future calendar quarters as set forth in Section 7.3.3(c) herein.

7.3.2 Reporting. As of the First Commercial Sale of any Licensed Products in the Field in the Territory, within [***] ([***]) days after the end of each calendar quarter, Licensee shall deliver to Bioeq

a written report setting forth in reasonable detail, on a Licensed Product-by-Licensed Product basis, the calculation of (a) the aggregate Net Sales achieved for such Licensed Product in such calendar quarter (including a detailed description of invoiced gross sales prices and all deductions made pursuant to Section 1.49), (b) the aggregate Gross Margins achieved for such Licensed Product in such calendar quarter (including a detailed description of all deductions and calculations made pursuant to Section 7.3.3 in arriving at such Gross Margin calculation), and (c) the calculation of the royalties owing by Licensee to Bioeq pursuant to Section 7.3 for such calendar quarter. Notwithstanding the Parties' confidentiality obligations pursuant to Section 11, Bioeq shall have the right to report Licensee's Net Sales reporting to its licensors on a confidential basis to the extent required under the relevant agreements with such licensors.

7.3.3 Calculation of Gross Margin from Net Sales. With respect to the calculation of aggregate Gross Margins achieved from the total amount of Net Sales of a Licensed Product in the Territory in a given calendar quarter (the ***Quarterly Net Sales Amount***):

(a) Licensee shall first deduct from the Quarterly Net Sales Amount [***] an amount equal to the supply price paid by Licensee to Bioeq (pursuant to the Manufacturing and Supply Agreement) for the supply of all such Licensed Product sold in the Territory for such calendar quarter [***];

(b) From such amount resulting after the application of Section 7.3.3(a) above, Licensee shall deduct (i) all Damages which have actually been paid by Licensee or its Affiliates to a non-Defendant Third Party, (ii) all Qualifying IP Clearance Litigation Costs which have actually been incurred by Licensee and (iii) [***], in each case of (i) - (iii), as of the end of such calendar quarter and which have not previously been deducted pursuant to this Section 7.3.3 either (a) in a prior calendar quarter or (b) against Net Sales of a different Licensed Product in the Territory in the same calendar quarter,

(c) From such amount resulting after the application of Section 7.3.3(b) above, Licensee shall deduct all amounts it is entitled to carry forward from prior calendar quarters pursuant to Section 7.3.1(c) hereunder;

(d) The amount resulting in Section 7.3.3(c) above shall reflect the Gross Margin achieved for such Licensed Product in such calendar quarter to be used for the purposes of calculating the royalty payable under Section 7.3.1.

7.3.4 Payment Timing. Bioeq shall invoice Licensee for all royalties due per calendar quarter promptly after Bioeq receives Licensee's royalty report for such calendar quarter to be delivered pursuant to Section 7.3.2. All amounts of royalties shown to have accrued by each report provided pursuant to Section 7.3.2 above shall be due and payable within [***] ([***]) days from receipt by Licensee of Bioeq's invoice.

7.3.5 Records. Licensee shall maintain, and shall ensure that its Affiliates maintain, records, in sufficient detail, which shall be complete and accurate and shall fully and properly reflect all Net Sales and Gross Margins indicated in the quarterly reports described in Section 7.3.2. For each quarterly report, Licensee shall maintain records reflecting the Net Sales and Gross Margins contained in such quarterly report for [***] ([***]) years following the date that such quarterly report is delivered to Bioeq. The provisions of this Section 7.3.5 shall survive the expiration or termination of this Agreement for [***] ([***]) years.

7.3.6 Audit Rights. Upon reasonable written request of Bioeq, and no more than once during a given calendar year, Licensee shall make all records reasonably necessary to verify the accuracy of its quarterly reports pursuant to Section 7.3.2 available for inspection by an independent auditor of an internationally recognized auditing firm during Licensee's standard business hours. Such audit shall be for the purpose of ensuring Licensee's compliance with its payment obligations hereunder only. Bioeq shall

pay all audit expenses, provided, however, that in the event the audit reveals a greater than [***] percent ([***]%) payment shortfall in the amounts owed to Bioeq by Licensee during the relevant period, Licensee shall reimburse all audit expenses to Bioeq. Bioeq shall treat all financial information subject to review under this Section 7.3.6 as confidential, and shall cause its accounting firm to retain all such financial information in confidence under Section 11 below. The provisions of this Section 7.3.6 shall survive the expiration or termination of this Agreement for [***] ([***]) years.

7.4 Late Payments. To the extent Licensee fails to make full payment to Bioeq hereunder on the due date for payment, without prejudice to any other right or remedy available to Bioeq, Bioeq shall be entitled to charge Licensee interest on such payments at a rate per annum equal to [***] ([***]) percentage points above the then-applicable 3-month EURIBOR rate (regardless of whether such rate is positive, negative, or zero), published at https://www.euribor-rates.eu/.

7.5 Payment Exchange Rate. All payments to be made by Licensee to Bioeq under this Agreement shall be made in EURO by bank wire transfer without deduction for wire transfer fees in immediately available funds to such bank account designated in writing by Bioeq from time to time. In the event that any moneys which are part of the calculation of the Gross Margins are paid or received by Licensee or its Affiliates in any currency other than EURO, for purposes of calculating royalties payable hereunder, such moneys shall be converted into EURO at the rate of exchange of the European Central Bank published in the afternoon of the last business day in the respective accounting period, published at https://www.ecb.europa.eu/stats/policy_and_exchange_rates/euro_reference_exchange_rates/ html/eurofxref-graph-usd.en.html.

7.6 No offset. Except as otherwise expressly permitted pursuant to this Agreement, the Parties shall not have any right to offset or otherwise withhold any amount owing to each other under this Agreement.

8.TAXATION

8.1 Sales Tax. All payments under this Agreement are expressed clear and free of all deductions and withholdings in respect of taxes and exclusive of Sales Tax. If and to the extent any Sales Tax is chargeable on any supply contemplated by this Agreement and owed to the competent tax authorities by the Party providing the supply, the Party receiving the supply shall pay an amount equal to such Sales Tax to the Party providing the supply against receipt of a proper invoice. The Party receiving the supply shall provide the Party providing the supply with documents required by Applicable Law in an effort to minimize Sales Tax. If at any time the Party providing the supply receives a refund (or credit or offset in lieu of a refund) of any Sales Taxes so paid by the Party receiving the supply, then the Party providing the supply receiving such refund or utilizing such credit or offset shall promptly pay over the amount of such refund, credit or offset to the Party receiving the supply, it being understood that the Party receiving the supply shall be liable for any subsequent disallowance of such refund, credit or offset.

8.2 Withholding Taxes. If any deductions or withholdings are required by Applicable Law to be made from any of the amounts payable pursuant to this Agreement, then the payor (the ***Paying Party***) shall pay to the recipient (the ***Payment Receiving Party***) such amount as will, after the deduction or withholding has been made, leave the Payment Receiving Party with the same amount as it would have been entitled to receive in the absence of any such requirement to make a deduction or withholding. The Payment Receiving Party shall provide the Paying Party with documentation required by Applicable Law to minimize withholding on behalf of the Payment Receiving Party.

8.3 Repayment Amount. To the extent that the Payment Receiving Party subsequently receives and is entitled to retain and utilise a cash-effective credit against or repayment of any of its taxes (any such credit referred to as a ***Saving***) in respect of such additional amount to be paid by the Paying Party

under clause 8.2 or the payment to which such additional amount relates, the Payment Receiving Party shall pay within [***] ([***]) [***] of obtaining the Saving, pay an amount (the ***Repayment Amount***) to the Paying Party which the Payment Receiving Party reasonably determines shall leave the Payment Receiving Party (after that Repayment Amount) in the same after-tax position as it would have been in but for its utilisation of the Saving.

9.INTELLECTUAL PROPERTY

9.1 Ownership. Each Party shall own or Control, and shall continue to own or Control all Intellectual Property Rights, Trademarks and Know-How owned or Controlled by such Party as of the Effective Date of this Agreement, subject to the licenses and other rights granted hereunder. With respect to the ownership of Inventions (including Improvements):

9.1.1 As between the Parties, Bioeq shall own all Inventions (including Improvements) developed, conceived or reduced to practice during the term of this Agreement solely by or on behalf of Bioeq (such Inventions, ***Bioeq Inventions***, and such Improvements, ***Bioeq Improvements***), and all Intellectual Property Rights and Know-How therein.

9.1.2 As between the Parties, Licensee shall own all Inventions (including Improvements) developed, conceived or reduced to practice during the term of this Agreement solely by or on behalf of Licensee (such Inventions, ***Licensee Inventions***, and such Improvements, ***Licensee Improvements***), and all Intellectual Property Rights and Know-How therein.

9.1.3 As between the Parties, the Parties shall jointly own all Inventions (including Improvements) developed, conceived or reduced to practice jointly by or on behalf of both Bioeq and Licensee (such Inventions, ***Joint Inventions***, and such Improvements, ***Joint Improvements***), and all Intellectual Property Rights and Know-How therein. Each Party hereby assigns to the other Party a joint equal and undivided interest in and to all Joint Inventions (including Joint Improvements) to effect such joint ownership of such Joint Inventions (including Joint Improvements). Each Party shall have the right to disclose and exploit the Joint Inventions (and Joint Improvements) without a duty of consent or accounting to the other Party, subject to the terms and conditions of this Agreement and the licenses granted hereunder. For those countries where a specific license is required for a joint owner of a Joint Invention or Joint Improvement to practice such Joint Invention or Joint Improvement, in such country, each Party hereby grants to the other Party a perpetual, irrevocable, non-exclusive, worldwide, royalty-free, fully paid-up license, transferable and sublicensable, under such Party's right, title and interest in and to such Joint Invention or Joint Improvement to freely exploit such Joint Invention or Joint Improvement in such country, subject to the terms and conditions of this Agreement and the licenses granted hereunder.

Notwithstanding Section 16.2, inventorship of Inventions (including Improvements) shall be determined by application of United States patent laws pertaining to inventorship, and ownership of Inventions (including Improvements) shall be determined by Inventorship.

9.2 Licenses to Improvements

9.2.1 Bioeq Improvements. Bioeq shall inform Licensee in writing of any Bioeq Improvements promptly after such Bioeq Improvements are developed or reduced to practice. For clarity, the exclusive license granted to Licensee pursuant to Section 2.1 shall extend to all Intellectual Property Rights and Know-How Controlled by Bioeq and embodied within, or claiming or covering the Bioeq Improvements.

9.2.2 Licensee Improvements. Licensee shall promptly inform Bioeq in writing of any Licensee Improvements promptly after such Licensee Improvements are developed or reduced to practice. Licensee hereby grants to Bioeq during the term of this Agreement (and, subject to Section 15.3.4, after termination

or expiration of this Agreement) a non-exclusive, fully-paid, irrevocable license (including the right to grant sublicenses) under all Intellectual Property Rights and Know-How Controlled by Licensee and embodied within, or claiming or covering the Licensee Improvements, to Develop, Manufacture, sell, import, or otherwise Commercialize Licensed Products outside of the Territory. [***]

9.2.3 Joint Improvements. The Parties' rights and obligations with respect to Joint Improvements shall be as set forth in Section 9.1.3.

9.3 Prosecution and Maintenance of Licensed Patents.

9.3.1 Patent Rights owned by Bioeq. The Parties are aware that Bioeq does not currently own any Patent Rights relating to the Licensed Products in the Field in the Territory. Should Bioeq own any Patent Rights relating to the Licensed Products in the Field in the Territory in the future, the Parties will discuss and agree in good faith appropriate procedures to coordinate the prosecution and maintenance of such Patent Rights among the Parties.

9.3.2 In-Licensed Licensed Patents. To the extent Bioeq has been granted rights in relation to the prosecution, maintenance or enforcement of any In-Licensed Licensed Patent under the agreement concluded with the relevant Third Party licensor (including, with respect to the [***]-Licensed Patents, the [***] Agreement), Bioeq shall, to the extent permitted under the relevant agreement with the Third Party licensor, (i) [***] inform Licensee on any material developments with respect to the filing, prosecution, maintenance or enforcement of such In-Licensed Licensed Patent in the Territory, including by providing copies of all substantive communications or any other substantive documents and (ii) provide Licensee with [***].

9.3.3 Licensee Inventions. For clarity, Licensee shall have the sole right to control the filing, prosecution, and maintenance of Patent Rights claiming or covering the Licensee Inventions (including the Licensee Improvements).

9.3.4 Joint Inventions. The Parties will discuss and agree in good faith on appropriate procedures to coordinate the prosecution and maintenance of Patent Rights claiming or covering the Joint Inventions (including the Joint Improvements) prior to taking any action to do the same.

9.4 Patent Dance; Defense against Third Party Infringement Claims.

9.4.1 BPCIA Proceedings. Notwithstanding the fact that the Parties acknowledge and agree that Bioeq will be the initial holder of the Biologics License Application filed for each Licensed Product in the Territory in Bioeq's own name, as between the Parties, with respect to each Licensed Product, Licensee shall have the sole right and shall use Commercially Reasonable Efforts to control the initiation and participation of Bioeq in the pre-litigation processes of the BPCIA generally set forth in 42 U.S.C. § 262(1), including the process commonly referred to as the "patent dance" and the "notice of commercial marketing" (collectively, the ***BPCIA Proceedings***) with respect to each Licensed Product. Without limiting the foregoing:

(a) Bioeq will notify Licensee within [***] ([***]) [***] of submitting a Biologics License Application for the Licensed Product in the Territory, and will notify Licensee on the same day that such Biologics License Application is accepted by the FDA. Bioeq shall, upon request from Licensee, provide the Reference Product sponsor with timely confidential access to such Biologics License Application for the Licensed Product as well as certain Licensed Product Manufacturing information as permitted under 42 U.S.C. § 262(l)(l)-(2) (referred to hereafter ***as Initiating Patent Dance Proceedings***). Licensee shall have the right to control the scope of the disclosures of Licensed Product Manufacturing information to the Reference Product sponsor, provided that Licensee will take Bioeq's comments into good faith

consideration in connection therewith. For clarity, in no event will Bioeq Initiate Patent Dance Proceedings unless directed to do the same by Licensee, and, upon the request of Licensee, will negotiate with the Reference Product sponsor whether to utilize a different mechanism for information exchange other than that specified in 42 U.S.C. §261(1)(1).

(b) After Initiating Patent Dance Proceedings, Bioeq will fully cooperate with Licensee in connection with "Paragraph 3" information exchange and "Paragraph 5" negotiation and resolution proceedings with the Reference Product sponsor pursuant to 42 U.S.C. §261(l)(3)-(5), including by keeping Licensee fully informed with respect to, and providing Licensee a copy of, all communications received from the Reference Product sponsor/its designee on the same day as receipt thereof. Licensee shall have final decision-making authority with respect to all communications and negotiations with the Reference Product sponsor in connection therewith, including [***], provided that Licensee will take Bioeq's comments into good faith consideration in connection therewith. For clarity, Licensee shall have the sole right to direct and control any negotiations regarding securing a license or other rights to Intellectual Property Rights, Know-How or Trademarks owned or controlled by the Reference Product sponsor during the course of and in connection with the BPCIA Proceedings.

(c) Licensee, at its sole discretion, shall control the timing of providing notice of commercial marketing to the Reference Product sponsor under 42 U.S.C. §262(1)(8)(B), and shall have final decision-making authority with respect to all communications and negotiations with the Reference Product sponsor in connection therewith. Bioeq shall fully cooperate with Licensee in connection therewith and shall communicate and negotiate with the Reference Product sponsor solely as directed by Licensee.

(d) Bioeq shall, and shall use Commercially Reasonable Efforts to cause its Affiliates (including [***]), CMOs, licensors, and other relevant contractors (including, for the avoidance of doubt, [***] and [***]) to fully cooperate with Licensee's requests and to be available for consultation in connection with the BPCIA Proceedings. Licensee shall have the right to select, approve and direct the primary outside counsel to be used by Bioeq in connection with the BPCIA Proceedings, and will be solely responsible for the costs of engaging such outside counsel for such purposes; provided that Bioeq shall have the right, at its sole cost and expense, to engage and consult secondary outside counsel in connection with such activities ([***]).

(e) The support provided by Bioeq and its Affiliates (including [***]) under this Section 9.4.1 shall be provided free of charge to Licensee, except that Licensee shall reimburse [***] for their [***] costs incurred in connection with supporting the BPCIA Proceedings.

(f) The costs of any support provided by Bioeq's CMOs, licensors, and other relevant contractors (including [***] and [***]) under this Section 9.4.1 shall be borne by Licensee and shall constitute Qualifying IP Clearance Litigation Costs.

9.4.2 Defense of Infringement Claims. Additionally, and without limiting Section 9.4.1, each Party shall promptly notify, in writing, the other Party upon learning of any notice, allegation, suit, or other proceeding against either Party, or any of their respective Affiliates, subcontractors, suppliers, licensors, licensees or customers, of infringement, misappropriation or misuse of any Third Party Intellectual Property Rights or Know-How as a result of the actual or planned Commercialization of any Licensed Product in the Field in the Territory or the actual or planned Manufacturing of such Licensed Product for Commercialization in the Field in the Territory, including any infringement claim brought under the BPCIA (an ***Infringement Claim***). As between the Parties, Licensee shall have the primary right and use Commercially Reasonable Efforts to control the defense against any such Infringement Claim (irrespective of whether such Infringement Claim was brought against Licensee, Bioeq or any of their respective Affiliates, subcontractors, suppliers, licensors, licensees or customers (collectively referred to as ***Defendants***)), including directing all aspects, stages, motions and proceedings of litigation (including

motions or proceedings under the BPCIA) as well as bringing any counter-claims against the Infringement Claim, as well as electing to settle such Infringement Claim (subject to Section 9.4.2(h)) (collectively ***Defend*** or ***Defense***). The Parties shall cooperate in relation to any such Defense as follows:

(a) As between the Parties, Licensee shall have the sole right, and at its sole cost and expense, to select the primary outside counsel to jointly represent the Defendant(s) named in such Infringement Claim and to direct and control the Defense thereof ("**Primary Outside Defense Counsel**"). If Licensee is not a named Defendant in such Infringement Claim, Licensee may, at its sole discretion, join as a named Defendant in such Infringement Claim (to the extent permitted by Applicable Law).

(b) Prior to undertaking any action of Defense, Licensee shall notify Bioeq in writing and shall, upon Bioeq's request, and in connection with Primary Outside Defense Counsel, disclose to, and discuss with, Bioeq in good faith (i) the [***], (ii) [***] and (iii) [***].

(c) Licensee shall give due consideration to Bioeq's comments with respect to items discussed between the Parties pursuant to this Section 9.4.2, but shall have the final decision-making authority on all aspects relating to the Defense of such Infringement Claim (including with respect to directing Primary Outside Defense Counsel with respect to actions taken in connection with the Defense).

(d) Licensee shall, through Primary Outside Defense Counsel, keep Bioeq reasonably informed of all material developments in connection with any Defense of such Infringement Claim, including by providing Bioeq with copies of draft and filed filings, motions, pleadings and other material submissions and communications (including oral communications) with the relevant judicial authority relating to such Defense of such Infringement Claim, sufficiently in advance, where reasonably possible, for Bioeq to comment on such Defense of such Infringement Claim. Licensee shall give due consideration to Bioeq's comments.

(e) Upon Licensee's request, Bioeq shall fully cooperate with Licensee in any such Defense, including in connection with the discussions between the Parties as set forth in Section 9.4.2(b), and, if requested by Licensee, by being joined as a party or allowing Licensee to be joined as a party (to the extent permitted by Applicable Law) to the relevant Infringement Claim. Without limiting the foregoing, Bioeq shall, and shall use Commercially Reasonable Efforts to cause its Affiliates and their employees, CMOs, licensors, and other relevant contractors, representatives and agents (including, for the avoidance of doubt, [***], [***], and [***]) to be available and cooperate fully with Licensee in such discussions, including by making relevant witnesses, documents and information available to Licensee and Primary Outside Defense Counsel in connection with the Defense of such Infringement Claim.

(f) The support provided by Bioeq and its Affiliates (including [***]) under this Section 9.4.2 shall be free of charge to Licensee, except that Licensee shall reimburse [***] for their [***] costs incurred in connection with supporting the Defense of any Infringement Claim.

(g) The costs of any support provided by Bioeq's CMOs, licensors, and other relevant contractors (including [***] and [***]) under this Section 9.4.2 shall be borne by Licensee and shall constitute Qualifying IP Clearance Litigation Costs.

(h) Licensee shall not enter into a settlement without [***] and in any such settlement Licensee shall always take into consideration the interest of Bioeq.

(i) Any recoveries obtained upon the final judgement or settlement of any Infringement Claim shall first be used to reimburse Licensee for its costs incurred in connection therewith. Any remaining recoveries shall be regarded as Gross Margin.

9.4.3 Damages.

(a) All amounts to be paid by the Defendants upon the final judgment or settlement in connection with the Defense of an Infringement Claim, or in securing a license or other rights to Intellectual Property Rights, Know-How, or Trademarks owned or controlled by the Reference Product sponsor during the course of and in connection with the BPCIA Proceedings, including [***] (collectively, ***Damages***) shall be borne by Licensee (or its Affiliate), and [***].

(b) Licensee may deduct Damages from the calculation of Gross Margin to be paid pursuant to Section 7.3 on a per calendar quarter basis as set forth in Section 7.3.3.

9.4.4 Qualifying IP Clearance Litigation Costs. Licensee may deduct Qualifying IP Clearance Litigation Costs from the calculation of Gross Margin to be paid pursuant to Section 7.3 on a per calendar quarter basis as set forth in Section 7.3.3.

9.4.5 Secondary Bioeq Outside Counsel. Notwithstanding Section 9.4.2 above, Bioeq shall have the right to be represented in any Defense of an Infringement Claim by a secondary outside counsel at its own cost and expense; provided that for clarity Licensee, through Primary Outside Defense Counsel, shall have final decision-making authority with respect to the control of the Defense of such Infringement Claim.

9.4.6 Notice and Cooperation. Without limiting Bioeq's obligations to cooperate with Licensee as set forth in this Section 9.4, Bioeq shall have the right to notify of and coordinate any Defense of an Infringement Claim with any of its Affiliates, subcontractors, suppliers, licensors or licensees in accordance with the terms of the agreements concluded with any such Affiliates, subcontractors, suppliers, licensors or licensees as they exist of the Effective Date.

9.5 Enforcement of Licensed Patents.

9.5.1 In the event that either Party becomes aware of a suspected infringement of any Licensed Patent as a result of the Development, Manufacture, or Commercialization, use, or importation of a Competitive Product in the Territory ("***Competitive Infringement***"), such Party shall notify the other Party promptly in writing, and following such notification, the Parties shall meet and confer. As between the Parties, and subject always to the terms and conditions of the relevant agreements pursuant to which such In-Licensed Licensed Patents are exclusively licensed to Bioeq (including, with respect to the [***]-Licensed Patents, the [***] Agreement):

9.5.2 [***] shall have the first right, but not the obligation, to enforce the Licensed Patents against such Competitive Infringement at its own expense, in its own name, and under its own direction and control, including by settling any such action or proceeding. Notwithstanding the preceding sentence, [***] shall not enter into a settlement that imposes a financial obligation upon [***] or which limits any of [***] in any Licensed Patent without [***] prior written consent (such consent not to be unreasonably withheld or delayed), and in any such settlement [***] shall always take into consideration the interest of [***].

9.5.3 [***] shall reasonably assist [***] in connection with [***] enforcing the Licensed Patents against such Competitive Infringement if so requested, and shall be named in or join such action or proceeding if required for [***] to bring such action. [***] shall reimburse [***] for its reasonable out-of-pocket costs incurred in connection with such activities, except that [***] shall be responsible for any costs of engaging its own outside legal counsel which [***] has the right to engage in connection with such action or proceeding.

9.5.4 If [***] elects not to exercise its rights under Section 9.5.2 within [***] ([***]) days of first becoming aware of such Competitive Infringement, then [***] shall have the right, but not the obligation, to enforce the Licensed Patents against such Competitive Infringement, and in such case (a) the first sentence of Section 9.5.2 and (b) Section 9.5.3 shall apply *mutatis mutandis* as if [***] were [***] and [***] were [***]. The Party exercising its enforcement rights under this Section 9.5 shall be referred to as the ***Enforcing Party***.

9.5.5 With respect to all recoveries obtained in connection with an enforcement action or proceeding undertaken pursuant to this Section 9.5, such recoveries shall first be used to reimburse the Enforcing Party for its costs incurred in connection therewith. Any remaining recoveries shall then be used to reimburse the other Party for its costs incurred in connection therewith. Any remaining recoveries shall (a) if [***] is the Enforcing Party, be retained 100% by [***] or (b) if [***] is the Enforcing Party, [***].

9.6 Common Interest Disclosures. With regard to any privileged or confidential information or opinions disclosed pursuant to this Agreement by a Party to the other Party regarding Patent Rights or other intellectual property or technology owned by the disclosing Party or a Third Party, the Parties agree that they may have a common legal interest in determining whether, and to what extent, such Patent Rights and other Intellectual Property Rights or Trademarks may affect any Licensed Product, and a further common legal interest in defending against any actual or prospective Third Party claims based on allegations of misuse or infringement of Patent Rights or other intellectual property rights relating to any Licensed Product. Accordingly, the Parties agree that all such information and materials obtained by the Parties from each other in which they have such a common legal interest may be subject to a separate common interest agreement mutually acceptable to the Parties (and any other parties which may be a party to such separate common interest agreement) that they may enter into with respect to such information and materials, upon the request of either Party. Such separate agreement would provide that: (a) [***]; (b) [***]; and (c) [***].

10. COVENANTS RELATING TO THE [***] AGREEMENT

10.1 [***] Agreement. Licensee acknowledges that it is aware of the terms and conditions of the license granted to Bioeq under the [***] Agreement (to the extent such terms have not be redacted in Annex 1) and accepts and agrees that all obligations of Bioeq under this Agreement shall be subject to the terms and conditions of the [***] Agreement.

10.2 Representations and Covenants in Relation to the Formycon Agreement.

10.2.1 Consent of [***]. Bioeq hereby represents and warrants to Licensee that it has, as of the Effective Date, obtained [***]'s written consent to enter into this Agreement (as is required pursuant to the Formycon Agreement), and that a copy of such written consent of [***] has been provided to Licensee.

10.2.2 Compliance with the Formycon Agreement. Bioeq shall maintain the [***] Agreement in full force and effect, shall not breach the [***] Agreement or the "***Services Agreement***" or the "***Clinical Supply Agreement***" (as such terms defined in the [***] Agreement) in any manner or take any other action that could result in [***] having the right to terminate the [***] Agreement and, in the event of any such breach, Bioeq shall use diligent efforts to expeditiously cure Bioeq's breach of the [***] Agreement. Bioeq shall promptly notify Licensee in writing if Bioeq sends or receives any notice of any breach of the [***] Agreement.

10.2.3 Amendments to the [***] Agreement. Bioeq shall not amend or terminate the [***] Agreement in any manner that would negatively affect the rights and/or obligations of Licensee under this Agreement.

10.2.4 Disputes. Bioeq shall promptly inform Licensee of any dispute under the [***] Agreement which may have a material effect on the Development or Commercialization of the Licensed Products in the Field in the Territory, and either Party shall reasonably cooperate with the other in the settlement of such dispute.

11.CONFIDENTIALITY

11.1 Obligation of Confidentiality. As of and after the Effective Date, all Confidential Information disclosed, revealed or otherwise made available to one Party (***Receiving Party***) by or on behalf of the other Party (***Disclosing Party***) under, or as a result of, this Agreement is made available to the Receiving Party solely to permit the Receiving Party to exercise its rights, and perform its obligations, under this Agreement. The Receiving Party shall not use any of the Disclosing Party's Confidential Information for any other purpose, and shall not disclose, reveal or otherwise make any of the Disclosing Party's Confidential Information available to any other person, firm, corporation or other entity, without the prior written authorization of the Disclosing Party, except as explicitly stated in this Agreement. An appropriate confidential disclosure agreement must be signed by any Third Party or Affiliate prior to receiving Confidential Information from either Party.

11.2 Additional Obligations. In furtherance of the Receiving Party's obligations under Section 11.1 hereof, the Receiving Party shall take all appropriate steps and shall implement all appropriate safeguards, to prevent the unauthorized use or disclosure of any of the Disclosing Party's Confidential Information available to any Third Party, without the prior written authorization of the Disclosing Party. Without limiting the generality of this Section 11.2, the Receiving Party may disclose any of the Disclosing Party's Confidential Information without the Disclosing Party's prior written authorization only to those of the Receiving Party's officers, employees, agents, consultants, licensees, potential licensees and financial investors that have need to know the Disclosing Party's Confidential Information, in order for the Receiving Party to exercise its rights and perform its obligations under this Agreement, and only if such officers agents, consultants, licensees, potential licensees and financial investors have executed appropriate non-disclosure agreements containing substantially similar terms regarding confidentiality, as those set out in this Agreement, or are otherwise bound by obligations of confidentiality effectively prohibiting the unauthorized use of the Disclosing Party's Confidential Information. In particular, Bioeq shall be entitled to disclose a [***] redacted copy of this Agreement to [***] (such redacted copy to be approved in writing by Licensee prior to provision to [***]) in order to obtain [***]'s approval to this Agreement, as required under the [***] Agreement. The Receiving Party shall furnish the Disclosing Party with immediate written notice of any unauthorized use or disclosure of any of the Disclosing Party's Confidential Information and shall take all actions that the Disclosing Party reasonably requests in order to prevent any further unauthorized use or disclosure of the Disclosing Party's Confidential Information.

11.3 Limitations. The Receiving Party's obligations under Sections 11.1 and 11.2 shall not apply to information that the Receiving Party can prove by written evidence that:

(a) passes into the public domain, or becomes generally available to the public through no fault of the Receiving Party;

(b) is disclosed, revealed or otherwise made available to the Receiving Party by a Third Party that is under no obligation of non-disclosure and/or non-use to the Disclosing Party;

(c) is required to be disclosed under Applicable Laws, rules of a securities exchange or by order of a court or arbitral tribunal; provided, however, that the Receiving Party shall furnish the Disclosing Party with prior written notice of such disclosure requirement as reasonably practicable, and shall use reasonable efforts to assist the Disclosing Party with obtaining confidential treatment with respect to or otherwise minimizing the required disclosure; or

(d) is independently developed by the Receiving Party without the use or benefit of Confidential Information of the Disclosing Party as evidenced by contemporaneous written records.

11.4 Material. Any biological or chemical material which is transferred by or on behalf of a Party or its Affiliates to the other Party or its Affiliates under this Agreement shall be used only for purposes of this Agreement, and shall not be used for any other purpose, [***]. The Party or its Affiliate receiving such material shall keep the material secure and safe from loss damage, theft, misuse and unauthorized access and shall use the material in accordance with all Applicable Laws, regulations and guidelines.

11.5 Return of Confidential Information. Upon termination of this Agreement for any reason whatsoever, the Receiving Party shall cease all use of and return to the Disclosing Party, or destroy, as the Disclosing Party shall specify in writing promptly upon such expiration or termination, all materials transferred pursuant to Section 11.4 and all copies of all documents and other materials that contain or embody any of the Disclosing Party's Confidential Information, except to the extent that the Receiving Party is required by Applicable Laws to retain such documents, and provided further that each Party may keep copies of all Confidential Information within its ordinary legal archives (including IT back-up systems). Within [***] ([***]) days after the date of expiration or termination of this Agreement, the Receiving Party shall furnish the Disclosing Party with a certificate, duly executed by an officer of the Receiving Party, confirming that the Receiving Party has complied with its obligations under this Section 11.4.

11.6 Survival. All of the Receiving Party's obligations under Sections 11.1 and 11.2 hereof, with respect to the protection of the Disclosing Party's Confidential Information shall for a period of [***] ([***]) [***] survive the expiration or termination of this Agreement for any reason whatsoever.

11.7 Public Announcements. Except as may be required by Applicable Laws or rules of a securities exchange, neither Party will originate any publicity, press or news release or other public announcement, written or oral, whether to the public press or otherwise, relating to the terms and conditions of this Agreement (***Announcement***) without the prior written approval of the other Party, such approval not to be unreasonably withheld. Notwithstanding the foregoing, the Parties agree that neither Party shall be restricted from disclosing in a subsequent Announcement any information which was previously disclosed in a prior Announcement or otherwise previously made publicly available pursuant to this Agreement.

12. REPRESENTATIONS, WARRANTIES AND COVENANTS

12.1 Mutual Representations. Each Party hereby represents and warrants to the other Party as of the Effective Date that (a) the person executing this Agreement is authorized to execute this Agreement; and (b) the execution, delivery and performance of this Agreement as well as the licenses granted hereunder do not conflict with any agreement, instrument or understanding, oral or written, to which such Party may be bound.

12.2 Bioeq Representations, Warranties, and Covenants. Bioeq hereby represents and warrants to Licensee as of the Effective Date and covenants, as applicable, that:

12.2.1 The [***] Agreement is in full force and effect and, to Bioeq's knowledge, there has been no material breach by either party to the [***] Agreement and there is no circumstance that would entitle [***] to terminate the [***] Agreement.

12.2.2 Bioeq has the right to grant the licenses and rights it purports to grant pursuant to this Agreement.

12.2.3 Bioeq is not aware of any pending or threatened litigation, nor has it received any written communications from Third Parties alleging that the Licensed Patents existing as of the Effective Date are invalid or unenforceable or that the exploitation of the Licensed Technology in the Field in the Territory will constitute an infringement or misappropriation of any rights of any Third Party.

12.2.4 To Bioeq's knowledge, neither Bioeq nor its licensors, suppliers, and CMOs (including [***]) has misappropriated any trade secrets of any Third Party in Developing the Licensed Products.

12.2.5 Bioeq has (and, to its knowledge, its licensors, suppliers and CMOs (including [***]) have) made Commercially Reasonable Efforts to protect information, inventions, and technology related to Licensed Products by designating information as confidential or as a trade secret and by taking reasonable steps to prevent disclosure of such confidential information and trade secrets.

12.2.6 Bioeq has (and, to its knowledge, its licensors, suppliers and CMOs (including [***]) have) maintained and will maintain (and will Use Commercially Reasonable Efforts to cause its licensors, suppliers and CMOs (including [***]) to maintain) appropriate skilled personnel and facilities to carry out its obligations under this Agreement.

12.2.7 To Bioeq's knowledge, the information contained within all submissions to, and filings, correspondence, and communications with Regulatory Authorities made by or on behalf of Bioeq or its Affiliates with respect to the Licensed Product is true and accurate in all material aspects and was generated in compliance with Applicable Law, and Bioeq will ensure that the information contained within all submissions to, and filings, correspondence, and communications with Regulatory Authorities to be made by or on behalf of Bioeq or its Affiliates with respect to the Licensed Product will be, to Bioeq's knowledge, true and accurate in all material aspects and will be generated in compliance with Applicable Law.

12.2.8 Bioeq will not use any employees or other persons performing services on behalf of Bioeq in relation to the Development, Manufacture, or Commercialization of Licensed Products that have been debarred or excluded, or are the subject of debarment or exclusion proceedings; and if Bioeq becomes aware that a person performing on its behalf in relation to the Development, Manufacture, or Commercialization of Licensed Products has been debarred or excluded, or has become the subject of debarment or exclusion proceedings, Bioeq shall promptly notify Licensee and shall prohibit such person from performing such activities on its behalf under this Agreement.

12.3 Licensee Representations, Warranties and Covenants. Licensee hereby represents and warrants to Bioeq as of the Effective Date and covenants, as applicable, that:

12.3.1 Licensee has the right to grant the licenses and rights it purports to grant pursuant to this Agreement.

12.3.2 [***]

12.3.3 [***]

12.3.4 [***]

12.3.5 Licensee will maintain (and will use Commercially Reasonable Efforts to cause its suppliers and CMOs to maintain) appropriate skilled personnel and facilities to carry out its obligations under this Agreement.

12.3.6 Licensee will ensure that the information contained within all submissions to, and filings, correspondence, and communications with Regulatory Authorities made by or on behalf of Licensee or its

Affiliates with respect to the Licensed Product ([***]) will be, to Licensee's knowledge, true and accurate in all material aspects and will be generated in compliance with Applicable Law.

12.3.7 Licensee will not use any employees or other persons performing services on behalf of Licensee in relation to the Development, Manufacture, or Commercialization of Licensed Products that have been debarred or excluded, or are the subject of debarment or exclusion proceedings; and if Licensee becomes aware that a person performing on its behalf in relation to the Development, Manufacture, or Commercialization of Licensed Products has been debarred or excluded, or has become the subject of debarment or exclusion proceedings, Licensee shall promptly notify Bioeq and shall prohibit such person from performing such activities on its behalf under this Agreement.

12.4 Disclaimer of Warranties. Except for those representations and warranties set forth in Sections 12.1 and 12.2 of this Agreement, neither Party makes any warranties, written, oral, express or implied, with respect to its performance under this Agreement or the results thereof. In particular, each Party disclaims all other warranties, express or implied, including warranties of merchantability, fitness for a particular purpose and non-infringement. [***]

13. INDEMNIFICATION AND LIMITATION OF LIABILITY

13.1 Indemnification by Bioeq. Subject to Section 13.4, Bioeq agrees to indemnify and hold Licensee harmless from and against all claims, suits, actions, proceedings brought by a Third Party (collectively ***Claims***) for damages, loss or liability, costs or expenses (including reasonable attorney's fees, settlement payments or third party royalties) (collectively ***Losses***) to the extent arising out of or related to:

(a) Bioeq's breach of any representation, warranty, covenant or obligation under this Agreement; or

(b) Bioeq's negligence, recklessness, or wilful, intentional or criminal wrongdoing;

except, in each case of (a)-(b) hereunder, to the extent such Losses are due to the events described in Section 13.2(a)-(c) below.

13.2 Indemnification by Licensee. Subject to Section 13.4 (and notwithstanding any other indemnification obligation assumed by Licensee under this Agreement), Licensee agrees to indemnify and hold Bioeq harmless from and against all Claims for Losses to the extent arising out of or related to:

(a) Licensee's breach of any representation, warranty, covenant or obligation under this Agreement;

(b) Licensee's Commercialization of the Licensed Products in the Field in the Territory; or

(c) Licensee's negligence, recklessness, or wilful, intentional or criminal wrongdoing;

except, in each case of (a)-(c) hereunder, to the extent such Losses are due to the events described in Section 13.1(a)-(b) above.

13.3 Indemnification Procedure. With respect to any indemnification obligations of either Party under this Agreement, the following conditions must be met for such indemnification obligations to become applicable:

(a) The Party requesting the indemnification (***Indemnified Party***) shall notify the other Party (***Indemnifying Party***) promptly in writing of any claim which may give rise to an obligation on the part of Indemnifying Party hereunder;

(b) The Indemnified Party shall use commercially reasonable efforts to avoid or mitigate any Losses which the Indemnified Party may suffer as a result of the Indemnifying Party's breach or wrongdoing; and

(c) To the extent Losses are the result of a Third Party claim, suit, action or proceeding (***Third Party Claim***), (i) the Indemnified Party shall not without the prior consent in writing of the Indemnifying Party make any admission or otherwise do anything, which may prejudice the defense against such a Third Party Claim; (ii) Indemnifying Party shall be allowed to timely undertake the sole control of the defense of any such Third Party Claim, including all negotiations for the settlement, or compromise of such claim or action at its sole expense; and (iii) the Indemnified Party shall at its expense render reasonable assistance, information, co-operation and authority to permit Indemnifying Party to defend such Third Party Claim.

13.4 Limitation of Liability. Except for a breach of Section 11 ("***Confidentiality***"), and without limiting a Party's indemnification obligations hereunder, in no event shall either Party be liable to the other Party in any manner for any special, non-compensatory, consequential, indirect, incidental, statutory or punitive damages of any kind, including lost profits and lost revenue, regardless of the form of action, whether in contract, tort, product liability or otherwise, even if informed of or aware of the possibility of any such damages in advance, except to the extent that such limitation of liability is contrary to the Applicable Law or any such special, non-compensatory, consequential, indirect, incidental, statutory or punitive damages have been awarded to a Third Party under a Third Party Claim.

14. GOVERNANCE

14.1 Committees. The Parties shall, within [***] ([***]) days following the Effective Date, establish (a) a Development and Manufacturing committee (***Development and Manufacturing Committee***) and (b) a Commercialization committee ("***Commercialization Committee***"). The Parties acknowledge and agree that the Development and Manufacturing Committee and the Commercialization Committee shall have no authority to amend or modify the terms and conditions of this Agreement or the Manufacturing and Supply Agreement

14.2 Development and Manufacturing Committee.

14.2.1 Composition of the Development and Manufacturing Committee. The Development and Manufacturing Committee shall have a total of at least [***] ([***]) members. At least [***] ([***]) of such members shall be appointed by Licensee, and at least [***] ([***]) of such members shall be appointed by Bioeq. Bioeq shall appoint one (1) of its members as chairman of the Development and Manufacturing Committee. Each Party may appoint substitutes or alternates for its Development and Manufacturing Committee members at any time by written notice to the other Party.

14.2.2 Responsibilities of the Development and Manufacturing Committee. The Development and Manufacturing Committee shall be responsible for overseeing and reviewing the activities of the Parties under this Agreement with respect to Development (including Manufacturing) activities for the Licensed Products to be conducted by the Parties hereunder. The Development and Manufacturing Committee shall, in particular:

(a) review and discuss the Development (including Manufacturing) activities of Bioeq to be conducted pursuant to Section 3;

(b) review and approve each Development & Manufacturing Plan as set forth in Section 3.2;

(c) approve all Development activities to be conducted by Bioeq which (i) [***] or (ii) [***] (X) [***] (Y) [***]; and

(d) review and discuss the regulatory activities to be conducted by the Parties pursuant to Article 4.

14.2.3 Meetings of the Development and Manufacturing Committee. Until [***] is obtained, meetings of the Development and Manufacturing Committee shall be scheduled at least once per calendar quarter, and additional ad hoc meetings shall be scheduled if reasonably requested by either Party. After [***], meetings of the Development and Manufacturing Committee shall be scheduled as reasonably requested by either Party. All meetings shall be made by video conference, audio conference or in person, as agreed by the Development and Manufacturing members from time to time, provided that at least one (1) Development and Manufacturing Committee meeting per calendar year shall be made in person. All meetings of the Development and Manufacturing Committee shall be held in English language and all documents and reports to be exchanged or discussed in the Development and Manufacturing Committee shall be in the English language. The chairman of the Development and Manufacturing Committee shall prepare minutes of each Development and Manufacturing Committee meeting and submit such minutes to each Development and Manufacturing Committee member with [***] ([***]) days of each Development and Manufacturing Committee meeting for their review and approval. Such meetings of the Development and Manufacturing Committee shall be considered finalized only upon the unanimous consent of all Development and Manufacturing Committee members. Each Party will bear all expenses it incurs in regard to participating in all meetings of the Development and Manufacturing Committee, including all travel and living expenses.

14.2.4 Decisions of the Development and Manufacturing Committee. Decisions of the Development and Manufacturing Committee for matters within its decision-making purview shall be made by unanimous consent and shall only be valid if at least one (1) Development and Manufacturing Committee member appointed by each Party is present at the relevant Development and Manufacturing Committee meeting. If the Development and Manufacturing Committee cannot agree on any particular topic within its decision-making purview within [***] ([***]) days after it has met and attempted to reach such decision, then either Party may, by written notice to the other, have such issue referred to resolution pursuant to Section 16.3.1 (except that the time-period for discussion by the senior executives of the Parties shall be [***] ([***]) days instead of [***] ([***]) days), and thereafter if such issue has still not been resolved, then [***]. The Parties acknowledge and agree, however, that with respect to [***], the relative rights and obligations of the Parties shall be as set forth in those relevant Sections of the Agreement and the Development and Manufacturing Committee shall serve solely as a forum for review and discussion in connection with such activities and shall have no decision-making authority with respect to such matters.

14.3 Commercialization Committee.

14.3.1 Composition of the Commercialization Committee. The Commercialization Committee shall have a total of at least [***] ([***]) members. At least [***] ([***]) of such members shall be appointed by Licensee, and at least [***] ([***]) of such members shall be appointed by Bioeq. Licensee shall appoint one (1) of its members as chairman of the Commercialization Committee. Each Party may appoint substitutes or alternates for its Commercialization Committee members at any time by written notice to the other Party.

14.3.2 Responsibilities of the Commercialization Committee. The Commercialization Committee shall be responsible for overseeing and reviewing the activities of either Parties under this Agreement with respect to the Commercialization activities for the Licensed Products to be conducted by the Parties hereunder. The Commercialization Committee shall, in particular:

(a) review and discuss the Commercialization activities (including activities to prepare for the First Commercial Sale, including matters regarding commercial supply of Licensed Product for sale in the

Territory pursuant to the Manufacturing and Supply Agreement) of Licensee to be conducted pursuant to Section 6;

(b) review and approve each Commercialization Plan as set forth in Section 6; and

(c) approve all Commercialization activities to be conducted by Licensee which [***].

14.3.3 Meetings of the Commercialization Committee. Starting [***] ([***]) calendar quarters prior to the anticipated First Commercial Sale of a Licensed Product in the Field in the Territory, meetings of the Commercialization Committee shall be scheduled at least once per calendar quarter, and additional ad hoc meetings shall be scheduled if reasonably requested by either Party. All meetings shall be made by video conference, audio conference or in person, as agreed by the Commercialization members from time to time, provided that at least one (1) Commercialization Committee meeting per calendar year shall be made in person. All meetings of the Commercialization Committee shall be held in English language and all documents and reports to be exchanged or discussed in the Commercialization Committee shall be in the English language. The chairman of the Commercialization Committee shall prepare minutes of each Commercialization Committee meeting and submit such minutes to each Commercialization Committee member with [***] ([***]) days of each Commercialization meeting for their review and approval. Such meetings of the Commercialization Committee shall be considered finalized only upon the unanimous consent of all Commercialization Committee members. Each Party will bear all expenses it incurs in regard to participating in all meetings of the Commercialization Committee, including all travel and living expenses.

14.3.4 Decisions of the Commercialization Committee. Decisions of the Commercialization Committee for matters within its decision-making purview shall be made by unanimous consent and shall only be valid if at least one (1) Commercialization Committee member appointed by each Party is present at the relevant Development and Manufacturing meeting. If the Commercialization Committee cannot agree on any particular topic within its decision-making purview within [***] ([***]) days after it has met and attempted to reach such decision, then either Party may, by written notice to the other, have such issue referred to resolution pursuant to Section 16.3.1 (except that the time-period for discussion by the senior executives of the Parties shall be [***] ([***]) days instead of [***] ([***]) days), and thereafter if such issue has still not been resolved, then [***].

15. TERM AND TERMINATION; NON-SOLICITATION

15.1 Term. Except as otherwise specified in this Agreement, the Parties' respective rights and obligations under this Agreement shall commence on the Effective Date and shall remain in full force for ten (10) years after the First Commercial Sale of the first Licensed Product, and shall thereafter automatically renew for an unlimited period of time unless otherwise terminated in accordance with Section 15.2.

15.2 Termination.

15.2.1 Termination for Breach. Either Party may terminate this Agreement upon material breach of any obligation under this Agreement by the other Party provided that such breach (if curable) is not cured within thirty (30) days following the receipt of written notice thereof by the non-breaching Party. If there is a dispute between the Parties as to whether a material breach has occurred or whether such breach was curable or has been cured by the other Party within the above cure period, notice of termination may only be given after the terminating Party has escalated the issue to the relevant senior executives pursuant to Section 16.3.1 and the senior executives have not been able to solve such dispute within thirty (30) days of such escalation.

15.2.2 Termination by Bioeq for Underperformance. Subject to the second sentence of this Section 15.2.2, Bioeq may notify Licensee of its intent to terminate this Agreement anytime within thirty ([***]) days following the end of any [***] ([***]) month time period starting [***] ([***]) months after the First Commercial Sale of the first [***] Product in the Field in the Territory upon written notice to Licensee, if Licensee, with respect to its sales of Licensed Products in the Field in the Territory, has not achieved an average market share of at least [***] percent ([***]%) of the [***] (such market excluding for clarity in all cases [***]), calculated based on [***] in the Field in the Territory in the [***] ([***]) months prior to the end of such [***] ([***]) month time period (i.e., for example, in months [***] of the [***] after the First Commercial Sale of such [***] Product) (***Minimum Market Share Requirement***); upon Licensee's receipt of such notice from Bioeq, if Licensee does not achieve the Minimum Market Share Requirement, applied mutatis mutandis, during the subsequent [***] ([***]) months period following its receipt of such notice from Bioeq (***Licensee Cure Period***), Bioeq may terminate this Agreement upon written notice to Licensee; provided further, that the termination right described in this Section 15.2.2 shall apply only if [***], and provided further that such failure of Licensee to achieve the Minimum Market Share Requirement (i) is not due to any [***] (including [***]); (ii) not due to any [***] Bioeq's right to notify Licensee of its intent to terminate this Agreement in accordance with the first sentence of this Section 15.2.2 shall apply only until [***] ([***]) days after the [***] ([***]) anniversary of the First Commercial Sale of the first [***] Product in the Field in the Territory, after which Bioeq shall have no further rights under this Section 15.2.2.

15.2.3 Termination by Bioeq for Development or Commercialization of a Competitive Product by Licensee. Bioeq may terminate this Agreement immediately upon written notice to Licensee, if Licensee conducts any clinical development of, markets, sells or distributes any Competitive Product in the Territory, whether directly or indirectly through the intermediary of a Third Party or its Affiliates (***Restricted Activities***); provided, that in the event that Restricted Activities are being or would be deemed to be conducted by Licensee solely in connection with a Competitor Change of Control, Bioeq may not terminate this Agreement in accordance with this Section 15.2.2 and instead may terminate this Agreement in accordance with Section 15.2.9.

15.2.4 Termination by Bioeq for challenge of Patent Rights. Bioeq may terminate this Agreement immediately upon written notice to Licensee, if Licensee or any of its Affiliates or sublicensees directly or indirectly challenge the validity or enforceability of, or oppose any extension of or the grant of a supplementary protection certificate with respect to, any Licensed Patent in any legal, court, administrative or other governmental proceeding.

15.2.5 Termination by Licensee for Convenience. Licensee may terminate this Agreement for convenience upon eighteen (18) months' advance written notice to Bioeq; provided, however, that any such termination for convenience shall not become effective prior to twelve (12) months after the First Commercial Sale of the first Licensed Product. In the event of any such termination for convenience by Licensee, [***]

15.2.6 Termination by Licensee for Development Delay.

(a) Licensee may terminate this Agreement immediately upon written notice sent to Bioeq any time between [***] and until the receipt of first Regulatory Approval of any Licensed Product in the Field in the Territory if (a) Bioeq has failed to obtain any Regulatory Approval for any Licensed Product in the Field in the Territory on or prior to [***], and (b) [***].

(b) Any time prior to [***], if [***], as reasonably determined based on the relevant facts and circumstances existing at such time, conclude that the first Regulatory Approval for any Licensed Product in the Field in the Territory could not reasonably be expected to be obtained by [***] (such relevant facts and circumstances to include the [***] for [***] in the Territory, the [***], and the [***] (e.g., [***], etc.),

Licensee may terminate this Agreement upon written notice to Bioeq. If [***] that the first Regulatory Approval for any Licensed Product in the Field in the Territory could not reasonably be expected to be obtained by [***], within [***] days of [***] notifying [***] in writing of its determination thereof, then the Parties shall negotiate in good faith and use reasonable efforts to settle such disagreement in accordance with Section 16.3.1 for the provided [***] ([***]) day period, provided, however, notwithstanding Section 16.3, either Party may initiate proceedings in relation to such disagreement at any time regardless of the expiration of such [***] ([***]) day period. Any such proceedings shall be finally and exclusively resolved by binding arbitration according to the [***], as applicable on the date of commencement of the arbitration proceedings, by [***] ([***]) [***] appointed mutually by the Parties within [***] ([***]) days of the commencement of arbitration, provided, however, if the Parties are unable to appoint such arbitrator within such [***] ([***]) day period, then the arbitrator shall be appointed by the [***]. The arbitrator shall be someone who has at least [***] ([***]) years of relevant background, experience, and expertise in the biopharmaceutical industry, and specifically as to the subject matter of the dispute to which such arbitrator is to opine on (e.g., [***]. The place of such arbitration shall be [***]. Exclusive language of the arbitration proceedings shall be English. The costs of the arbitration proceeding shall be [***]. The Parties agree that such judgment or award may be enforced in any court of competent jurisdiction. The Parties undertake to keep confidential all awards in their arbitration, together with all materials in the proceedings created for the purpose of the arbitration and all other documents produced by the other Party in the proceedings not otherwise in the public domain, save and to the extent that disclosure may be required by a Party by legal duty, to protect or pursue a legal right or to enforce or challenge an award in legal proceedings before a court or other judicial authority. The Parties shall complete any and all arbitrations subject to this Section 15.2.6 within [***] ([***]) days from the commencement of the arbitration.

15.2.7 Termination by Licensee for Regulatory Reasons. Licensee may terminate this Agreement immediately upon written notice to Bioeq in the event that Bioeq receives [***], in each case, with respect to the first Biologics License Application for such Licensed Product filed by Bioeq with the FDA in accordance with Section 4.1.1 (***Adverse Regulatory Event***). Bioeq shall notify Licensee in writing immediately of any such Adverse Regulatory Event which may occur.

15.2.8 Termination for Insolvency. Either Party may terminate this Agreement immediately if an Insolvency Event occurs (save as part of a bona fide reorganisation not involving insolvency) in respect of the other Party.

(a) **Effect of Bankruptcy**. In the event of the rejection of this Agreement by or on behalf of a Party (***Bankrupt Party***) in the event of an Insolvency Event of such Party, all licenses and rights to licenses granted under or pursuant to this Agreement by the Bankrupt Party to the other Party (***Non Bankrupt Party***) are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the United States Bankruptcy Code (***Bankruptcy Code***), licenses of rights to "intellectual property" as defined under Section 101(35 A) of the Bankruptcy Code. The Parties agree that the Non Bankrupt Party, as a licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code, and that upon commencement of a bankruptcy proceeding by or against the Bankrupt Party under the Bankruptcy Code, the Non Bankrupt Party shall be entitled to a complete duplicate of, or complete access to (as the Non Bankrupt Party deems appropriate) any such intellectual property and all embodiments of such intellectual property. Such duplicates shall be promptly delivered, and such access shall promptly be provided, to the Non Bankrupt Party (i) upon any such commencement of a bankruptcy proceeding, upon written request therefor by the Non Bankrupt Party, unless the Bankrupt Party elects to continue to perform all of its obligations under this Agreement or (ii) if not delivered under (i) above, upon the rejection of this Agreement by or on behalf of the Bankrupt Party, upon written request therefor by the Non Bankrupt Party. The provisions of this Section 15.2.6(b)(a) are without prejudice to any rights the Non Bankrupt Party may have arising under the Bankruptcy Code or other Applicable Law.

15.2.9 Termination for Competitor Change of Control. Licensee shall notify Bioeq in writing within [***] ([***]) days after entry by Licensee into a definitive agreement which would result in a Competitor Change of Control. During the period between when Licensee enters into a definitive agreement which would result in a Competitor Change of Control and when such definitive agreement is consummated, Licensee shall have the right to divest all such Competitive Products which would be acquired upon the consummation of the transaction giving rise to such Competitor Change of Control. Upon the consummation of such definitive agreement, if Licensee has not then divested all such Competitive Products such that a Competitor Change of Control has occurred, Bioeq may, upon sending written notice to Licensee within sixty (60) days thereafter, terminate this Agreement.

15.2.10 Effect of Termination of the [***] Agreement. Without limiting Bioeq's obligations under Article 10, in the event that the [***] Agreement is terminated by [***], Bioeq will notify Licensee thereof immediately, and Licensee may terminate this Agreement upon written notice to Bioeq.

15.2.11 Written Notice. Any termination shall only be valid if made in writing and delivered to the other Party under the address set forth in Section 16.1.

15.3 Effect of Termination. In case of any termination or expiration of this Agreement, all rights and obligations of the Parties shall cease immediately, unless otherwise indicated in this Section below or elsewhere in this Agreement:

15.3.1 Sale of Inventory. Licensee shall be permitted, at Bioeq's choice (if this Agreement is terminated by Bioeq pursuant to Sections 15.2.1, 15.2.2, 15.2.3, 15.2.4, 15.2.8 or 15.2.9, or by Licensee pursuant to Section 15.2.5) or at Licensee's choice (if this Agreement is terminated by Licensee pursuant to Sections 15.2.1, 15.2.6, 15.2.7 or 15.2.8), to cither (a) continue selling its and its Affiliates' inventory of Licensed Products existing on the termination effective date in accordance with this Agreement for a maximum period of [***] ([***]) days (in which case all terms and conditions of this Agreement, including Licensee's obligation to report and pay royalties, shall continue to apply to such continued sale) or (b) sell such inventory to Bioeq at the supply price paid by Licensee to Bioeq for such inventory in accordance with the Manufacturing and Supply Agreement.

15.3.2 Transfer of Biologics License Application Approvals. Licensee shall, within [***] ([***]) days of the effective date of termination of the Agreement at the latest (and at no cost to Bioeq if this Agreement is terminated by Bioeq pursuant to Sections 15.2.1, 15.2.2, 15.2.3, 15.2.4, 15.2.8 or 15.2.9, or by Licensee pursuant to Section 15.2.5, or at Bioeq's cost and expense if this Agreement is terminated by Licensee pursuant to Sections 15.2.1, 15.2.6, 15.2.7 or 15.2.8, as applicable) transfer and assign to Bioeq or its designee all of Licensee's right, title and interest in and to any and all Biologics License Applications and Biologics License Application Approvals controlled by Licensee for the Licensed Products in the Field in the Territory as of the effective date of such termination, including any and all documentation pertaining to such filings and Biologics License Application Approvals (provided that the physical or electronic transfer of files and documentation in connection with such transfer and assignment of rights may occur after such [***] ([***]) day period without being deemed a breach of this Section 15.3.2 by Licensee). In addition, upon Bioeq's request, Licensee shall notify the competent Regulatory Authority of such transfer, supply Bioeq with all documents already prepared by Licensee or its Affiliates for the filing of applications in relation to the Licensed Products with any Regulatory Authority and/or apply for the closing of any such application. Notwithstanding any other rights Bioeq may have under this Agreement or Applicable Law; if Licensee does not transfer and assign to Bioeq or its designee its rights in any Biologics License Applications and Biologics License Application Approvals controlled by Licensee for the Licensed Products in the Field in the Territory within the above [***] ([***]) day time period (provided that the physical or electronic transfer of files and documentation in connection with such transfer and assignment

of rights may occur after such [***] ([***]) day period without being deemed a breach of this Section 15.3.2 by Licensee), [***].

15.3.3 Co-operation. Licensee shall (at no cost to Bioeq if this Agreement is terminated by Bioeq pursuant to Sections 15.2.1, 15.2.2, 15.2.3, 15.2.4, 15.2.8 or 15.2.9, or by Licensee pursuant to Section 15.2.5, or at Bioeq's cost and expense if this Agreement is terminated by Licensee pursuant to Sections 15.2.1, 15.2.6, 15.2.7 or 15.2.8, as applicable) use Commercially Reasonable Efforts to cooperate with Bioeq or its designee, and provide [***] reasonable assistance and support, to [***] Bioeq or its designee to take over the Commercialization of the Licensed Products in the Field in the Territory [***] following the effective date of such termination, including by (a) using Commercially Reasonable Efforts to provide [***], (b) disclosing and assigning (to the extent permitted under the relevant agreement) to Bioeq Licensee's existing agreements relating solely to the Commercialization of the Licensed Product in the Territory, including with [***], to the extent legally possible ([***]) and (c) transferring Licensed Product-specific marketing materials, including [***]. With respect to any such information, materials or agreements provided to Bioeq pursuant to this Section 15.3.3, Licensee may redact information relating to other products which are not Licensed Products as well as proprietary information of the relevant Third Party from such information, materials, or agreements prior to providing the same to Bioeq. Additionally, to the extent Licensee has agreements relating to the Commercialization of both the Licensed Products and other products in the Territory with wholesalers, distributors, pharmacies, hospitals, health insurances and other relevant parties, upon request from Bioeq, Licensee shall introduce Bioeq to such parties and [***].

15.3.4 Licensee Improvements. The license granted by Licensee pursuant to Section 9.2.2 shall be extended to also include the Development, Manufacture, sale, import or other Commercialization of Licensed Products in the Field in the Territory, and, unless this Agreement is terminated by Bioeq pursuant to pursuant to Sections 15.2.1, 15.2.2, 15.2.3, 15.2.4, 15.2.8 or 15.2.9, or by Licensee pursuant to Section 15.2.5 (in [***]), such license shall thereafter be royalty-bearing on Bioeq on Net Sales (applied *mutatis mutandis* as if Bioeq were Licensee, and additionally applying to sales by sublicensees of Bioeq) by Bioeq, its Affiliates, and its sublicensees of Licensed Products in the Field in the Territory which have [***] Licensee Improvement, at [***].

15.3.5 License to Licensee-Controlled Trademark. Solely in the event that this Agreement is terminated by Bioeq pursuant to Sections 15.2.1, 15.2.2, 15.2.3, 15.2.4, 15.2.8 or 15.2.9 or by Licensee pursuant to Section 15.2.5 , Licensee shall grant, and hereby grants to Bioeq an exclusive, royalty-free, fully paid, sublicenseable, license to use the Licensee-Controlled Trademarks which were actually used by Licensee to Commercialize the Licensed Products in the Territory in connection with Bioeq's Commercialization of the Licensed Products in the Territory. If this Agreement is terminated by Licensee pursuant to Sections 15.2.1, 15.2.6, 15.2.7 or 15.2.8, such license shall be royalty bearing on Bioeq at [***].

15.3.6 Reimbursement of Milestone Payments. Upon termination by Licensee for development delay pursuant to Section 15.2.6, Bioeq shall refund to Licensee all milestone payments pursuant to Section 7.2 received from Licensee during the term of this Agreement.

15.3.7 Accrued Payment Claims. Termination of this Agreement for any reason whatsoever shall not relieve Licensee of its obligations to pay all amounts payable to Bioeq which have accrued prior to, but remain unpaid as of, the date of termination hereof, or which accrue thereafter. Upon termination of this Agreement any accrued payment obligations shall become immediately due and payable.

15.3.8 Survival. Articles 1, 8, 11 (and with respect to Sections 11.1-11.2, in accordance with Section 11.6), and 13 (solely as to Claims for Losses arising during the term of the Agreement), and Sections 7.3.5, 7.3.6, 9.1, 9.2.2 (in accordance with and as modified by Section 15.3.4), 9.2.3, 9.2.4, 9.6, 15.3, 15.4 (as applicable) and 16 of this Agreement shall survive any termination or expiration of this Agreement.

15.4 **Non-Solicitation**. Each Party agrees that, during the [***] ([***]) [***] period starting from the Effective Date, such Party will not, directly or indirectly, solicit for employment any employee of the other Party or its Affiliates or otherwise induce or attempt to induce such employees to terminate their employment with such other Party or such other Party's Affiliates; provided, however, that general public solicitations and advertisements not directed at employees of the other Party, and the extension of offers to persons who respond to such general solicitations and advertisements, will not be deemed violations of this provision. Upon breach of this non-solicitation obligation set forth in this Section 15.4, [***].

16. GENERAL PROVISIONS

16.1 **Notices**. Any consent, notice or report required or permitted to be given or made under this Agreement by one of the Parties to the other shall be in writing by certified, overnight mail and addressed to such other Party at its address indicated below, or to such other address as the addressee shall have last furnished in writing to the addressor, and shall be effective upon receipt by the addressee.

If to Bioeq: Bioeq IP AG
[***]

Attention: [***]

If to Licensee : Coherus BioSciences, Inc.
333 Twin Dolphin Drive, Suite 600
Redwood City, CA, 94065, USA

Attention: [***]

16.2 **Applicable Law**. This Agreement shall be governed by and construed in accordance with the laws of [***], without regard to the conflicts of law principles thereof, and [***].

16.3 **Dispute Resolution**.

16.3.1 The Parties shall negotiate in good faith and use reasonable efforts to settle any dispute, controversy or claim arising from or related to this Agreement or the breach thereof. If the Parties cannot resolve such dispute, controversy or claim, either Party may escalate the matter further to the following senior executives of the Parties for final discussion and resolution within [***] ([***]) days:

For Bioeq: [***]

For Licensee: Chief [***]

16.3.2 If the senior executives are not able to resolve the matter in dispute within the above [***] ([***]) [***] period, either Party may initiate proceedings in relation to such matter. Any such proceedings shall be finally resolved by binding arbitration according to the [***], as applicable on the date of commencement of the arbitration proceedings, by three (3) arbitrators appointed as follows: each Party shall select one (1) arbitrator, and the two arbitrators so selected by the Parties shall select the third and final arbitrator. If the arbitrators selected by the Parties are unable or fail to agree upon the third arbitrator within [***] ([***]) [***] after the Parties appoint the two arbitrators, then the [***] shall appoint the President of the Tribunal. All arbitrators selected shall have the requisite background, experience and expertise in the biopharmaceutical industry to assist with resolution of the dispute. Place of arbitration shall be [***]. Exclusive language of the arbitration proceedings shall be English. Each Party shall bear its own costs and

expenses and attorneys' fees in connection with such arbitration, and the Parties shall share equally all costs of engaging the three (3) arbitrators and using the [***] to arbitrate such matter (unless the arbitration results in a decision and judgment otherwise). The Parties agree that such judgment or award may be enforced in any court of competent jurisdiction.

16.3.3 Notwithstanding anything to the contrary, a Party may seek preliminary measures, including a temporary restraining order or a preliminary injunction from any court of competent jurisdiction in order to prevent immediate and irreparable injury, loss, or damage on a provisional basis, pending the decision of the arbitral tribunal on the ultimate merits of any dispute

16.3.4 The Parties undertake to keep confidential all awards in their arbitration, together with all materials in the proceedings created for the purpose of the arbitration and all other documents produced by the other Party in the proceedings not otherwise in the public domain, save and to the extent that disclosure may be required by a Party by legal duty, to protect or pursue a legal right or to enforce or challenge an award in legal proceedings before a court or other judicial authority.

16.4 Assignment. Except as otherwise expressly provided under this Agreement, neither Party may assign or otherwise transfer this Agreement or any right or obligation hereunder (whether voluntarily, by operation of law or otherwise), without the prior express written consent of the other Party; except however, that either Party shall be permitted to effect such an assignment or transfer without the consent of the other Party to (a) any of its Affiliates or (b) in connection with a sale of all or substantially all of its assets to which this Agreement relates, whether by merger, acquisition, asset sale, stock purchase, or otherwise, but in any event subject to Bioeq's ability to terminate this Agreement in accordance with Section 15.2.9 (for the avoidance of doubt, such termination right pursuant to Section 15.2.9 shall apply *mutatis mutandis* in case of assignment of the Agreement to a Competitor in all cases listed under subsection (b) above). Any purported assignment or transfer in violation of this Section 16.4 shall be null and void.

16.5 Subcontracting. Bioeq shall be entitled to subcontract any of its obligations under this Agreement only with the prior written consent of Licensee, except that such prior written consent of Licensee shall not be required for Bioeq to subcontract to (a) its Affiliates or (b) [***], [***] and [***] and the subcontractors listed in Schedule 16.5, provided that it shall remain liable for the performance of its obligations under this Agreement. Licensee shall be entitled to freely subcontract or delegate any of its rights or obligations under this Agreement to its Affiliates or to Third Parties, provided that (i) all sales of Licensed Products in the Field in the Territory continue to be made by Licensee or its Affiliates (or their wholesalers or distributors) and (ii) Licensee shall remain liable for the performance of its obligations under this Agreement.

16.6 Construction. This Agreement will be fairly interpreted in accordance with its terms and without any strict construction in favour of or against any Party. The words "include", "includes", and "including", "such as", "for example", or any other words or phrases of enumerative meaning shall be deemed to be followed by the phrase "(but without limitation)".

16.7 Severability. Whenever possible, each provision of this Agreement shall be interpreted in such manner as to be valid and enforceable under Applicable Laws, but if any provision of this Agreement is held to be prohibited by or invalid or unenforceable under Applicable Laws, such provision shall be ineffective only to the extent of such prohibition, invalidity or unenforceability, without invalidating the remainder of such provisions or the remaining provisions of this Agreement, and shall be replaced by a valid and enforceable provisions which comes closest to the commercial intention of the replaced provision.

16.8 Independent Contractors. Each Party hereby acknowledges that the Parties shall be independent contractors and that the relationship between the Parties shall not constitute a joint venture or

agency. Neither Party shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party, without the prior consent of the other Party to do so.

16.9 Waiver. The waiver by a Party of any right hereunder, or of any failure to perform or breach by the other Party hereunder, shall not be deemed a waiver of any other right hereunder or of any other breach or failure by the other Party hereunder whether of a similar nature or otherwise.

16.10 Modification. This Agreement (including the attached Annexes) shall not be modified without the prior written consent of each Party. In the event that the terms of any Annex is inconsistent with the terms of this Agreement, this Agreement shall control, unless otherwise explicitly agreed to in writing by the Parties.

16.11 Entire Agreement. This Agreement (including the attached Annexes and Schedules) together with the Manufacturing and Supply Agreement and the Pharmacovigilance Agreement described in Section 4.6 contains the entire understanding of the Parties with respect to the subject matter hereof. To the extent of any conflict between the terms and conditions of this Agreement and the terms and conditions of the Manufacturing and Supply Agreement or Pharmacovigilance Agreement, the terms and conditions of this Agreement shall control unless otherwise expressly set forth to the contrary in the Manufacturing and Supply Agreement or Pharmacovigilance Agreement. All other express or implied representations, agreements and understandings with respect to the subject matter hereof, either oral or written, heretofore made, are expressly superseded by this Agreement.

16.12 Counterparts. This Agreement may be executed in counterparts, all of which together shall constitute one and the same instrument.

(*End of Agreement — Signatures on the following page*)

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the Effective Date.

Bioeq IP AG

By: /s/ Hannes Teissl /s/ Nicola Mikulcik Date: November 02, 2019

Name: Hannes Teissl Nicola Mikulcik

Title: Board Member Board Member

Coherus BioSciences, Inc.

By: /s/ Dennis M. Lanfear Date: November 4, 2019

Name: Dennis M. Lanfear

Title: Chairman & Chief Executive

Annex 1

[***] Agreement

Omitted pursuant to Regulation S-K, Item 601(a)(5)

Annex 2

Term Sheet for Manufacturing Supply Agreement

Omitted pursuant to Regulation S-K, Item 601(a)(5)

Schedule 1.38

Licensed Patents

Omitted pursuant to Regulation S-K, Item 601(a)(5)

Schedule 3.2

Initial Development & Manufacturing Plan

Omitted pursuant to Regulation S-K, Item 601(a)(5)

Schedule 3.5.1

[***]

Omitted pursuant to Regulation S-K, Item 601(a)(5)

Schedule 6.2(c)

Initial Commercialization Commitments

Omitted pursuant to Regulation S-K, Item 601(a)(5)

Schedule 6.3

Contents of Commercialization Plan for Planned Activities

Omitted pursuant to Regulation S-K, Item 601(a)(5)

Schedule 16.5

Pre-Approved Subcontractors

Omitted pursuant to Regulation S-K, Item 601(a)(5)

Exhibit 10.30

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and would likely cause competitive harm to the registrant if publicly disclosed.

EXECUTION VERSION

LICENSE AGREEMENT

This LICENSE AGREEMENT (this "Agreement") is entered into as of January 13th, 2020 (the "Effective Date") by and between Innovent Biologics (Suzhou) Co., Ltd., a PRC corporation ("Innovent") and Coherus BioSciences, Inc., a Delaware corporation ("Coherus"). Innovent and Coherus are each referred to herein by name or as a "Party" or, collectively, as the "Parties."

RECITALS

WHEREAS, Innovent owns or controls intellectual property rights related to the development, manufacture and commercialization of certain biosimilar products, including biosimilar products designated as IBI-301 and IBI-305, respectively;

WHEREAS, Coherus is a company focused on the development, manufacture and commercialization of biosimilar products; and

WHEREAS, Coherus wishes to obtain an exclusive license from Innovent, and Innovent wishes to grant an exclusive license to Coherus, the intellectual property rights related to certain of Innovent's biosimilar products subject to and in accordance with the terms and conditions of this Agreement.

NOW, THEREFORE, in consideration of the foregoing and the mutual agreements set forth below, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

1. DEFINITIONS

1.1 "aBLA" means an abbreviated Biologics License Application filed with the FDA in the United States, as defined in Section 351(k) of the Public Health Services Act (42 U.S.C. 262(k)).

1.2 "Accounting Standards" means, with respect to Coherus and its Affiliates or sublicensees, U.S. generally accepted accounting principles in effect at the relevant time, consistently applied, and with respect to Innovent and its Affiliates, International Financial Reporting Standards in effect at the relevant time, consistently applied.

1.3 "Acquirer" has the meaning set forth in Section 14.4.

1.4 "Additional Active" means an active pharmaceutical or active biological ingredient that is not a Licensed Antibody.

1.5 "Affiliate" means any Person which, directly or indirectly through one (1) or more intermediaries, controls, is controlled by, or is under common control with a Party. For purposes of this Section 1.5 only, the term "control" (including, with correlative meanings, the terms "controlled by" and "under common control with") as used with respect to a Person means: (a) direct or indirect ownership of fifty percent (50%) or more of the voting securities or other voting interest of any Person (including attribution from related parties); or (b) the possession, directly or indirectly, of the power to direct, or cause the direction of, the management and policies of such Person, whether through ownership of voting securities, by contract, as a general partner, as a manager, or otherwise.

1.6 "Agreement" has the meaning set forth in the Preamble.

1.7 "Agreement Payments" has the meaning set forth in Section 8.5(b)(i).

1.8 "Alliance Manager" has the meaning set forth in Section 3.2.

1.9 "Anti-Corruption Laws" means any and all Applicable Law that relates to anti-corruption or anti-bribery, including the U.S. Foreign Corrupt Practices Act.

1.10 "Applicable Law" means all applicable laws, statutes, rules, regulations, treaties (including tax treaties), orders, judgments or ordinances having the effect of law of any national, multinational, federal, state, provincial, county, city, or other political subdivision, including, to the extent applicable, GCP, GLP, and GMP, as well as all applicable data protection and privacy laws, rules, and regulations, including, to the extent applicable, the United States Department of Health and Human Services privacy rules under the Health Insurance Portability and Accountability Act and the Health Information Technology for Economic and Clinical Health Act and the EU Data Protection Directive (Council Directive 95/46/EC) and applicable laws implementing the EU Data Protection Directive and the General Data Protection Regulation (2016/679), the Foreign Corrupt Practices Act of 1977, or any comparable laws in any country, and all export control laws.

1.11 "Approved CMO" has the meaning set forth in Section 7.3(b).

1.12 "Auditor" has the meaning set forth in Section 8.6(b).

1.13 "Bevacizumab Antibody" means the antibody known as IBI-305 that is (a) a recombinant humanized monoclonal antibody directed against the vascular endothelial growth factor, and (b) (i) covered by Patents Controlled by Innovent and/or (ii) (A) incorporates, combines or uses proprietary Know-How Controlled by Innovent, or (B) derived from Innovent's proprietary cell lines. For clarity, an antibody is deemed "covered by" a Patent where such Patent is an issued Patent or a pending patent application, and an antibody will not be deemed to not constitute a Bevacizumab Antibody solely as a result of the abandonment or expiration of the last Patent Controlled by Innovent that covers such antibody.

1.14 "Bevacizumab Existing Regulatory Materials" has the meaning set forth in Section 5.2(a)(i).

1.15 "Bevacizumab Existing Regulatory Material Transfer Date" means the date on which all of the Bevacizumab Existing Regulatory Materials that the Parties through the JSC in accordance with Section 3.1(c)(i) determine need to be translated into the English language under Section 5.2(a)(i) are provided by or on behalf of Innovent to Coherus.

1.16 "Bevacizumab Field" means the treatment, prevention or amelioration of any human diseases and conditions as included in the label of the Bevacizumab Reference Product.

1.17 "Bevacizumab Licensed Product" means all products containing the Bevacizumab Antibody; provided that, with respect to an Innovent Combination Product containing a Bevacizumab Antibody, the Bevacizumab Licensed Product shall include the Bevacizumab Antibody portion of such Innovent Combination Product, but exclude [***].

1.18 "Bevacizumab Product Term" has the meaning set forth in Section 13.1(a).

1.19 "Bevacizumab Reference Product" means the biologic drug products containing drug substance Bevacizumab and sold under the trademark Avastin®.

1.20 "Bevacizumab Reference Price" means the weighted average price as determined by (a) [***] and (b) [***].

1.21 "Biosimilar Product" means, with respect to a product, a biological medicinal product or biological product for human use which: (a) is highly similar to such product notwithstanding minor differences in clinically inactive components; (b) has no clinically meaningful differences with regard to such product in terms of safety, purity, or potency, as determined by Applicable Law or any applicable Regulatory Authority; and (c) is approved for use (i) in the U.S., under 42 U.S.C § 262(k) as a biosimilar biological product (as defined in 42 U.S.C. § 262(i)(1), (2)) and for which such product is the reference product (as defined in 42 U.S.C. § 262(i)(4)) or (ii) in any other country or jurisdiction, pursuant to an equivalent regime in such country or jurisdiction, and for which such product is the reference product.

1.22 "Biologics License Application" or "BLA" means a request for permission to introduce, or deliver for introduction, a biologic product into interstate commerce (21 CFR 601.2) to the FDA, including any supplements, addendums, or amendments thereto.

1.23 "BPCIA" means the Biologics Price Competition and Innovation Act of 2009, as amended from time to time.

1.24 "BPCIA Proceedings" has the meaning set forth in Section 9.4(a).

1.25 "Business Day" means any day other than: (a) a Saturday or Sunday or (b) any day on which commercial banks in [***] are authorized or required by Applicable Law to remain closed.

1.26 "Calendar Quarter" means each of the three (3)-month periods ending March 31, June 30, September 30, and December 31; provided, that: (a) the first Calendar Quarter of the Term shall extend from the Effective Date to the end of the first complete such three (3)-month period thereafter; and (b) the final Calendar Quarter of the Term shall end on the last day of the Term.

1.27 "Calendar Year" means the period beginning on the Effective Date and ending on December 31 of the calendar year in which the Effective Date falls, and thereafter each successive period of twelve (12) consecutive calendar months beginning on January 1 and ending on December 31; provided, that the final Calendar Year of the Term shall end on the last day of the Term.

1.28 "Clinical Trial" means any human clinical trial of a pharmaceutical or biological product and includes Phase 1 Clinical Trial and Phase 3 Clinical Trial.

1.29 "Clinical Trial Data" has the meaning set forth in Section 5.3(c).

1.30 "Code" has the meaning set forth in Section 13.4(b).

1.31 "CMO" means a Third Party contract manufacturing organization.

1.32 "Coherus" has the meaning set forth in the Preamble.

1.33 "Coherus Indemnitees" has the meaning set forth in Section 12.2.

1.34 "Coherus Inventions" has the meaning set forth in Section 9.1(e).

1.35 "Coherus IP" means any and all Coherus Inventions Controlled by Coherus or any of its Affiliates during the Term that is necessary or reasonably useful for (a) the Development, Manufacture, or Commercialization of the Licensed Antibody, including the Licensed Antibody portion of an

Innovent Combination Product in the Innovent Territory; or (b) for the Development of the Licensed Antibody portion of the Innovent Combination Products in the Territory.

1.36 "Coherus Licensed Patents" has the meaning set forth in Section 9.1(e).

1.37 "Coherus Patent Infringement" has the meaning set forth in Section 9.3(c)(i).

1.38 "Combination Product" means: (a) a product that contains a Licensed Product and one (1) or more Additional Actives; or (b) a Licensed Product that is co-packaged or combined with one (1) or more products containing one (1) or more Additional Actives, and such Licensed Product and product(s) containing such Additional Actives are sold for a single price.

1.39 "Commercialization" means any and all activities directed to the commercialization of a product, including marketing, detailing, promotion, market research, distributing, order processing, handling returns and recalls, booking sales, customer service, administering, and commercially selling such product, importing, exporting, and transporting such product for commercial sale, and seeking Pricing Approval of a product (if applicable), whether before or after Regulatory Approval has been obtained, as well all regulatory compliance with respect to the foregoing. For clarity, "Commercialization" does not include: (a) Manufacturing; or (b) the conduct of any Clinical Trials or other trials commenced after Regulatory Approval. When used as a verb, "Commercialize" means to engage in Commercialization.

1.40 "Commercialization Plan" has the meaning set forth in Section 6.2(b).

1.41 "Commercially Reasonable Efforts" means, with respect to a particular activity or product and a party, that measure of efforts and resources that is consistent with the efforts and resources that a biopharmaceutical or biotechnology company of comparable size and resources as such party normally commits to its own activities or products that it is actively developing or commercializing and that are of a similar potential value, stage of research or development, life cycle and commercial potential, taking into account all relevant factors that such party would normally take into account, including issues of safety and efficacy, product profile, the competitiveness of alternative products (including generic products), the patent or other proprietary position of such product (including patent coverage and regulatory exclusivity), the regulatory requirements involved and the potential profitability of such product.

1.42 "Competitor Agreement" has the meaning set forth in Section 13.3.

1.43 "Confidential Information" means, with respect to a Party, all confidential and proprietary information, including chemical or biological materials, chemical structures, sequence information, commercialization plans, correspondence, customer lists, data, development plans, formulae, improvements, Know-How, processes, regulatory filings, reports, strategies, techniques, or other information, in each case, that are disclosed by or on behalf of such Party to the other Party pursuant to this Agreement, regardless of whether any of the foregoing are marked "confidential" or "proprietary" or communicated to the other Party by or on behalf of the disclosing Party in oral, written, visual, graphic, or electronic form.

1.44 "Control," "Controls," or "Controlled" means with respect to any Intellectual Property Right, or Confidential Information, the ability of a Party or its Affiliates, as applicable (whether through ownership or license (other than a license granted in this Agreement)) to grant to the other Party the licenses or sublicenses as provided herein, or to otherwise disclose such Intellectual Property Right or Confidential Information to the other Party, without violating the terms of any then-existing agreement with any Third Party at the time such Party or its Affiliates, as applicable, would

be required hereunder to grant the other Party such license or sublicenses as provided herein or to otherwise disclose such Intellectual Property Right or Confidential Information to the other Party. Notwithstanding the foregoing, a Party will be deemed not to Control any Intellectual Property Right, Confidential Information, compound, or molecule (including any antibody) that is owned or in-licensed by an Acquirer except: (a) with respect to any such Intellectual Property Right arising as a result of activities of employees or consultants of the Acquirer who participate in activities under this Agreement, or have access to Confidential Information under this Agreement after a change of control of such Party or an acquisition of all or substantially all of the assets of such Party to which this Agreement relates; or (b) to the extent that any such Intellectual Property Right is included in or used in furtherance of a Party's activities under this Agreement by the Acquirer after a change of control of such Party or acquisition of all or substantially all the assets of such Party to which this Agreement relates.

1.45 "Cure Period" has the meaning set forth in Section 13.2(a).

1.46 "Damages" has the meaning set forth in Section 9.4(e).

1.47 "Development" means: (a) research activities (including drug discovery, identification, or synthesis) with respect to a product; or (b) preclinical and clinical drug development activities and other development activities with respect to a product, including test method development and stability testing, toxicology, formulation, process development, qualification and validation, quality assurance, quality control, Clinical Trials (including Clinical Trials and other trials commenced after Regulatory Approval), statistical analysis and report writing, the preparation and submission of INDs and BLAs, regulatory affairs with respect to the foregoing, and all other activities necessary or useful or otherwise requested or required by a Regulatory Authority or as a condition or in support of obtaining or maintaining a Regulatory Approval. For clarity, "Development" does not include Manufacturing. When used as a verb, "Develop" means to engage in Development.

1.48 "Disclosing Party" has the meaning set forth in Section 10.1.

1.49 "Dispute" has the meaning set forth in Section 14.6(b)(i).

1.50 "Dollars" or "$" means the legal tender of the United States.

1.51 "Effective Date" has the meaning set forth in the Preamble.

1.52 "Electronic Delivery" has the meaning set forth in the Section 14.11.

1.53 "Existing Regulatory Materials" means Bevacizumab Existing Regulatory Materials and Rituximab Existing Regulatory Materials, as applicable.

1.54 "FDA" means the U.S. Food and Drug Administration (and any successor entity thereto).

1.55 "Field" means the Bevacizumab Field and the Rituximab Field.

1.56 "First Commercial Sale" means, on a Licensed Product-by-Licensed Product and country-by-country basis, the first sale of such Licensed Product in such country for use or consumption by the general public (following receipt of all Regulatory Approvals that are required in order to sell such Licensed Product in such country) and for which any of Coherus or its Affiliates or sublicensees has invoiced sales of Licensed Products in the Territory; provided, however, that the following shall not constitute a First Commercial Sale: (a) any sale to an Affiliate or sublicensee, unless such Affiliate or sublicensee is the last Person in the distribution chain of the Licensed Product; (b) any

use of such Licensed Product in Clinical Trials or non-clinical development activities with respect to such Licensed Product by or on behalf of a Party; or (c) any disposal or transfer of such Licensed Product for a bona fide charitable purpose, compassionate use, or samples.

1.57 "FTE" means the equivalent of the work of one (1) person full time for one (1) Calendar Year (consisting of at least a total of [***] ([***]) hours per Calendar Year).

1.58 "FTE Rate" means the rate of USD [***] ($[***]) per FTE for an employee of Innovent.

1.59 "GCP" means the applicable then-current ethical and scientific quality standards for designing, conducting, recording, and reporting Clinical Trials as are required by applicable Regulatory Authorities or Applicable Law in the relevant jurisdiction, including, in the United States, Good Clinical Practices established through FDA guidance, and, outside the United States, Guidelines for Good Clinical Practice – ICH Harmonized Tripartite Guideline (ICH E6).

1.60 "GLP" means the applicable then-current good laboratory practice standards as are required by applicable Regulatory Authorities or Applicable Law in the relevant jurisdiction, including, in the United States, those promulgated or endorsed by the FDA in U.S. 21 C.F.R. Part 58, or the equivalent thereof as promulgated or endorsed by the applicable Regulatory Authorities outside of the United States.

1.61 "GMP" means all applicable then-current good manufacturing practice standards relating for fine chemicals, intermediates, bulk products, or finished pharmaceutical or biological products, as are required by applicable Regulatory Authorities or Applicable Law in the relevant jurisdiction, including, as applicable: (a) all applicable requirements detailed in the FDA's current Good Manufacturing Practices regulations, U.S. 21 C.F.R. Parts 210 and 211; and (b) all Applicable Law promulgated by any Governmental Authority having jurisdiction over the manufacture of the applicable compound or pharmaceutical or biological product, as applicable.

1.62 "Governmental Authority" means any: (a) federal, state, local, municipal, foreign, or other government; (b) governmental or quasi-governmental authority of any nature (including any agency, board, body, branch, bureau, commission, council, department, entity, governmental division, instrumentality, office, officer, official, organization, representative, subdivision, unit, and any court or other tribunal); (c) multinational governmental organization or body; or (d) entity or body exercising, or entitled to exercise, any executive, legislative, judicial, administrative, regulatory, police, military, or taxing authority or power of any nature.

1.63 "Greater China" means the PRC, Hong Kong, Macau and Taiwan.

1.64 "[***]" has the meaning set forth in Section 14.6(b)(ii).

1.65 "IND" means an investigational new drug application (including any amendment or supplement thereto) submitted to the FDA pursuant to U.S. 21 C.F.R. Part 312, including any amendments thereto. References herein to IND shall include, to the extent applicable, any comparable filing(s) outside the U.S. for the investigation of any product in any other country or group of countries (such as a Clinical Trial Application in the PRC).

1.66 "Indemnification Claim Notice" has the meaning set forth in the Section 12.3(a).

1.67 "Indemnitee" has the meaning set forth in the Section 12.3(a).

1.68 "Indemnitor" has the meaning set forth in the Section 12.3(a).

1.69 "Indication" means an entirely separate and distinct disease or medical condition in humans: (a) that a pharmaceutical or biological product that has not yet received Regulatory Approval for which it intends to treat; or (b) for which a pharmaceutical or biological product has received Regulatory Approval (as reflected in the label claim for such product), as applicable.

1.70 "Innovent" has the meaning set forth in the Preamble.

1.71 "Innovent Combination Product" means any product that is a combination of (a) a Licensed Antibody and (b) one (1) or more Additional Actives that are Innovent Pipeline Assets, whether or not in fixed dosage form.

1.72 [***].

1.73 "Innovent Indemnitees" has the meaning set forth in Section 12.1.

1.74 "Innovent Inventions" has the meaning set forth in Section 9.1(c).

1.75 "Innovent IP" means the Innovent Patents and the Innovent Know-How.

1.76 "Innovent Know-How" means any and all Know-How Controlled by Innovent or any of its Affiliates as of the Effective Date or thereafter during the Term that is necessary or reasonably useful for the Development, Manufacture, or Commercialization of the Licensed Products in the Field in the Territory.

1.77 "Innovent Patents" means any and all Patents Controlled by Innovent or its Affiliates as of the Effective Date or at any time during the Term that are necessary or reasonably useful for the Development, Manufacture, or Commercialization of the Licensed Products in the Field in the Territory.

1.78 "Innovent Patent Infringement" has the meaning set forth in Section 9.3(a)(i).

1.79 "Innovent Pipeline Assets" means all active pharmaceutical or active biological compounds or ingredients that are (a) owned or otherwise Controlled by Innovent or any of its Affiliates or (b) at any time are otherwise covered by Patents or Know-How owned or otherwise Controlled by Innovent or any of its Affiliates, in each case (a) and (b) excluding Licensed Antibodies and Licensed Products.

1.80 "Innovent Territory" means the world, excluding the Territory.

1.81 "Innovent Transferee" has the meaning set forth in Section 13.8(b).

1.82 "Intellectual Property Rights" shall mean all Patents, trade secrets, copyrights, trademarks, moral rights, Know-How and any and all other intellectual property or proprietary rights now known or hereafter recognized in any jurisdiction.

1.83 "Invention" means any process, method, composition of matter, article of manufacture, discovery, or finding that is first conceived or first generated through the activities performed pursuant to this Agreement and any and all Intellectual Property Rights therein.

1.84 "JSC" has the meaning set forth in Section 3.1(a).

1.85 "Joint IP" has the meaning set forth in Section 9.1(d).

1.86 "Joint Patents" has the meaning set forth in Section 9.1(d).

1.87 "Joint Patent Infringement" has the meaning set forth in Section 9.3(b)(i).

1.88 "Know-How" means algorithms, data, information, inventions, knowledge, methods (including methods of use or administration or dosing), practices, results, software, techniques, technology, and trade secrets, including analytical and quality control data, analytical methods (including applicable reference standards), assays, batch records, chemical structures and formulations, compositions of matter, cell-lines and products thereof, biological materials, formulae, materials, manufacturing data, pharmacological, toxicological and clinical test data and results, processes, reports, research data, research tools, sequences, standard operating procedures, and techniques, in each case, whether patentable or not, and, in each case, tangible manifestations thereof.

1.89 "Knowledge" means, with respect to a Party, the actual knowledge of those persons of such Party listed on Exhibit A.

1.90 "Licensed Antibody" means Bevacizumab Antibody and, subject to Section 2.3(c), Rituximab Antibody.

1.91 [***].

1.92 "Licensed Products" shall mean Bevacizumab Licensed Product and, subject to Section 2.3(c), Rituximab Licensed Product.

1.93 "Manufacture" means all activities related to the manufacturing of a product or any component or ingredient thereof, including the production, manufacture, processing, filling, finishing, packaging, labeling, shipping, and holding of product or any intermediate thereof, including process development, process qualification and validation, scale-up, commercial manufacture and analytic development, product characterization, stability testing, quality assurance, and quality control.

1.94 [***].

1.95 "Manufacturing and Supply Agreement" has the meaning set forth in Section 7.2.

1.96 "Manufacturing Technology Transfer" has the meaning set forth in Section 7.3(c).

1.97 "Manufacturing Technology Transfer Agreement" has the meaning set forth in Section 7.3(b).

1.98 "Manufacturing Technology Transfer Reimbursement" has the meaning set forth in Section 7.3(c).

1.99 "Manufacturing Technology Transfer Triggering Payment" has the meaning set forth in Section 7.3(a).

1.100 "Material Breach" has the meaning set forth in Section 13.2(a).

1.101 "Milestone Event" has the meaning set forth in Section 8.3(a).

1.102 "Milestone Payment" has the meaning set forth in Section 8.3(a).

1.103 "Milestone Payment Amount" has the meaning set forth in Section 8.3(a).

1.104 "Net Sales" means the gross amount invoiced by Coherus or any of its Affiliates or sublicensees for the sale or other disposition of a Licensed Product to a Third Party, less the following deductions to the extent applicable in accordance with applicable Accounting Standards:

(a) normal and customary trade, cash, and quantity discounts, allowances, and credits allowed or paid, in the form of deductions actually allowed with respect to sales of such Licensed Product (to the extent not already reflected in the amount invoiced, and excluding commissions for commercialization);

(b) retroactive price reductions, allowances, or credits actually granted upon rejections or returns of Licensed Product, including for recalls or damaged good and billing errors;

(c) discounts, chargeback payments, rebates, and reimbursements granted to wholesalers and other distributors, pharmacies and other retailers, managed care organizations, group purchasing organizations, or other buying groups, pharmacy benefit management companies, health maintenance organizations, federal, state, provincial, local, or other governments, and any other providers of health insurance coverage, health care organizations, or other health care institutions (including hospitals), health care administrators, or patient assistance or other similar programs;

(d) compulsory payments and cash rebates related to the sales of such Licensed Product paid to a Governmental Authority (or agent thereof) pursuant to Applicable Law by reason of any national or local health insurance program or similar program, including required chargebacks and retroactive price reductions, to the extent allowed and taken, including government levied fees as a result of healthcare reform policies (including annual fees due under Section 9008 of the United States Patient Protection and Affordable Care Act of 2010 (Pub. L. No. 111-48));

(e) reasonable and customary freight, shipping insurance and other transportation expenses to the extent they are separately itemized and included in the gross amount invoiced and charged to the buyer, provided that in any given Calendar Quarter, the amount of any such deductions in aggregate shall not be in excess of [***] percent ([***]%) of Net Sales with respect to such Calendar Quarter;

(f) tariffs, duties, import, export, excise, sales, use, turnover, value-added, and other similar taxes (other than taxes based on income); customs duties; or other government charges, in each case, imposed on the sale of Licensed Product to the extent included in the price and separately itemized on the invoice, including VAT;

(g) other similar and customary deductions which are in accordance with applicable Accounting Standards; and

(h) amounts invoiced for sales of Licensed Product that are written off as uncollectible after reasonable collection efforts.

Each of the foregoing deductions shall be determined as actually incurred from the books and records of Coherus, its Affiliates or sublicensees maintained in accordance with the Accounting Standards, consistently applied. Even if there is overlap between any of deductions set forth in Section 1.104(a) through Section 1.104(h) above, each individual item shall only be deducted once in the overall Net Sales calculation.

Notwithstanding the foregoing, sales of a Licensed Product by and among Coherus, its Affiliates, and its (sub)licensees shall be deemed a sale for the purposes of Net Sales only in the event such of Coherus, its Affiliate, or (sub)licensee that is the purchaser is the ultimate end user of such Licensed Product.

Any Licensed Products used for promotional or advertising purposes, used for Clinical Trials, preclinical trials or other research purposes, free samples, named patient use, compassionate use, patient assistance, charitable use or distributed at no charge to patients unable to purchase the same shall not be included in Net Sales. Donations, dispositions or transfers for charitable reasons, which dispositions or transfers are at or below cost, shall also not be included in Net Sales.

With respect to Combination Products, the following shall apply:

In the event a Licensed Product is sold as a Combination Product, Net Sales of the Combination Product will be calculated by multiplying the total Net Sales of the Combination Product by the fraction A/(A+B), where A is the average per unit Net Sales in the applicable country in the Territory of the Licensed Product sold separately (without any Additional Active) in the same formulation and dosage in a comparable Indication, and B is the sum of the average per unit Net Sales in the applicable country in the Territory of all Additional Actives (in the same formulation and dosage in a comparable Indication as in the Combination Product) in the Combination Product, as applicable, in each case sold separately during the applicable Calendar Quarter. If A or B cannot be determined because average selling prices for the Licensed Product or the Additional Active(s) are not available separately in a particular country, then the Parties shall discuss an appropriate allocation of Net Sales to the Licensed Product and to the Additional Active(s), and thereafter Coherus will determine the allocation of Net Sales for the relevant transactions in good faith based on an equitable method of determining the same that takes into account, in the Territory, variations in potency, the relative contribution of each therapeutically active ingredient, and relative value to the end user of each therapeutically active ingredient.

1.105 "New Regulatory Materials" has the meaning set forth in Section 5.2(b).

1.106 "NMPA" has the meaning set forth in Section 5.2(a)(i).

1.107 "Option" has the meaning set forth in Section 2.3(a).

1.108 "Option Effective Date" has the meaning set forth in Section 2.3(c).

1.109 "Option Exercise" has the meaning set forth in Section 2.3(b).

1.110 "Option Exercise Notice" has the meaning set forth in Section 2.3(b).

1.111 "Option Fee" has the meaning set forth in Section 8.2.

1.112 "Option Period" has the meaning set forth in Section 2.3(b).

1.113 "Party(ies)" has the meaning set forth in the Preamble.

1.114 "Patent Extensions" has the meaning set forth in Section 9.5.

1.115 "Patents" means: (a) U.S. patents and patent applications in any country or supranational jurisdiction worldwide; (b) any substitutions, divisionals, continuations, continuations-in-part, reissues, renewals, registrations, confirmations, and the like of any such patents or patent applications; (c) foreign counterparts of any of the foregoing; and (d) any and all extensions or restorations by existing or future extension or restoration mechanisms, including revalidations,

reissues, re-examinations and extensions, including any supplementary protection certificates of any of the foregoing.

1.116 "Payee" means a Party receiving a payment under this Agreement.

1.117 "Payor" means a Party owing or making a payment under this Agreement.

1.118 "Person" means any individual, partnership, joint venture, limited liability company, corporation, firm, trust, association, unincorporated organization, governmental authority or agency, or any other entity not specifically listed herein.

1.119 "Phase 1 Clinical Trial" means a Clinical Trial which provides for the first introduction into humans of a product, conducted in normal volunteers or patients to get information on product safety, tolerability, immunogenicity, pharmacological activity, or pharmacokinetics, as more fully defined in 21 C.F.R. § 312.21(a) (or the foreign equivalent thereof).

1.120 "Phase 3 Clinical Trial" means any clinical trial of an investigational product in patients that incorporates accepted endpoints for confirmation of statistical significance of efficacy and safety with the aim to obtain Regulatory Approval in any country as described in 21 C.F.R. 312.21(c), or a comparable Clinical Trial prescribed by the relevant Regulatory Authority in a country other than the United States. The investigational product can be administered to patients as a single agent or in combination with other investigational or marketed agents.

1.121 "PRC" means the People's Republic of China, which for purposes of this Agreement excludes Hong Kong, Macau and Taiwan.

1.122 "Pricing Approval" means any approval, agreement, determination, or decision establishing prices that can be charged to consumers for a pharmaceutical or biological product or that will be reimbursed by Governmental Authorities for a pharmaceutical or biological product, in each case, in a country where Governmental Authorities approve or determine pricing for pharmaceutical or biological products for reimbursement or otherwise.

1.123 "Prime Rate" means for any day a per annum rate of interest equal to the "prime rate," as published in the "Money Rates" column of The Wall Street Journal, from time to time, or if for any reason such rate is no longer available, a rate equivalent to the base rate on corporate loans posted by at least percent (70%) of the ten largest U.S. banks.

1.124 "Prior CDA" means that certain mutual confidentiality agreement, by and between Innovent and Coherus dated April 22, 2019.

1.125 "Prosecution and Maintenance" or "Prosecute and Maintain" means, with regard to a Patent, the preparation, filing, prosecution, and maintenance of such Patent, as well as re-examinations, reissues, appeals, and requests for patent term adjustments with respect to such Patent, together with the initiation or defense of interferences, oppositions, *inter partes* review, derivations, re-examinations, post-grant proceedings, and other similar proceedings (or other defense proceedings with respect to such Patent, but excluding the defense of challenges to such Patent as a counterclaim in an infringement proceeding) with respect to the particular Patent, and any appeals therefrom. For clarification, "Prosecution and Maintenance" or "Prosecute and Maintain" shall not include any other enforcement actions taken with respect to a Patent.

1.126 "Receiving Party" has the meaning set forth in Section 10.1.

1.127 "Reference Price" means the Bevacizumab Reference Price or the Rituximab Reference Price, as applicable.

1.128 "Regulatory Approval" means all approvals, licenses, and authorizations of the applicable Regulatory Authority necessary for the marketing and sale of a pharmaceutical or biological product for a particular Indication in a country or region (including separate Pricing Approvals, as necessary), and including the approvals by the applicable Regulatory Authority of any expansion or modification of the label for such Indication.

1.129 "Regulatory Authority" means any national or supranational Governmental Authority, including the FDA in the U.S. or any health regulatory authority in any country or region that is a counterpart to the foregoing agencies, in each case, that holds responsibility for development and commercialization of, and the granting of Regulatory Approval for, a pharmaceutical or biological product in such country or region.

1.130 "Regulatory Materials" means the regulatory registrations, applications, authorizations, and approvals (including approvals of BLAs, INDs, supplements and amendments, pre- and post-approvals, Pricing Approvals, and labeling approvals), Regulatory Approvals, and other submissions made to or with any Regulatory Authority, including drug master files, for research, development (including the conduct of Clinical Trials), manufacture, or commercialization of a pharmaceutical or biological product in a regulatory jurisdiction, together with all related correspondence to or from any Regulatory Authority and all documents referenced in the complete regulatory chronology for each BLA, IND, and foreign equivalents of any of the foregoing.

1.131 "Rituximab Antibody" means the antibody known as IBI-301 that is (a) a chimeric, murinehuman monoclonal antibody directed against the B-lymphocyte specific antigen CD20, and (b) (i) covered by Patents Controlled by Innovent and/or (ii) (A) incorporates, combines or uses proprietary Know-How Controlled by Innovent, or (B) derived from Innovent's proprietary cell lines. For clarity, an antibody is deemed "covered by" a Patent where such Patent is an issued Patent or a pending patent application, and an antibody will not be deemed to not constitute a Rituximab Licensed Antibody solely as a result of the abandonment or expiration of the last Patent Controlled by Innovent that covers such antibody.

1.132 "Rituximab Existing Regulatory Materials" has the meaning set forth in Section 5.2(a)(ii).

1.133 "Rituximab Existing Regulatory Materials Transfer Date" means the date on which all of the Rituximab Existing Regulatory Materials that the Parties through the JSC in accordance with Section 3.1(c)(ii) determine need to be translated into the English language under Section 5.2(a)(ii)(A) are provided by or on behalf of Innovent to Coherus.

1.134 "Rituximab Field" means the treatment, prevention or amelioration of any human diseases and conditions as included in the label of the Rituximab Reference Product.

1.135 "Rituximab Licensed Product" means all products containing the Rituximab Antibody; provided that, with respect to an Innovent Combination Product containing a Rituximab Antibody, the Rituximab Licensed Product shall include the Rituximab Antibody portion of such Innovent Combination Product, but exclude [***].

1.136 "Rituximab Reference Product" means the biologic drug products containing drug substance Rituximab and sold under the trademark Rituxan®.

1.137 "Rituximab Reference Price" means the weighted average price as determined by (a) [***] and (b) [***].

1.138 "Rituximab Product Term" has the meaning set forth in Section 13.1(b).

1.139 "ROFR Exercise Period" has the meaning set forth in Section 2.3(e).

1.140 "Royalty Floor" has the meaning set forth in Section 8.4(c)(i).

1.141 "Security Regulators" has the meaning set forth in Section 10.3(a)(i).

1.142 "Senior Executive" means: (a) with respect to Innovent, [***]; and (b) with respect to Coherus, [***].

1.143 "Sintilimab Antibody" means the antibody known as IBI-308 that is a recombinant human monoclonal antibody directed against the negative immunoregulatory human cell surface receptor programmed cell death 1 and all variants, fragments or derivatives thereof.

1.144 "Sintilimab Product" means all products containing the Sintilimab Antibody.

1.145 "Taxes" has the meaning set forth in Section 8.5(b)(i).

1.146 "Term" has the meaning set forth in Section 13.1(d).

1.147 "Territory" means the United States and Canada, including each of their respective territories and possessions.

1.148 "Third Party" means any Person other than Innovent or Coherus that is not an Affiliate of Innovent or of Coherus.

1.149 "Third Party Claim" means any and all suits, claims, actions, proceedings, or demands brought by a Third Party.

1.150 "Third Party Consideration" has the meaning set forth in Section 2.3(e).

1.151 "Third Party Infringement Claim" has the meaning set forth in Section 9.4(a).

1.152 "Transaction Notice" has the meaning set forth in Section 2.3(e).

1.153 "Transfer Taxes" has the meaning set forth in Section 8.5(b)(i).

1.154 "Transition Assistance" has the meaning set forth in Section 13.8(d).

1.155 "United States" or "U.S." means the United States of America and all of its territories and possessions.

1.156 "Upfront Payment" has the meaning set forth in Section 8.1.

2. BEVACIZUMAB LICENSE; RITUXIMAB OPTION; SINTILIMAB EXCLUSIVITY

Bevacizumab Exclusive License

. As of the Effective Date and subject to the terms and conditions of this Agreement, Innovent hereby grants to Coherus a royalty-bearing, exclusive, non-transferable (except as provided in Section 14.4) and sublicenseable (subject to Section 2.5) license, under the

Innovent IP to Develop, Manufacture (subject to Section 7.3), and Commercialize, the Bevacizumab Licensed Product in the Bevacizumab Field in the Territory.

Rituximab Non-Exclusive License

. As of the Effective Date and subject to the terms and conditions of this Agreement, Innovent hereby grants to Coherus a fully-paid, non-exclusive, non-transferable (except as provided in Section 14.4) and non-sublicenseable license, under the Innovent IP solely for Coherus, its Affiliates or designees to hold meetings with the FDA to discuss filing an IND, aBLA and other Regulatory Materials in the Territory using the Rituximab Existing Regulatory Materials transferred by Innovent to Coherus in accordance with Section 5.2(a)(ii)(A) ("Rituximab Non-Exclusive License"). The term of the Rituximab Non-Exclusive License shall terminate automatically on the earlier of (a) the Option Effective Date and (b) expiration of the Option Period, unless otherwise mutually agreed by the Parties.

2.3 Rituximab Option.

(a) Innovent hereby grants Coherus [***] option, during the Option Period, to obtain an exclusive license, under the Innovent IP to Develop, Manufacture (subject to Section 7.3), and Commercialize the Rituximab Licensed Product in the Rituximab Field in the Territory in accordance with the terms and conditions provided in this Agreement (the "Option").

(b) Coherus may exercise the Option (the "Option Exercise") at any time (subject to Section 2.3(e)) beginning on [***] and ending on the first anniversary of the Rituximab Existing Regulatory Materials Transfer Date ("Option Period") by providing written notice (the "Option Exercise Notice") to Innovent. If no Option Exercise occurs pursuant to this Section 2.3(b) within the Option Period, then Coherus shall have no further rights with respect to the Rituximab Licensed Product under this Agreement.

(c) Upon (i) Coherus's Option Exercise in accordance with Section 2.3(b) and (ii) Coherus's payment of the Option Fee in accordance with Section 8.2, Rituximab Licensed Product shall be deemed a Licensed Product for all purposes of this Agreement ("Option Effective Date").

(d) As of the Option Effective Date and subject to the terms and conditions of this Agreement, Innovent shall grant and hereby grants to Coherus a royalty-bearing, exclusive, non-transferable (except as provided in Section 14.4) and sublicenseable (subject to Section 2.5) license, under the Innovent IP to Develop, Manufacture (subject to Section 7.3), and Commercialize the Rituximab Licensed Product in the Rituximab Field in the Territory.

(e) During the Option Period, prior to the consummation of any Third Party transaction through which Innovent or its Affiliates propose to grant such Third Party a license under the Innovent IP to Develop, Manufacture, and Commercialize, the Rituximab Licensed Product in the Rituximab Field in the Territory, Innovent shall, not later than [***] ([***]) days prior to the consummation of such transaction, provide Coherus a written notice describing the material terms and conditions (including the amount and form of consideration for the entire transaction) of such transaction ("Transaction Notice"). Coherus may exercise its Option in accordance with Section 2.3(b) within [***] ([***]) days of such notice ("ROFR Exercise Period") by providing Innovent with an Option Exercise Notice, provided, if the consideration offered by such Third Party ("Third Party Consideration"), in the aggregate, under such Third Party transaction exceeds the (i) [***], (ii) [***] and (iii) [***], in the aggregate, then Coherus's Option Exercise Notice shall state that Coherus shall pay Innovent greater than or equal to the amount of consideration offered by such Third Party

as Third Party Consideration for Coherus to exercise its Option in accordance with Section 2.3(b) and upon Innovent's receipt of such Option Exercise Notice, the Parties shall negotiate in good faith, for a period not to exceed [***] ([***]) days, the terms of such Option consideration under which Coherus may exercise its Option. If (A) Coherus fails to provide Innovent with an Option Exercise Notice prior to expiration of the ROFR Exercise Period, or (B) the Parties fail to negotiate such terms within the [***] ([***]) day period, Innovent shall be free to consummate the Third Party transaction and Coherus shall have no further rights to the Rituximab Licensed Product in the Field in the Territory.

2.4 License Grant to Innovent. Subject to this Section 2.4, Coherus hereby grants to Innovent a perpetual, irrecoverable, non-exclusive, royalty-free, non-transferable (except as provided in Section 14.4), and sublicenseable (through multiple tiers and subject to Section 2.5) license, under the Coherus IP, to (a) Develop, Manufacture, and Commercialize the Licensed Antibodies in the Innovent Territory; and (b) Develop the Licensed Antibodies portion of an Innovent Combination Products in the Territory. In no event shall Innovent sublicense or transfer the non-exclusive license granted under this Section 2.4 independent of a Licensed Antibody.

2.5 Sublicense.

(a) Subject to the terms and conditions of this Agreement, either Party may grant sublicenses of the licenses granted to such Party by the other Party under Section 2.1 and 2.2 and Section 2.5, as applicable, to its Affiliates and Third Parties, whose primary business is the provision of Development related services to its clients, solely for the purposes of receiving Development related services from such Third Party. Either Party may grant sublicenses of the licenses granted to such Party by the other Party under Section 2.1 and 2.2 and Section 2.5, as applicable, to its Affiliates and Third Parties, whose primary business is the provision of Manufacturing related services to its clients, solely for the purposes of receiving Manufacturing related services from such Third Party, and in the case of Coherus in accordance with Section 7.3(b) and Section 7.3(f). For all other sublicenses, neither Party may grant sublicenses of the licenses granted to such Party under Section 2.1 and 2.2 and Section 2.4, as applicable, without first providing to the other Party a reasonable explanation of the capabilities and financial wherewithal of the prospective sublicensee and obtaining the other Party's prior written consent, which such consent shall not be unreasonably withheld, delayed or conditioned.

(b) Each Party shall not grant a sublicense of licenses granted to such Party by the other Party under Section 2.1 and 2.2 and Section 2.5, as applicable, to a Person that has been debarred or disqualified by a Regulatory Authority. Each Party shall ensure that each sublicensee is subject to written agreement that is consistent with the terms and conditions of this Agreement, including the following terms and conditions Article 10 (Confidentiality) and Intellectual Property (Article 9) and if Coherus is the sublicensor, records and audit rights (Section 8.6). Each Party shall promptly provide a copy of the executed agreement with each sublicensee to the other Party upon the other Party's written request, which copy may be redacted to remove [***] terms and other such terms that are not directly related to this Agreement. Each Party shall remain liable to the other Party for any breach or default of the applicable terms and conditions of this Agreement by any of its sublicensees.

2.6 Innovent Retained Rights. Notwithstanding anything to the contrary in this Agreement, Innovent hereby expressly retains, on behalf of itself (and its Affiliates and other licensees), (a) all rights under the Innovent IP to fulfill, either itself, its Affiliates or through subcontractors, Innovent's obligations under this Agreement; and (b) the non-exclusive right to Develop the Innovent

Combination Product in the Territory; provided that (i) prior to initiating the Development of any Innovent Combination Product in the Territory, Innovent shall provide Coherus with a written notice [***] to conduct such Development with a [***] plan for such Development; (ii) the Parties shall discuss the Development of such Innovent Combination Product in the Territory through the JSC; and (iii) the Parties shall coordinate the Development of such Innovent Combination Product in the Territory by or on behalf of Innovent through the JSC; [***]. Innovent shall not [***]. Notwithstanding the foregoing, Innovent may [***]. For clarity, Innovent may [***]. Subject to Coherus's right to exclusively Commercialize the Licensed Products in the Territory, the Parties agree that in the event Innovent wishes to Commercialize an Innovent Combination Product in the Territory, the Parties shall [***].

2.7 No Implied Licenses. Except as otherwise expressly provided in this Agreement, under no circumstances shall a Party or any of its Affiliates, as a result of this Agreement, obtain any ownership interest, license, or other right in or to any Intellectual Property Rights of the other Party, including tangible or intangible items owned, controlled, or developed by the other Party, or provided by the other Party to the receiving Party at any time, in each case, pursuant to this Agreement.

2.8 Right of First Negotiation. For a period of [***] days from the Effective Date, the Parties shall negotiate on [***] with respect to the terms and conditions under which Coherus may obtain a license under Patents and Know-How Controlled by Innovent with respect to the [***] for the [***].

3. COLLABORATION GOVERNANCE

Joint Steering Committee

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(a) Innovent and Coherus shall establish a Joint Steering Committee in accordance with this Article 3 (the "JSC"). The JSC shall remain in effect from the Effective Date through the Term. The JSC shall serve as a forum for discussing and sharing information in accordance with this Agreement and discussing strategy regarding the Development, Manufacture and Commercialization of the Licensed Products, among other activities.

(b) Composition of the JSC**.** Each Party shall appoint [***] ([***]) representatives as its voting members of the JSC. The first meeting of the JSC shall be held within [***] ([***]) days of the Effective Date. The JSC shall be co-chaired by a representative of Coherus and a representative of Innovent. The co-chairpersons shall be responsible for calling meetings, setting the agenda, circulating the agenda at least [***] ([***]) days prior to each meeting and distributing minutes of the meetings within [***] ([***]) days following such meetings (provided that each co-chairperson may elect to delegate the performance of its responsibilities to other members of the JSC from time to time), but shall not otherwise have any greater power or authority than any other member of the JSC. Each Party shall disclose to the co-chairpersons any proposed agenda items, along with appropriate information at least [***] ([***]) [***] in advance of each meeting of the JSC. Each member of the JSC selected by each Party shall have substantial experience in biopharmaceutical product development, manufacturing and/or commercialization and other such expertise as appropriate to the activities of the JSC. Each Party may replace its members of the JSC upon written notice to the other Party and shall replace its members as the expertise required by the JSC changes over time and as the Licensed Products advance through Development, Manufacture and Commercialization.

(c) Responsibilities of the JSC. The JSC's responsibilities shall include, among others, the following:

(i) promptly after the Effective Date, agree upon the scope and facilitate the transfer of all Bevacizumab Existing Regulatory Materials by Innovent to Coherus in accordance with Section 5.2(a)(i);

(ii) promptly after the Effective Date, agree upon the scope and facilitate the transfer of all Rituximab Existing Regulatory Materials by Innovent to Coherus in accordance with Section 5.2(a)(ii);

(iii) facilitating the exchange of information, data and regulatory strategies between the Parties with respect to the Development of the Licensed Products both in the Territory and outside the Territory as well as both in the Field;

(iv) discuss the Commercialization Plan prepared or updated by Coherus;

(v) share information regarding the Commercialization of the Licensed Products in the Territory;

(vi) discuss and comment on each Party's clinical summaries, synopsis, and protocols with respect to the Development of Licensed Products and Innovent Combination Products in the Territory; and

(vii) discuss such other matters as the Parties mutually agree to discuss at the JSC.

Meetings of the JSC

. The JSC shall hold meetings at such times and places as shall be determined by a majority of the entire membership of the committee, but in no event, shall such meetings be held less frequently than once every [***] ([***]) months. Meetings of the JSC shall be held via internet, telephonically or by videoconference; provided that at least [***] ([***]) meetings per year shall be held in person. Meetings of the JSC shall be effective if at least [***] ([***]) members of the JSC, representing each Party, are in attendance or participating in the meeting. Each Party shall be responsible for the expenses incurred in connection with its employees, consultants and its members of the JSC attending or otherwise participating in JSC meetings.

(e) Coherus shall consider in good faith any comments provided by Innovent in relation to the Development, Manufacturing, or Commercialization of the Licensed Products in the Territory by or behalf of Coherus in the Territory. Innovent shall consider in good faith any comments provided by Coherus in relation to the Development of the Innovent Combination Products by or on behalf of Innovent in the Territory.

3.2 Alliance Managers. Within [***] ([***]) days following the Effective Date, each Party shall appoint (and notify the other Party of the identity of) a representative having the appropriate qualifications (including a general understanding of pharmaceutical Development and Commercialization issues) to act as its alliance manager under this Agreement (the "Alliance Manager"). The Alliance Managers shall serve as the primary contact points between the Parties regarding the activities contemplated by this Agreement. The Alliance Managers shall (a) facilitate the flow of information; and (b) otherwise promote communication, coordination and collaboration between the Parties, providing single point communication for seeking consensus both internally within each Party's respective organization, including facilitating review of external corporate

communications, and raising cross-Party or cross-functional disputes in a timely manner. Each Party may replace its Alliance Manager by written notice to the other Party.

4. DEVELOPMENT.

4.1 Responsibility. Subject to the terms and conditions of this Agreement, including this Article 4, Coherus shall (a) have the sole right (and shall solely control, at its discretion), itself or with or through its Affiliates, sublicensees, or other Third Parties, to Develop the Licensed Products in the Field in the Territory; [***]; and (b) update the JSC from time to time during the Term on the Development activities performed by or on behalf of Coherus.

4.2 Phase 1 Clinical Trial. During the Term, Coherus shall (i) use Commercially Reasonable Efforts to conduct all Development activities related to the Licensed Products in the Field in the Territory, and (ii) promptly inform Innovent of any corporate decision of Coherus to discontinue the Development of the Licensed Products in the Territory. Without limiting the foregoing, Coherus shall:

(a) conduct [***] to support the aBLA for each Bevacizumab Licensed Product and Rituximab Licensed Product, if applicable, in the respective Field in the Territory, which shall rely upon all other Clinical Trial results and other Regulatory Materials transferred from Innovent in accordance with Section 5.2(a), as applicable;

(b) [***] for the Bevacizumab Licensed Product with the FDA within [***] ([***]) months from the Bevacizumab Existing Regulatory Material Transfer Date [***], subject to any additional information, data and/or results that the FDA may request, and in such event the [***] shall not commence until such time Coherus obtains or is provided with such additional Existing Regulatory Materials are provided by Innovent to information, data and/or results that the FDA requested are submitted to the FDA. The Parties agree that [***]

(c) [***] for a Bevacizumab Licensed Product with the FDA in the Bevacizumab Field in the United States within [***] ([***]) months following the Effective Date; and (ii) after Coherus exercises the Option, the [***] for a Rituximab Licensed Product with the FDA in the Rituximab Field in the United States within [***] ([***]) months following the Option Effective Date, provided, in each case (i) and (ii), if the applicable Existing Regulatory Materials, as translated in English, are not transferred by Innovent to Coherus within the [***] ([***]) month and the [***] ([***]) month period as set forth in Section 5.2(a)(i) and Section 5.2(a)(ii)(A), as applicable, then the [***] ([***]) month period for the corresponding Licensed Product under this Section 4.2(c) shall be extended by the duration of time until such Existing Regulatory Materials are provided by Innovent to Coherus in accordance with Section 5.2(a)(i) and Section 5.2(a)(ii)(A), as applicable. The Parties agree that [***]. The Parties agree that the [***] ([***]) month period set forth herein for each Licensed Product shall be renegotiated in good faith in the event of a recommendation or order by a Regulatory Authority in the Territory to conduct an additional (A) Clinical Trial and/or (B) analytical and/or bioanalytical activities or studies in the Territory..

4.3 Rituximab Antibodies and the Rituximab Licensed Products. Prior to the Option Effective Date, Innovent shall (a) be solely responsible for the Development (and Manufacture, or having Manufactured, for the purposes thereof) of the Rituximab Antibodies and the Rituximab Licensed Products at [***] sole cost and expense, and (b) at each meeting of the JSC or as otherwise agreed by the Parties, Innovent shall provide the JSC with written reports or presentations summarizing its

activities with respect to the Development and associated Manufacture of the Rituximab Antibodies and the Rituximab Licensed Products. Each report or presentation will cover such activities since the previous JSC meeting, including a summary of results, information, and data generated and any material developments and activities planned with respect to the Rituximab Antibodies or the Rituximab Licensed Products. Prior to the Option Effective Date, upon request by the JSC or by Coherus, Innovent will reasonably provide the JSC with such other then-existing information and such additional access to records with respect to the Rituximab Licensed Products and the Rituximab Licensed Products as the JSC or Coherus may reasonably request, including the underlying information used to support such summaries. For clarity, the foregoing shall not be deemed or interpreted to impose on Innovent any obligation to conduct any Development of the Rituximab Antibodies and the Rituximab Licensed Products in the Field in the Territory.

5. REGULATORY

Regulatory Matters

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(a) Responsibility. Subject to the terms and conditions of this Agreement, Coherus shall (i) have the sole right (and shall solely control, at its discretion), itself or with or through its Affiliates, sublicensees, or other Third Parties, and (ii) use Commercially Reasonable Efforts, to (A) prepare, and submit to applicable Regulatory Authorities, all Regulatory Materials for Licensed Products in the Territory; and (B) obtain and maintain all Regulatory Approvals for Licensed Products in the Territory.

(b) Communications with Regulatory Authorities. Subject to the terms and conditions of this Agreement, including Section 2.6, (i) Coherus shall have the exclusive right to correspond or communicate with Regulatory Authorities regarding the Licensed Products in the Field in the Territory; and (ii) unless required by Applicable Law, Innovent, its Affiliates, and its permitted subcontractors shall not correspond or communicate with Regulatory Authorities regarding any Licensed Product without first obtaining Coherus's prior written consent in the Field in the Territory. If Innovent, its Affiliates, or its permitted subcontractors receive any correspondence or other communication from a Regulatory Authority regarding a Licensed Product, Innovent shall provide Coherus with access to or copies of all such material written or electronic correspondence promptly after its receipt.

(c) Innovent Support. Innovent shall use Commercially Reasonable Efforts to provide Coherus with reasonable assistance as may be reasonably requested by Coherus from time to time in connection with Coherus's preparation, submission to Regulatory Authorities and maintenance of Regulatory Materials for Licensed Products in the Field in the Territory, including, upon Coherus's reasonable prior request, attending meetings with Regulatory Authorities regarding any Licensed Product; provided that Coherus shall [***].

Regulatory Materials

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(a) Existing Regulatory Materials.

(i) Existing Regulatory Materials for the Bevacizumab Licensed Products. Promptly after the Effective Date, Innovent shall assign and transfer (and hereby does assign and transfer), or cause to be assigned and transferred to the extent not owned by Innovent, to Coherus (or its designee), any and all Regulatory Materials for the Bevacizumab Licensed Products in the Territory held by or on behalf of Innovent, its Affiliates or contractors as of or prior to the Effective Date (the "Bevacizumab

Existing Regulatory Materials"), including providing true, accurate, and complete hard or electronic copies thereof to Coherus that may include key reports, information and data including sections of any BLA submitted by Innovent to the Chinese National Medical Products Administration ("NMPA"), clinical reports, patient data, chemistry, manufacturing and control data and analytics, immunogenicity data, and any additional materials mutually determined by the Parties through the JSC; provided, that in the event such assignment is not permitted under Applicable Law with respect to one or more Bevacizumab Existing Regulatory Materials, Innovent shall hold such Regulatory Materials in trust for, or for the sole benefit of, Coherus or its designee. From and after such assignment and transfer, Coherus (or its designee) shall have the sole right, in its sole discretion, to file, maintain, and hold title to all Bevacizumab Existing Regulatory Materials. To the extent any Bevacizumab Existing Regulatory Materials are not in the English language, Innovent shall provide to Coherus no later than [***] ([***]) months from the Effective Date formal English translations of such Bevacizumab Existing Regulatory Materials that the Parties through the JSC determine need to be translated (with the Parties having an obligation to make such determination through the JSC within [***] ([***]) days of the Effective Date, unless otherwise agreed by the Parties), such translations to be performed by certified translators in the medical and/or scientific field, for such Regulatory Materials sufficient for Coherus to file an IND, aBLA and other Regulatory Materials for the Bevacizumab Licensed Product in the Territory.

(ii) Existing Regulatory Materials for the Rituximab Licensed Products.

(A) Promptly after the Effective Date, Innovent shall transfer, or cause to be transferred to the extent not owned by Innovent, to Coherus (or its designee), any and all Regulatory Materials for the Rituximab Licensed Products in the Territory held by or on behalf of Innovent, its Affiliates or contractors as of or prior to the Effective Date (the "Rituximab Existing Regulatory Materials"), including providing true, accurate, and complete hard or electronic copies thereof to Coherus that may include key reports, information and data including sections of any BLA submitted by Innovent to the NMPA, clinical reports, patient data, chemistry, manufacturing and control data and analytics, immunogenicity data, and any additional materials mutually determined by the Parties through the JSC. To the extent any Rituximab Existing Regulatory Materials are not in the English language, Innovent shall provide to Coherus no later than [***] ([***]) months from the Effective Date formal English translations of such Rituximab Existing Regulatory Materials that the Parties through the JSC determine need to be translated (with the Parties having an obligation to make such determination through the JSC within [***] ([***]) days of the Effective Date, unless otherwise agreed by the Parties), such translations to be performed by certified translators in the medical and/or scientific field for such Rituximab Existing Regulatory Materials sufficient for Coherus to hold meetings with the FDA to discuss filing an IND, aBLA and other Regulatory Materials for the Rituximab Licensed Product in the Territory. The cost of translating the Rituximab Existing Regulatory Materials into English shall be borne [***], which shall include any costs and expense incurred by Innovent prior to the Effective Date directly in connection with such translation, to the extent reasonably documented.

Notwithstanding anything to the contrary herein, in no event shall any Rituximab Existing Regulatory Material be deemed assigned or exclusively licensed by Innovent to Coherus prior to the Option Effective Date.

(B) Promptly after the Option Effective Date, Innovent shall assign or cause to be assigned to the extent not owned by Innovent, to Coherus (or its designee) the Rituximab Existing Regulatory Materials, provided, that in the event such assignment is not permitted under Applicable Law with respect to one or more Rituximab Existing Regulatory Materials, Innovent shall hold such Regulatory Materials in trust for, or for the sole benefit of, Coherus or its designee. From and after such assignment, Coherus (or its designee) shall have the sole right, in its sole discretion, to file, maintain, and hold title to all Rituximab Existing Regulatory Materials.

(b) New Regulatory Materials. All Regulatory Materials generated or arising from or in connection with activities under this Agreement with respect to Licensed Products in the Field in the Territory, including solely with respect to the Licensed Antibody portion of any Innovent Combination Product (the "New Regulatory Materials") shall be owned by and held in the name of Coherus or its designee, provided, that in the event such ownership is not permitted under Applicable Law with respect to one or more of such New Regulatory Materials, Innovent shall hold such New Regulatory Materials in trust for, or for the sole benefit of, Coherus or its designee.

Right of Reference; Access to Data

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(a) Prior to the time at which Existing Regulatory Materials in the Territory are transferred and assigned to Coherus or its designee under Section 5.2(a), or in the event of failure to transfer and assign any Regulatory Materials to Coherus or its designee, as required by Section 5.2(a)(i) and Section 5.2(a)(ii)(A), as applicable, Coherus and its designees shall have, and Innovent (on behalf of itself and its Affiliates) hereby grants to Coherus and its designees, access and a right of reference (without any further action required on the part of Innovent, its Affiliates or contractors, whose authorization to file this consent with any Regulatory Authority is hereby granted) to all such Regulatory Materials and all data contained or referenced therein for Coherus and its designees to exercise its rights and perform its obligations under this Agreement with respect to Licensed Products. In all cases, Coherus and its designees shall have access to all data contained or referenced in all such Regulatory Materials, and Innovent shall ensure that Coherus and its designees are afforded such access.

(b) Upon transfer and assignment of the Existing Regulatory Materials in the Territory and the data contained or referenced therein to Coherus or its designee in accordance with Section 5.2(a), Coherus shall grant and hereby grants to Innovent and its designees a right of reference (without any further action required on the part of Coherus, its Affiliates or contractors, whose authorization to file this right of reference with any Regulatory Authority is hereby granted) to (i) such Existing Regulatory Materials, including any INDs transferred and assigned to Coherus as an Existing Regulatory Material, and all data contained or referenced therein and (ii) the New Regulatory Materials and all data contained or referenced therein, solely for Innovent and its designees to (A) Develop, Manufacture, Commercialize and seek and maintain Regulatory Approvals for the Licensed Antibodies, Licensed Product, and Innovent Combination Products in the

Innovent Territory and (B) Develop and seek and maintain Regulatory Approvals for the Licensed Antibody portion of an Innovent Combination Product in the Territory. In all cases, Innovent and its designees shall have access to all data contained or referenced in all such Regulatory Materials, and Coherus shall ensure that Innovent and its designees are afforded such access at [***] cost and expense and with reasonable prior written notice and during normal business hours if such access requires actual site visits and/or reasonably substantial assistance of Coherus.

(c) Notwithstanding anything to the contrary herein, including this Article 5, each Party shall have the right to use, [***], any and all data generated or otherwise collected by or on behalf of the other Party through the conduct of any Clinical Trial in connection with a Licensed Product in such other Party's territory ("Clinical Trial Data"). Each Party shall obligate each Affiliate, licensee and sublicensee, as applicable, to provide the other Party with the applicable Clinical Trial Data, as provided under this Section 5.3(c).

5.4 Innovent's Review Rights.

(a) Coherus shall provide Innovent with the copies of all material Regulatory Materials relating to a Licensed Product [***] following its submission or communication to the applicable Regulatory Authority in their submitted or communicated form.

(b) Coherus shall provide Innovent with copies of all material Regulatory Materials relating to a Licensed Product received from any Regulatory Authority in the Territory [***] upon receipt.

(c) Coherus shall reasonably inform and provide reasonable details to Innovent of any material communications with a Regulatory Authority relating to the Licensed Product through the JSC.

6. COMMERCIALIZATION

General

. Subject to the terms and conditions of this Agreement, Coherus shall have the sole right (and shall solely control, at its discretion), itself or with or through its Affiliates, sublicensees, or other Third Parties, to Commercialize the Licensed Products in the Field in the Territory. All such Commercialization shall be at Coherus's sole cost and expense.

6.2 Diligence Obligations. Coherus shall use Commercially Reasonable Efforts to Commercialize the Licensed Products in the Field in the Territory. Without limiting the generality of the foregoing, Coherus commits to:

(a) use Commercially Reasonable Efforts to Commercialize each Licensed Product promptly following First Commercial Sale of such Licensed Product in the Field in the Territory;

(b) Beginning [***] ([***]) Calendar Quarters prior to the anticipated First Commercial Sale of a Licensed Product in the Field in the Territory, Coherus shall provide a written plan to the JSC for review (the "Commercialization Plan") setting forth in reasonable detail the planned Commercialization activities (or preparations for First Commercial Sale, as applicable) in relation to the Licensed Products planned for the [***] ([***]) Calendar Quarters following such Calendar Quarter. Such Commercialization Plan shall be updated and reviewed by the JSC [***] at least on an annual basis.

(c) on a Licensed Product-by-Licensed Product and country-by-country basis, (x) use Commercially Reasonable Efforts to [***], and (y) on a periodic basis, through the JSC, provide [***] of (1) [***] and (2) [***], in the aggregate, in each case (1) and (2), [***]. [***]

(A) [***].

(B) [***].

7. MANUFACTURING

7.1 Manufacturing. Subject to the terms and conditions of this Agreement and the Manufacturing and Supply Agreement, Innovent shall supply the Licensed Products to Coherus for Development and Commercialization in the Territory.

7.2 Manufacturing and Supply Agreement. Within [***] ([***]) months following the Effective Date, the Parties shall negotiate in good faith and execute a written manufacturing and supply agreement (the "Manufacturing and Supply Agreement") to govern the Manufacturing and supply of the Licensed Products by Innovent to Coherus. Innovent shall supply the Licensed Products to Coherus that may include finished, packaged form or brite stock form or other form agreed by the Parties, for a supply price equal to [***] percent ([***]%) of Innovent's [***] for such Licensed Products (each, a "Purchase Price"), provided, in no event shall the Purchase Price for the Bevacizumab Licensed Product exceed $[***] Dollars for the [***] vial and $[***] Dollars for the [***] vial. The Manufacturing and Supply Agreement shall include other customary provisions, including Coherus's right to audit Innovent's Manufacturing [***], which the Parties shall negotiate in good faith. The Parties shall enter into a separate quality agreement regarding the supply of the Licensed Products by Innovent to Coherus incorporating provisions that are standard in the pharmaceutical field in parallel with the execution of the Manufacturing and Supply Agreement, and in any event prior to any delivery of the Licensed Products from Innovent to Coherus.

7.3 Manufacturing Technology Transfer.

(a) Without limiting the other provisions of Article 7, if Coherus wishes to Manufacture the commercial supply of the Licensed Product(s), it shall submit a written request to Innovent and pay a one-time [***] Dollars ($[***]) as a technology transfer triggering fee (in addition to the Manufacturing Technology Transfer Reimbursement) for each Licensed Product that it wishes to Manufacture (the "Manufacturing Technology Transfer Triggering Payment"). For clarity, the maximum Manufacturing Technology Transfer Triggering Payments payable by Coherus to Innovent under this Agreement shall be [***] Dollars ($[***]).

(b) Within [***] ([***]) days following Innovent's receipt of the applicable Manufacturing Technology Transfer Triggering Payment, the Parties shall negotiate in good faith and enter into a manufacturing technology transfer agreement for the transfer of the relevant Innovent IP to Coherus, any of its Affiliates or one (1) Third Party CMO (the "Manufacturing Technology Transfer Agreement"); provided that (i) any Third Party CMO to be used by Coherus for the Manufacture of the Licensed Product in the Territory in accordance with this Agreement shall require Innovent's prior written consent, not to be unreasonably withheld, delayed or conditioned (the "Approved CMO").

(c) Pursuant to the Manufacturing Technology Transfer Agreement, (i) Innovent shall transfer from Innovent or its Affiliates to Coherus, its Affiliates or the Approved CMO (in writing

or in an electronic format) of all data, information, and other Know-How Controlled by Innovent and its Affiliates that is necessary or reasonably useful for the Manufacture of the applicable Licensed Product(s) to enable Coherus, its Affiliates or the Approved CMO to Manufacture such Licensed Product(s) in a manner substantially similar to the process employed by or on behalf of Innovent to Manufacture the applicable Licensed Product(s); (ii) such transfers shall include, without limitation, any and all data, information, regulatory filings, assets, DNA, protein sequences, constructs and cell lines, and other materials required for Manufacture, or reasonably useful for the Manufacture of the applicable Licensed Product(s) (collectively with clause (i), "Manufacturing Technology Transfer"); (iii) at the reasonable request of Coherus from time to time, Innovent shall make its employees and consultants (including personnel of its Affiliates and Third Party CMOs) available to Coherus, its Affiliates or the Approved CMO to provide reasonable consultation and technical assistance in order to ensure an orderly Manufacturing Technology Transfer for the Licensed Products to Coherus, its Affiliates and the Approved CMO and to assist Coherus, its Affiliates and the Approved CMO in the Manufacture of the Licensed Products; provided that Coherus shall reimburse Innovent for the reasonable and documented actual costs incurred by or on behalf of Innovent that are directly related to the Manufacturing Technology Transfer at the FTE Rate (the "Manufacturing Technology Transfer Reimbursement"); and (iv) Innovent shall have the rights to request Coherus to conduct audits of the Approved CMO and Innovent shall have the right to be present for any such audit and require Coherus to remediate any deficiency uncovered by such audit.

(d) Coherus shall pay Innovent a one-time [***] Dollars ($[***]) upon the completion of the applicable Manufacturing Technology Transfer as mutually agreed upon by the Parties in accordance with each Manufacturing Technology Transfer Agreement ("Manufacturing Technology Transfer Completion Payments"). For clarity, the maximum Manufacturing Technology Transfer Completion Payments payable by Coherus to Innovent under this Agreement shall be [***] Dollars ($[***])

(e) Innovent shall not be obligated to (i) perform the Manufacturing Technology Transfer as described in Sections 7.3(b) and 7.3(c) more than [***] for the Bevacizumab Licensed Products or more than [***] for the Rituximab Licensed Products (subject to Section 2.3) and (ii) perform more than [***] Manufacturing Technology Transfers for all Licensed Products. Any additional Manufacturing Technology Transfer requested by Coherus shall be subject to the Parties' mutual written agreement.

(f) Upon completion of a Manufacturing Technology Transfer for a Licensed Product, Coherus shall be free to transfer technology for each Licensed Product that it wishes to Manufacture to its Affiliates or one or more Third Party CMOs. Innovent shall have the rights to request Coherus to conduct audits of such CMOs and Innovent shall have the right to be present for any such audit and require Coherus to remediate any deficiency uncovered by such audit.

8. FINANCIAL TERMS

8.1 Upfront Payments. In consideration for entering into this Agreement, including the grant of the licenses by Innovent to Coherus pursuant to Section 2.1 and the Option pursuant to Section 2.3(a), Coherus shall pay to Innovent a one-time, non-refundable, non-creditable upfront payment in the amount of Five Million Dollars ($5,000,000) ("Upfront Payment"). The Upfront Payment shall be due within [***] ([***]) days of the Effective Date.

8.2 Option Fee. Promptly after its Option Exercise in accordance with Section 2.3(b), but no later than [***] thereof, Coherus shall pay Innovent Five Million Dollars ($5,000,000) as the Option Exercise fee ("Option Fee").

Milestone Payments

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(a) Milestones. In addition, Coherus shall pay Innovent the following one-time, non-refundable, non-creditable milestone payments (each, a "Milestone Payment") upon the first occurrence of each of the following milestone events (each, a "Milestone Event") set forth below with respect to the Licensed Product(s). For clarity, each milestone payment amount for each Milestone Event ("Milestone Payment Amount") shall be paid only once for each Licensed Products.

(i) Bevacizumab Licensed Product

	Bevacizumab Product Milestone Event	**Bevacizumab Product Milestone Payment Amount**
B1.	[***]	[***] Dollars ($[***])
B2.	[***]	[***] Dollars ($[***])
B3.	[***]	[***] Dollars ($[***])
B4.	[***]	[***] Dollars ($[***])

(ii) Rituximab Licensed Product

	Rituximab Product Milestone Event	**Rituximab Product Milestone Payment Amount**
R1.	[***]	[***] Dollars ($[***])
R2.	[***]	[***] Dollars ($[***])
R3.	[***]	[***] Dollars ($[***])
R4.	[***]	[***] Dollars ($[***])

(iii) For the avoidance of doubt, the maximum amount of Milestone Payment Amounts payable by Coherus under Section 8.3(a)(i) is Forty Million Dollars ($40,000,000) and under Section 8.3(a)(ii) is Forty Million Dollars ($40,000,000).

(b) Invoice and Payment of Milestone Payment Amounts. With respect to Milestone Events B1, B2, R1 and R2, Coherus shall notify and remit payment to Innovent within [***] ([***]) days after such Milestone Event was first achieved by Coherus under this Agreement. With respect to Milestone Events B3, B4, R3 and R4, Coherus shall notify and remit payment to Innovent within [***] ([***]) days after the end of the Calendar Year during which such Milestone Event was first achieved by Coherus under this Agreement.

Royalties

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(a) Royalty Rates.

(i) On a Licensed Product-by-Licensed Product in the United States, a [***] ([***]%) royalty on the annual Net Sales of a Licensed Product in a Calendar Year in the United States, provided, however, if during the Term, the Reference Price of the applicable Licensed Product in the United States is reduced by [***] percent ([***]%) or more ("Royalty Event") then the following royalty rate shall apply for the Calendar Quarter following the Royalty Event, whereby, Coherus shall pay Innovent a tiered royalty on incremental annual Net Sales of such Licensed Product in a Calendar Year in the United States. Such royalty payments shall be equal to the following portions of annual Net Sales of the applicable Licensed Product in the United States multiplied by the applicable royalty rate set forth below for such portion of annual Net Sales for each such Licensed Product in the United States during the Term. For clarity, the royalties (and royalty tiers) shall be calculated separately on a Licensed Product-by-Licensed Product basis.

Annual Net Sales in the United States	**Royalty Rate**
The portion of the annual Net Sales of a Licensed Product in the United States that is less than or equal to [***] Dollars ($[***])	[***] Percent ([***]%)
The portion of the annual Net Sales of a Licensed Product in the United States that is that is greater than to [***] Dollars ($[***])	[***] Percent ([***]%)

The applicable royalty rate set forth in the table above shall apply only to that portion of the annual Net Sales of a given Licensed Product in the United States during a given Calendar Year that falls within the indicated range.

(ii) On a Licensed Product-by-Licensed Product in Canada, a [***] ([***]%) royalty on the annual Net Sales of a Licensed Product in a Calendar Year Canada.

(b) Royalty Reductions; Third Party Payments. If Coherus, any of its Affiliates, or any of its sublicensees obtains a right or license under any Intellectual Property Right of a Third Party that is necessary for the Development, Manufacturing, or Commercialization of a Licensed Product in the Field in the Territory by or on behalf of Coherus, its Affiliates, or its sublicensees (including in connection with any settlement agreement entered into subject to Section 9.4(e)), and such Development, Manufacture or Commercialization would result in a payment to such Third Party, then Coherus may deduct from the royalty payments that would otherwise have been due under Section 8.4(a) with respect to annual Net Sales in a particular calendar quarter, an amount equal to [***] percent ([***]%) of the amount of any payments (including payments for obtaining such right or license, royalties, milestones, amounts paid in settlement, and any other amounts) paid or accrued by Coherus or any of

its Affiliates or sublicensees to such Third Party that are attributable to such right or license or the exercise thereof during such Calendar Quarter, subject to Section 8.4(c).

(c) Royalty Floor.

(i) For any Calendar Quarter during the Term for a Licensed Product in a particular country in the Territory, the operation of Section 8.4(b) or Section 9.4(e), shall not reduce the final royalty payment to less than [***] percent ([***]%) of the royalties otherwise payable to Innovent for such Licensed Product pursuant to Section 8.4(a) prior to the application of any deductions or reductions pursuant to Section 8.4(b) or Section 9.4(e) in such country during such calendar quarter (the "Royalty Floor").

(ii) Subject to the Royalty Floor, any amount of royalty reduction or deduction that Coherus is entitled to take pursuant to Section 8.4(b) or Section 9.4(e) with respect to a particular Licensed Product in a particular country which is not taken as a result of the application of the Royalty Floor shall be carried forward, and Coherus may reduce subsequent royalty payment amounts due to Innovent hereunder with respect to such Licensed Product in such country in accordance with this Section 8.4(c) by such amount, until the full amount of deductions and reductions that Coherus was entitled to apply to reduce royalty payments has been applied. For the avoidance of doubt, any carry forward of any unused royalty reduction or deduction pursuant to this Section 8.4(c)(ii) shall not in any event reduce the final royalty payment to less than [***] percent ([***]%) of the royalties otherwise payable to Innovent for such Licensed Product pursuant to Section 8.4(a) prior to the application of any deductions or reductions pursuant to Section 8.4(b) or Section 9.4(e) or carry forward pursuant to this Section 8.4(c)(ii) in such country during such calendar quarter.

Royalty Payments

. After the First Commercial Sale of any Licensed Products in the Field in the Territory, (i) within [***] ([***]) days after the end of each Calendar Quarter, Coherus shall deliver to Innovent a written report setting forth in reasonable detail, on a Licensed Product-by-Licensed Product basis, the calculation of (A) the aggregate Net Sales achieved for such Licensed Product in the Territory in such Calendar Quarter and (B) the calculation of the royalties owing by Coherus to Innovent pursuant to this Section 8.4 for such Calendar Quarter; and (ii) all amounts of royalties shall be due and payable within [***] ([***]) days after the end of the corresponding Calendar Quarter.

Additional Payment Terms

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(a) Payment. All payments to be made by Coherus to Innovent under this Agreement shall be made in U.S. Dollars by bank wire transfer in immediately available funds to such bank account designated in writing by Innovent from time to time.

(b) Taxes; Withholding.

(i) Generally. Except as set forth in this Section 8.5(b), the Payee shall be liable for all income and other taxes (including interest) ("Taxes") imposed upon any payments made by the Payor to Payee under this Agreement ("Agreement Payments"). The amounts set forth herein are exclusive of all applicable sales or use, goods and services, value added, consumption or other similar fees or taxes ("Transfer Taxes") arising on the Agreement Payments, and the Payor shall be

responsible for and pay any such Transfer Taxes imposed on it with respect to the Agreement Payments due to the Payee hereunder.

(ii) Tax Withholding. If Applicable Law requires the withholding of Taxes, the Payor shall subtract the amount thereof from the Agreement Payments and remit such withheld amount to the relevant Governmental Authority in a timely manner; provided, however, that (A) before making such withholding, the Payor shall notify the Payee of such requirement and provide such assistance to the Payee, including the provision of such documentation as may be required by the Governmental Authority, as may be reasonably necessary in the Payee's efforts to claim an exemption from or reduction of such Taxes under Applicable Laws, including under the benefit of any present or future treaty against double taxation; and (B) Payor shall consider in good faith implementing any reasonable tax position with respect to the Agreement Payments that is directed at obtaining an exemption, reduction, or refund of any such Taxes. For the avoidance of doubt, Payor's remittance of such withheld Taxes, together with payment to the Payee of the remaining Agreement Payments and any interest for any late payment, shall constitute Payor's full satisfaction of Agreement Payments under this Agreement. After any Taxes are paid to a Governmental Authority, the Payor shall promptly (as available) submit to the Payee appropriate proof of payment of the withheld Taxes as well as the official receipts within a reasonable period of time, but in no event exceeding [***] ([***]) days following the payment. The Payor shall further provide the Payee with reasonable assistance in seeking a refund of, or obtaining a credit with respect to, such withheld Taxes. Notwithstanding the foregoing, if, as a result of Payor (1) assigning this Agreement, (2) extending its rights or obligations pursuant to Section 14.15 or (3) changing its domicile, additional Taxes become due that would not have otherwise been due hereunder with respect to Agreement Payments, Payor shall be responsible for all such additional withholding Taxes and shall pay Payee such amounts as are necessary to ensure that Payee receives the same amount as it would have received had no such assignment, extension of rights or obligations, or change in domicile been made.

(iii) Tax Cooperation. The Parties shall cooperate with respect to all documentation required by any taxing authority or reasonably requested by either Party to secure a reduction in the rate of applicable withholding taxes.

(c) Interest. Coherus shall pay Innovent interest on any amounts overdue under this Agreement at a per annum rate of [***] percent ([***]%) points above the Prime Rate assessed from the day payment was initially due; provided, however, that in no case shall such interest rate exceed the highest rate permitted by Applicable Law. The payment of such interest shall not foreclose a Party from exercising any other rights it may have because any payment is overdue.

8.6 Records; Audit Rights.

(a) Records. Each Party shall (and shall ensure that its Affiliates and sublicensees will) keep complete, true, and accurate books and records in accordance with its Accounting Standards in relation to this Agreement. Each Party shall (and shall ensure that its Affiliates and sublicensees will) keep such books and records for at least [***] ([***]) years following the Calendar Year to which they pertain or for such longer period of time as required under any Applicable Law.

(b) Audit Rights. During the Term, at the written request of Innovent, which shall not be made more frequently than [***] per Calendar Year, upon at least [***] ([***]) days' prior written notice from Innovent, and at the expense of Innovent, Coherus shall, and Coherus shall cause its Affiliates and sublicensees to, permit an independent, nationally-recognized certified public accountant selected by Innovent and reasonably acceptable to Coherus (the "Auditor") to inspect, during regular business hours, the relevant records required to be maintained by Coherus, its Affiliates and sublicensees under Section 8.6(a) or otherwise reasonably necessary to verify the accuracy of royalty reports for such Calendar Year and Coherus's performance and compliance with this Agreement; provided, that such audit right shall not apply to records beyond [***] ([***]) years from the end of the Calendar Year to which they pertain and that records for a particular period may only be audited [***]. Prior to its inspection, the Auditor shall enter into a confidentiality agreement with both Parties having obligations of confidentiality and non-use no less restrictive than those set forth in Article 10 and limiting the disclosure and use of such information by such accountant to authorized representatives of the Parties and the purposes germane to Section 8.6(a). With respect to the accuracy of royalty reports, the Auditor shall report to Innovent only whether the particular amounts being audited were accurate and, if not, the amount of any discrepancy, and the Auditor shall not report any other information to Innovent. Innovent shall treat the results of any Auditor's review of Coherus's records as Confidential Information of Coherus subject to the terms of Article 10. In the event such audit leads to the discovery of a discrepancy to Innovent's detriment, Coherus shall, within [***] ([***]) days after receipt of such report from the Auditor, pay any undisputed amount of the discrepancy. Innovent shall pay the Auditor's full cost of the audit unless the underpayment of amounts due Innovent is more than [***] percent ([***]%) of the amount due for the entire period being examined, in which case Coherus shall pay the reasonable cost charged by the Auditor for such review. Any undisputed overpayments by Coherus revealed by an examination shall be paid by Innovent within [***] ([***]) days of Innovent's receipt of the applicable report.

8.7 Non-Refundable and Non-Creditable Payments. Notwithstanding the non-refundable or non-creditable nature of any payments hereunder, but subject to the limitations set forth in Section 12.4, nothing in this Agreement shall limit either Party's rights to assert or obtain damages for breach of this Agreement, including damages calculated based on the payments made under this Agreement.

9. INTELLECTUAL PROPERTY

Inventorship and Ownership

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(a) Pre-existing IP. Subject only to the rights expressly granted to the other Party under this Agreement, each Party shall retain all rights, title and interests in and to any Intellectual Property Rights that are Controlled by such Party prior to the Effective Date or developed or acquired independently of this Agreement.

(b) The determination of inventorship under this Agreement, including the inventorship of Inventions, shall be determined in accordance with the U.S. patent laws and the rules and regulations of the U.S. Patent and Trademark Office.

(c) As between the Parties, all Inventions made or created by or on behalf of Innovent shall be owned by Innovent ("Innovent Inventions"). Coherus hereby assigns any and all of its right, title and interest in and to the Innovent Inventions to Innovent, and all such Innovent Inventions shall be included in the Innovent Know-How and Innovent Patents, as

applicable, to the extent such Innovent Inventions otherwise meet the definition of Innovent Know-How and Innovent Patents, as applicable, and licensed to Coherus pursuant to this Agreement pursuant to Article 2.

(d) All Inventions made or created jointly by each Party's (or any of its Affiliates') employees, independent contractors, or consultants in the course of conducting activities under this Agreement, together with all Patents therein ("Joint Patents") shall be jointly owned by the Parties ("Joint IP"). Joint IP shall be owned jointly by Coherus and Innovent on the basis of an equal, undivided interest without a duty to account to the other Party and shall be deemed to be Controlled by each Party, subject to the licenses granted under this Agreement. Notwithstanding anything to the contrary herein, each Party shall have the right to use such Joint IP solely in connection with the Licensed Products in such Party's respective territory. In no event shall either Party have the right to sell or otherwise transfer its interest in such Joint IP to its Affiliates or a Third Party, in each case, without the consent of the other Party, independent of a Licensed Product.

(e) As between the Parties, all Inventions made or created on behalf of Coherus shall be owned by Coherus ("Coherus Inventions"). Innovent hereby assigns any and all of its right, title and interest in and to the Coherus Inventions to Coherus and solely those Coherus Inventions that directly relate to the Licensed Antibodies, including Patents covering such Coherus Inventions (such Patents, "Coherus Licensed Patents"), shall be included in the Coherus IP licensed to Innovent pursuant to Section 2.4.

(f) Each Party shall, and shall cause its sublicensees and Affiliates, and all independent contractors, employees and agents of such Party, to cooperate with the other Party and take all reasonable actions and execute such agreements, declarations, assignments, legal instruments and documents as may be reasonably required to perfect the other Party's right, title and interest in and to Inventions, and Patents thereon, and other Intellectual Property Rights as set forth in this Section 9.1. Each Party shall also include provisions in its relevant agreements with Third Parties that affect the intent of this Section 9.1.

Prosecution and Maintenance

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(a) Innovent Patents.

(i) Innovent shall be responsible for the Prosecution and Maintenance of the Innovent Patents at its own cost and expense. Innovent shall keep Coherus [***] informed of the status of the Innovent Patents and, prior to making any filings or submissions to any Governmental Authority with respect to any Innovent Patent, shall provide a copy thereof to Coherus for its review and comment. Innovent shall provide Coherus with [***].

(ii) Innovent shall notify Coherus of any decision not to file applications for, cease the Prosecution and Maintenance of, or not continue to pay the expenses for the Prosecution and Maintenance of, any Innovent Patents. Innovent shall provide such notice at least [***] ([***]) days prior to any filing or payment due date, or any other due date that requires action, in connection with such Innovent Patent. In such event, Innovent shall permit Coherus, at [***] expense, to file or to continue Prosecution and Maintenance of such Innovent Patent.

(b) Joint Patents

(i) Coherus shall be responsible for the Prosecution and Maintenance of the Joint Patents at [***] cost and expense. Coherus shall keep Innovent reasonably informed of the status of the Joint Patents and, prior to making any filings or submissions to any Governmental Authority with respect to any Joint Patent, shall provide a copy thereof to Innovent for its review and comment. Coherus shall provide Innovent with a reasonable opportunity to comment substantively on the Prosecution and Maintenance of the Joint Patents before taking [***] action, and shall use good faith efforts to incorporate into the relevant filing or submission all reasonable comments consistent with this Agreement made thereon by Innovent.

(ii) Coherus shall notify Innovent of any decision not to file applications for, cease the Prosecution and Maintenance of, or not continue to pay the expenses for the Prosecution and Maintenance of, any Joint Patents. Coherus shall provide such notice at least [***] ([***]) days prior to any filing or payment due date, or any other due date that requires action, in connection with such Joint Patent. In such event, Coherus shall permit Innovent, at [***] expense, to file or to continue Prosecution and Maintenance of such Joint Patent.

(c) Coherus Licensed Patents. Coherus shall be solely responsible for the Prosecution and Maintenance of the Coherus Licensed Patents at its own cost and expense. Coherus shall keep Innovent reasonably informed of the status of the Coherus Licensed Patents and any decision not to file applications for, cease the Prosecution and Maintenance of any such Coherus Licensed Patents.

(d) Each Party hereby agrees to reasonably cooperate with one another with respect to the Prosecution and Maintenance of the Innovent Patents, Joint Patents and Coherus Licensed Patents, as applicable, for which such Party is responsible pursuant to this Agreement, including by: (i) making its employees, and using reasonable efforts to make its licensees, sublicensees, independent contractors, agents and consultants, reasonably available to the other Party (or to the other Party's authorized attorneys, agents or representatives), to the extent reasonably necessary to enable such Party to undertake Prosecution and Maintenance of Patents as contemplated by this Agreement; and (ii) endeavoring in good faith to coordinate its efforts with the other Party to minimize or avoid interference with the Prosecution and Maintenance of the other Party's Patents that are subject to this Agreement.

Enforcement

.

(a) Innovent Patents.

(i) Each Party shall promptly notify the other Party of any infringement by a Third Party of any Innovent Patent in the Territory of which it becomes aware, including any declaratory judgment, opposition, or similar action alleging the invalidity, unenforceability, or non-infringement with respect to such Innovent Patent ("Innovent Patent Infringement").

(ii) [***] shall have the first right, but not the obligation, to bring and control any legal action or take such other actions as it deems appropriate in connection with any actual or potential Innovent Patent Infringement of any Innovent Patent anywhere in the Territory as it reasonably determines appropriate, at its cost and expense. At the request and expense of [***], [***] shall provide reasonable assistance in connection with [***] legal or other actions in connection with any such Innovent

Patent Infringement, including by executing reasonably appropriate documents, cooperating in discovery, and joining as a party to the action if required. [***] may join [***] as a party plaintiff if [***] is an indispensable party to such proceeding and [***] agrees to be joined as a party. Additionally, [***] shall have the right to be represented in any such action by counsel of its own choice at [***] sole cost and expense.

(iii) If [***] elects not to exercise its rights under Section 9.3(a)(ii) within [***] ([***]) days of first becoming aware of an Innovent Patent Infringement, then [***] shall have the right, but not the obligation, to enforce the Innovent Patents against such Innovent Patent Infringement. Any cost and expense that Coherus incurs in connection with its enforcement of such Innovent Patent Infringement shall be borne by [***]. At the request [***] [***], [***] shall provide reasonable assistance in connection with [***] legal or other actions in connection with any such Innovent Patent Infringement, including by executing reasonably appropriate documents, cooperating in discovery, and joining as a party to the action if required. [***] may join [***] as a party plaintiff if [***] is an indispensable party to such proceeding and [***] agrees to be joined as a party. Additionally, [***] shall have the right to be represented in any such action by counsel of its own choice at [***] sole cost and expense.

(iv) With respect to all recoveries obtained in connection with an enforcement action or proceeding undertaken pursuant to this Section 9.3(a), such recoveries shall first be used to reimburse the enforcing Party for its costs incurred in connection therewith. Any remaining recoveries shall then be used to reimburse the other Party for its costs incurred in connection therewith. Any remaining recoveries shall be paid [***] percent ([***]%) to the enforcing Party and [***] percent ([***]%) to the non-enforcing Party.

(b) Joint Patents.

(i) Each Party shall promptly notify the other Party of any infringement by a Third Party of any Joint Patent in the Territory of which it becomes aware, including any declaratory judgment, opposition, or similar action alleging the invalidity, unenforceability, or non-infringement with respect to such Joint Patent ("Joint Patent Infringement").

(ii) Coherus shall have the first right, but not the obligation, to bring and control any legal action or take such other actions as it deems appropriate in connection with any actual or potential Joint Patent Infringement of any Joint Patent anywhere in the Territory as it reasonably determines appropriate, at [***] cost and expense. At the request [***] of Coherus, Innovent shall provide reasonable assistance in connection with Coherus's legal or other actions in connection with any such Joint Patent Infringement, including by executing reasonably appropriate documents, cooperating in discovery, and joining as a party to the action if required. Coherus may join Innovent as a party plaintiff if Innovent is an indispensable party to such proceeding and Innovent agrees to be joined as a party. Additionally, Innovent shall have the right to be represented in any such action by counsel of its own choice at Innovent's sole cost and expense.

(iii) If Coherus elects not to exercise its rights under Section 9.3(b)(ii) within [***] ([***]) days of first becoming aware of a Joint Patent Infringement, then Innovent

shall have the right, but not the obligation, to enforce the Joint Patents against such Joint Patent Infringement. Any cost and expense that Innovent incurs in connection with its enforcement of such Joint Patent Infringement shall be borne by [***]. At the request [***] of Innovent, Coherus shall provide reasonable assistance in connection with Innovent's legal or other actions in connection with any such Joint Patent Infringement, including by executing reasonably appropriate documents, cooperating in discovery, and joining as a party to the action if required. Innovent may join Coherus as a party plaintiff if Coherus is an indispensable party to such proceeding and Coherus agrees to be joined as a party. Additionally, Coherus shall have the right to be represented in any such action by counsel of its own choice at Coherus's sole cost and expense.

(iv) With respect to all recoveries obtained in connection with an enforcement action or proceeding undertaken pursuant to this Section 9.3(b), such recoveries shall first be used to reimburse the enforcing Party for its costs incurred in connection therewith. Any remaining recoveries shall then be used to reimburse the other Party for its costs incurred in connection therewith. Any remaining recoveries shall be paid [***] percent ([***]%) to the enforcing Party and [***] percent ([***]%) to the non-enforcing Party.

(c) Coherus Licensed Patents.

(i) Each Party shall promptly notify the other Party of any infringement by a Third Party of any Coherus Licensed Patent in the Territory of which it becomes aware, including any declaratory judgment, opposition, or similar action alleging the invalidity, unenforceability, or non-infringement with respect to such Coherus Licensed Patent ("Coherus Patent Infringement").

(ii) Coherus shall have the sole right, but not the obligation, to bring and control any legal action or take such other actions as it deems appropriate in connection with any actual or potential Coherus Patent Infringement of any Coherus Licensed Patent anywhere in the Territory as it reasonably determines appropriate, at [***] cost and expense. At the request [***] of Coherus, Innovent shall provide reasonable assistance in connection with Coherus's legal or other actions in connection with any such Coherus Patent Infringement, including by executing reasonably appropriate documents, cooperating in discovery, and joining as a party to the action if required. Coherus may join Innovent as a party plaintiff if Innovent is an indispensable party to such proceeding and Innovent agrees to be joined as a party. Additionally, Innovent shall have the right to be represented in any such action by counsel of its own choice at Innovent's sole cost and expense.

(iii) If Coherus elects not to exercise its rights under Section 9.3(c)(ii) within [***] ([***]) days of first becoming aware of a Coherus Patent Infringement, then it shall provide reasonable notice to Innovent.

(iv) With respect to all recoveries obtained in connection with an enforcement action or proceeding undertaken pursuant to this Section 9.3(c), such recoveries shall first be used to reimburse the enforcing Party for its costs incurred in connection therewith. Any remaining recoveries shall then be used to reimburse the other Party for its costs incurred in connection therewith. Any remaining recoveries shall be paid to [***].

Defense

.

(a) Each Party shall promptly notify the other Party of any claim alleging that the Development, Manufacture, or Commercialization of the Licensed Products in the Territory infringes, misappropriates, or otherwise violates any Intellectual Property Rights of any Third Party, including the pre-litigation processes of the BPCIA generally set forth in 42 U.S.C. § 262(l), including the process commonly referred to as the "patent dance" and the "notice of commercial marketing" (collectively, the "BPCIA Proceedings") with respect to each Licensed Product ("Third Party Infringement Claim"). In any such instance, the Parties shall [***] thereafter discuss in good faith the best response to such notice of such Third Party Infringement Claim.

(b) Coherus shall have the first right, but not the obligation, to defend, and take other actions (including to settle) with respect to any claim of Third Party Infringement Claim; provided, that, in no event shall Coherus without [***] (i) settle any Third Party Infringement Claim or (ii) compromise any Third Party Infringement Claim by admitting that any Third Party Patent is valid or enforceable. Any cost and expense that Coherus incurs in connection with its enforcement of such Third Party Infringement Claim shall be borne by [***]. Innovent shall have the right to be represented in any such action by counsel of its own choice at Innovent's sole cost and expense.

(c) If Coherus elects not to, or fails to, exercise its rights under Section 9.4(b) within [***] ([***]) days of its first receipt of notice of the applicable Third Party Infringement Claim, then Innovent shall have the right, but not the obligation, to defend, and take other actions (including to settle) with respect to such Third Party Infringement Claim at [***] cost and expense; provided, that, in no event shall Innovent without first obtaining the prior written consent of Coherus, which consent shall not be unreasonably withheld, conditioned, or delayed (i) settle any Third Party Infringement Claim or (ii) compromise any Third Party Infringement Claim by admitting that any Third Party Patent is valid or enforceable. Coherus shall have the right to be represented in any such action by counsel of its own choice at Coherus's sole cost and expense.

(d) Recovery. Any recoveries obtained upon the final judgement or settlement of any Third Party Infringement Claim shall first be used to reimburse the defending Party for its costs incurred in connection therewith. Any remaining recoveries shall be paid [***] percent ([***]%) to the enforcing Party and [***] percent ([***]%) to the non-enforcing Party.

(e) Damages. All amounts to be paid by the defendants upon the final judgment or settlement in connection with the defense of a Third Party Infringement Claim, or in securing a license or other rights to Intellectual Property Rights Controlled by the Third Party plaintiff(s), including any reference product sponsor during the course of and in connection with the BPCIA Proceedings, including [***] (collectively, "Damages") shall be borne equally by Coherus and Innovent, provided that (i) [***] but instead (ii) [***].

Patent Extensions

. Upon Coherus's request, Innovent shall obtain patent term restoration (including under the Drug Price Competition and Patent Term Restoration Act), supplemental protection certificates or their equivalents, and patent term extensions (collectively, "Patent Extensions") with respect to the Innovent Patents. If Innovent does not take any action required by this Section 9.5 within [***] ([***]) days of Coherus's request or if Innovent requests in writing for Coherus to take the actions necessary in connection with the applicable Patent Extension, then in each case Coherus shall be authorized and entitled to proceed with applications for such Patent

Extension in the name of Innovent, as deemed appropriate by Coherus, and Innovent shall provide any reasonably necessary information and assistance to Coherus.

10. CONFIDENTIALITY

10.1 Nondisclosure. Each Party agrees that a Party (the "Receiving Party") which receives the Confidential Information of the other Party (the "Disclosing Party") pursuant to this Agreement shall: (a) maintain in confidence such Confidential Information using not less than the efforts that such Receiving Party uses to maintain in confidence its own proprietary information of similar kind and value, but in no event less than a reasonable degree of efforts; (b) not disclose such Confidential Information to any Third Party without first obtaining the prior written consent of the Disclosing Party, except for disclosures expressly permitted pursuant to this Article 10; and (c) not use such Confidential Information for any purpose except those permitted under this Agreement, including, in the case of Coherus, the exercise of the rights and licenses granted to Coherus hereunder. The obligations of confidentiality, non-disclosure, and non-use under this Section 10.1 shall be in full force and effect from the Effective Date until [***] ([***]) years following the expiration of the Term. The Receiving Party shall return all copies of or destroy the Confidential Information of the Disclosing Party disclosed or transferred to it by the Disclosing Party pursuant to this Agreement, within [***] ([***]) days after the expiration or termination of this Agreement; provided, however, that a Party may retain: (i) Confidential Information of the Disclosing Party to exercise rights and licenses which expressly survive such termination or expiration pursuant to this Agreement; and (ii) one (1) copy of all other Confidential Information in archives solely for the purpose of establishing the contents thereof.

10.2 Exceptions. Section 10.1 shall not apply with respect to any portion of the Confidential Information of the Disclosing Party to the extent that such Confidential Information:

(a) was known to the Receiving Party or any of its Affiliates, as evidenced by written records, without any obligation to keep it confidential or any restriction on its use, prior to disclosure by the Disclosing Party;

(b) is subsequently disclosed to the Receiving Party or any of its Affiliates by a Third Party lawfully in possession thereof and without any obligation to keep it confidential or any restriction on its use;

(c) is published by a Third Party or otherwise becomes publicly available or enters the public domain, either before or after it is disclosed to the Receiving Party, without any breach by the Receiving Party of its obligations hereunder; or

(d) is independently developed by or for the Receiving Party or any of its Affiliates, as evidenced by written records, without reference to or reliance upon the Disclosing Party's Confidential Information.

Any combination of features or disclosures shall not be deemed to fall within the foregoing exclusions merely because individual features are published or available to the general public or in the rightful possession of the Receiving Party unless the combination itself and principle of operation are published or available to the general public or in the rightful possession of the Receiving Party.

10.3 Authorized Disclosure.

(a) Disclosure. Notwithstanding Section 10.1, the Receiving Party may disclose Confidential Information belonging to the Disclosing Party in the following instances:

(i) to comply with Applicable Law (including the rules and regulations of the U.S. Securities and Exchange Commission or any national securities exchange in any jurisdiction in the Territory) (collectively, the "Securities Regulators") or with judicial process (including prosecution or defense of litigation) if, in the reasonable opinion of the Receiving Party's counsel, such disclosure is necessary for such compliance or for such judicial process (including prosecution or defense of litigation); provided, that reasonable steps are taken to ensure confidential treatment of such Confidential Information to the extent available;

(ii) disclosure to governmental or other regulatory agencies in order to obtain Patents, to obtain or maintain approval to conduct Clinical Trials, or to market the Licensed Products under this Agreement, in each case, in accordance with this Agreement; provided, that reasonable steps are taken to ensure confidential treatment of such Confidential Information to the extent available;

(iii) disclosure to any of its officers, employees, consultants, agents, or Affiliates; provided, that such persons are bound by legally enforceable obligations to maintain the confidentiality of the Disclosing Party's Confidential Information in a manner consistent with the confidentiality provisions of this Agreement; provided, however, that, in each of the above situations in this Section 10.3(a)(iii), the Receiving Party shall remain responsible for any failure by any Person who receives Confidential Information from such Receiving Party pursuant to this 10.3(a)(iii) to treat such Confidential Information as required under this Article 10;

(iv) disclosure to any actual or potential collaborators, licensees, sublicensees or subcontractors in connection with the Development, Manufacture and Commercialization of Licensed Products, or to such Party's actual or potential acquirers, investors, or lenders as part of their due diligence investigations; provided, that, prior to any such disclosure, each such disclosee is bound by written obligations of confidentiality, non-disclosure, and non-use no less restrictive than the obligations set forth in this Article 10 to maintain the confidentiality thereof and not to use such Confidential Information except as expressly permitted by this Agreement; provided, however, that, in each of the above situations in this Section 10.3(a)(iv), the Receiving Party shall remain responsible for any failure by any Person who receives Confidential Information from such Receiving Party pursuant to this Section 10.3(a)(iv) to treat such Confidential Information as required under this Article 10; and

(v) disclosure to its advisors (including attorneys and accountants) in connection with activities under this Agreement; provided, that, prior to any such disclosure, each such disclosee is bound by written obligations of confidentiality, non-disclosure, and non-use no less restrictive than the obligations set forth in this Article 10 (provided, however, that in the case of legal advisors, no written agreement shall be required), to maintain the confidentiality thereof and not to use such Confidential Information except as expressly permitted by this Agreement; provided, however, that, in each of the above situations in this Section 10.3(a)(v), the Receiving Party shall remain responsible for any failure by any Person who receives Confidential Information from such Receiving Party pursuant to this

Section 10.3(a)(v) to treat such Confidential Information as required under this Article 10.

(b) Terms of Disclosure. If and whenever any Confidential Information is disclosed in accordance with this Section 10.3, such disclosure shall not cause any such information to cease to be Confidential Information, except to the extent that such disclosure results in a public disclosure of such information other than by breach of this Agreement.

10.4 Terms of this Agreement. The Parties agree that this Agreement and the terms hereof shall be deemed to be Confidential Information of both Innovent and Coherus, and each Party agrees not to disclose this Agreement or any terms hereof without obtaining the prior written consent of the other Party; provided, that each Party may disclose this Agreement or any terms hereof in accordance with the provisions of Section 10.3 or Section 10.6, as applicable.

10.5 Securities Filings; Disclosure under Applicable Law. Each Party acknowledges and agrees that the other Party may submit this Agreement to, or file this Agreement with, the Securities Regulators or to other Persons as may be required by Applicable Law, and if a Party submits this Agreement to, or files this Agreement with, any Securities Regulator or other Person as may be required by Applicable Law, such Party agrees to consult with the other Party with respect to the preparation and submission of a confidential treatment request for this Agreement. Notwithstanding the foregoing, if a Party is required by any Securities Regulator or other Person as may be required by Applicable Law to make a disclosure of the terms of this Agreement in a filing or other submission as required by such Securities Regulator or such other Person, and such Party has: (a) provided copies of the disclosure to the other Party reasonably in advance under the circumstances of such filing or other disclosure; (b) promptly notified the other Party in writing of such requirement and any respective timing constraints; and (c) given the other Party reasonable time under the circumstances from the date of provision of copies of such disclosure to comment upon and request confidential treatment for such disclosure, then such Party shall have the right to make such disclosure at the time and in the manner reasonably determined by its counsel to be required by the Securities Regulator or the other Person. Notwithstanding the foregoing, if a Party seeks to make a disclosure as required by a Securities Regulator or other Person as may be required by Applicable Law as set forth in this Section 10.6 and the other Party provides comments in accordance with this Section 10.6, the Party seeking to make such disclosure or its counsel, as the case may be, shall use good-faith efforts to incorporate such comments.

10.6 Publicity.

(a) Subject to Section 10.3, Section 10.5, and this Section 10.6(a), neither Party shall, and shall cause its Affiliates not to, issue any press release, publication (including publications in journals, posters, presentations at conferences, and abstracts submitted in advance of conferences), or other public statement disclosing this Agreement, the activities hereunder, or the transactions contemplated hereby, without first obtaining the prior written consent of the other Party, such consent not to be unreasonably delayed, withheld or conditioned; provided, that each Party shall be authorized to make any disclosure, without first obtaining [***] prior written consent, that is required by Applicable Law (including the U.S. Securities Act of 1933 and the U.S. Securities Exchange Act of 1934), the rules of any Securities Regulator, or by judicial process, subject to and in accordance with Section 10.3 and Section 10.5, as applicable. The contents of any press release, publication, or other public statement that has been reviewed and approved by the other Party may be re-released by each Party without re-obtaining the other Party's prior written consent in accordance with this Section 10.6(a).

(b) Notwithstanding the foregoing, the Parties shall mutually agree to a press release or public announcement regarding this Agreement and the terms hereof, such press release or public announcement to be issued promptly (but in no event later than [***] ([***]) [***]) after the Effective Date, or as otherwise agreed by the Parties. Either Party shall be authorized to use the information disclosed in any mutually approved press release or public announcement without the need to seek further consent or approval thereof from the other Party.

Use of Names

. Except as otherwise expressly set forth herein neither Party (or any of its respective Affiliates) shall use the name, trademark, trade name, or logo of the other Party or any of its Affiliates, or its or their respective employees, in any publicity, promotion, news release, or other public disclosure relating to this Agreement or its subject matter, without first obtaining the prior written consent of the other Party; provided, that such consent shall not be required to the extent use thereof may be required by Applicable Law, including the rules of any securities exchange or market on which a Party's or its Affiliate's securities are listed or traded. Each Party shall be authorized to use the name, trademark, trade name, or logo of the other Party in the manner that such other Party has previously approved, without the need to seek further consent or approval thereof from the other Party. Notwithstanding the foregoing, each Party shall be authorized to use the name and logo of the other Party on their websites or facilities to identify and demonstrate the collaboration relationship between the Parties in connection with this Agreement, without the need to seek further consent or approval thereof from the other Party.

11. REPRESENTATIONS AND WARRANTIES; COVENANTS

Representations and Warranties of Each Party

. Each Party hereby represents and warrants to the other Party, as of the Effective Date that:

(a) such Party is duly organized, validly existing, and in good standing under the Applicable Law of the jurisdiction of its formation and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof;

(b) such Party has taken all necessary corporate action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder;

(c) this Agreement has been duly executed and delivered on behalf of such Party and constitutes a legal, valid, and binding obligation, enforceable against it in accordance with its terms, except to the extent that enforcement of the rights and remedies created hereby is subject to: (i) bankruptcy, insolvency, reorganization, moratorium, and other similar laws of general application affecting the rights and remedies of creditors; or (ii) laws governing specific performance, injunctive relief, and other equitable remedies;

(d) the execution, delivery, and performance of this Agreement by such Party does not breach or conflict with any agreement or any provision thereof, or any instrument or understanding, oral or written, to which such Party (or any of its Affiliates) is a party or by which such Party (or any of its Affiliates) is bound, nor violate any Applicable Law of any Governmental Authority having jurisdiction over such Party (or any of its Affiliates);

(e) to the Knowledge of such Party, no government authorization, consent, approval, license, exemption of or filing or registration with any court or governmental department, commission, board, bureau, agency, or instrumentality, domestic or foreign, under any Applicable Law currently in effect, is or shall be necessary for, or in connection with, the

transactions contemplated by this Agreement, or for the performance by it of its obligations under this Agreement; and

(f) it has obtained all necessary authorizations, consents, and approvals of any Third Party that is required to be obtained by it for, or in connection with, the transactions contemplated by this Agreement, or for the performance by it of its obligations under this Agreement.

Representations and Warranties of Innovent

. Innovent hereby represents and warrants to Coherus that as of the Effective Date:

(a) to the Knowledge of Innovent, no written claim has been issued or served, or written threat of a claim or litigation made by any Person, against Innovent, its Affiliates, or its sublicensees, that alleges that any Innovent IP is invalid or unenforceable;

(b) Innovent has the full right and authority to grant all of the rights and licenses granted to Coherus (or purported to be granted to Coherus) hereunder, and neither Innovent nor its Affiliates have granted any right or license to any Third Party relating to any of the Innovent IP that would conflict with or limit the scope of any of the rights or licenses granted to Coherus hereunder and Innovent is the sole owner of the Innovent IP;

(c) Neither Innovent nor any of its Affiliates has granted any mortgage, pledge, claim, security interest, lien, or other charge of any kind on the Innovent IP. Innovent IP is free and clear of any mortgage, pledge, claim, security interest, lien, or charge of any kind, including any mortgage, pledge, claim, security interest, lien or charge of any kind;

(d) Innovent and its Affiliates have obtained from all individuals who participated in any material respect in the invention of any Innovent IP effective assignments of all ownership rights of such individuals in such Innovent IP, either pursuant to written agreement or by operation of law, and no Person who claims to be an inventor of an invention claimed in an Innovent Patent in the Field in the Territory is not identified as an inventor of such invention in the filed patent documents for such Innovent Patent;

(e) all of Innovent's and its Affiliates' officers, employees, and consultants who participated in any material respect in the invention of any Innovent IP have executed agreements or have existing obligations under Applicable Law obligating the individual to maintain as confidential Innovent's Confidential Information as well as confidential information of other parties (including of Coherus and its Affiliates) that such individual may receive in its performance under this Agreement, to the extent required to support Innovent's obligations under this Agreement;

(f) neither Innovent nor its Affiliates have received any written notice of any claim that any Patent or Know-How (including any trade secret right) Controlled by a Third Party would be infringed or misappropriated by the Development, Manufacture, or Commercialization of the Licensed Products in the Field in the Territory;

(g) to the Knowledge of Innovent, there are no claims, judgments, settlements, litigations, suits, actions, disputes, arbitration, judicial, or legal, administrative or other proceedings (except in the case of proceedings relating to the Prosecution and Maintenance of the Innovent IP in the ordinary course of business), or governmental investigations pending or, threatened against Innovent or its Affiliates which could reasonably be expected to adversely affect or restrict (i) the ability of Innovent to consummate or perform the transactions contemplated under this Agreement, or (ii) the Innovent IP or Innovent's Control thereof;

(h) neither Innovent nor any of its Affiliates has made a claim against a Third Party alleging that a Third Party is violating or has violated, is infringing or has infringed, or is misappropriating or has misappropriated any Innovent IP in the Territory, and, to the Knowledge of Innovent, no Innovent IP is being violated, infringed, or misappropriated by any Third Party in the Territory;

(i) to the Knowledge of Innovent, (i) neither Innovent nor any of its Affiliates has employed, or otherwise used in any capacity, the services of any Person suspended, proposed for debarment, or debarred under United States law, including under 21 U.S.C. § 335a, or any foreign equivalent thereof, with respect to the Development or Manufacture of the Licensed Products; and (ii) all Development and Manufacture (including non-clinical studies and Clinical Trials) related to the Licensed Products conducted by or on behalf of Innovent or its Affiliates has been conducted in accordance with in all material aspects of all Applicable Law (including, to the extent applicable, GCP, GLP, and GMP);

(j) Subject to Section 5.2(a), Innovent has not obtained, or filed, any INDs, BLAs, or Regulatory Approvals or any other form of regulatory application in the Field in the Territory for the conduct of Clinical Trials, marketing, or other purpose, for any Licensed Product in the Field in the Territory, and to the Knowledge of Innovent, no other Person has obtained, or filed for, any such INDs, BLAs, or Regulatory Approvals for such Licensed Products in the Field in the Territory; and

(k) to the Knowledge of Innovent, (i) no funding, facilities, or personnel of any Governmental Authority or any public or private educational or research institutions were used to develop or create any Innovent IP, and (ii) neither Innovent nor any of its Affiliates has entered into a government funding relationship, in each case (i) and (ii), that would result in rights to the Licensed Products residing in the U.S. Government, the National Institutes of Health, the National Institute for Drug Abuse, or other agency, and the licenses granted hereunder are not subject to overriding obligations to the U.S. Government as set forth in Public Law 96-517 (35 U.S.C. §§ 200-204), or any similar obligations under the laws of any other country in the Territory.

Representation and Warranty of Coherus

. Coherus hereby represents and warrants to Innovent that as of the Effective Date:

(a) there are no claims, judgments, settlements, litigations, suits, actions, disputes, arbitration, judicial, or legal, administrative, or other proceedings or governmental investigations pending or, to the Knowledge of Coherus, threatened against Coherus which would reasonably be expected to adversely affect or restrict the ability of Coherus to consummate or perform the transactions contemplated under this Agreement; and

(b) to the Knowledge of Coherus, neither Coherus nor any of its Affiliates has employed, or otherwise used in any capacity, the services of any Person suspended, proposed for debarment, or debarred under United States law, including under 21 U.S.C. § 335a, or any foreign equivalent thereof.

Covenants

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(a) Mutual Covenants.

(i) Each Party hereby covenants to the other Party that such Party and its Affiliates shall perform its activities pursuant to this Agreement in compliance (and shall

ensure compliance by any of its sublicensees and subcontractors) with all Applicable Law, including, to the extent applicable, GCP, GLP, GMP and Anti-Corruption Laws.

(ii) Each Party shall immediately notify the other Party in writing if any debarment under Section 335a of Title 21 of United States Code comes to its attention with respect to any person employed or otherwise used in any capacity for performing any activities under this Agreement, and shall promptly remove such person or entity from performing any activities related to or in connection with this Agreement.

(iii) during the Term, neither Party nor its Affiliates shall not employ, or otherwise use in any capacity, the services of any Person to perform any activities under this Agreement that is or has been suspended, proposed for debarment, or debarred under United States law, including under 21 U.S.C. § 335a, or any foreign equivalent thereof.

(b) Additional Coherus Covenants. Coherus hereby covenants to Innovent that:

(i) during the Term, Coherus shall not, and shall cause its Affiliates to not, Develop, Manufacture or Commercialize any Biosimilar Products of the Bevacizumab Reference Product, other than the Bevacizumab Licensed Product; and

(ii) during the Rituximab Product Term, Coherus shall not, and shall cause its Affiliates to not, Develop, Manufacture or Commercialize any Biosimilar Products of the Rituximab Reference Product, other than the Rituximab Licensed Product.

DISCLAIMER

. EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED (AND EACH PARTY HEREBY EXPRESSLY DISCLAIMS ANY AND ALL REPRESENTATIONS AND WARRANTIES NOT EXPRESSLY PROVIDED IN THIS AGREEMENT), INCLUDING WITH RESPECT TO ANY PATENTS OR KNOW-HOW, INCLUDING WARRANTIES OF VALIDITY OR ENFORCEABILITY, MERCHANTABILITY, FITNESS FOR A PARTICULAR USE OR PURPOSE, PERFORMANCE, AND NON-INFRINGEMENT OF ANY THIRD PARTY PATENT OR OTHER INTELLECTUAL PROPERTY RIGHT. NEITHER PARTY MAKES ANY REPRESENTATION OR WARRANTY, EITHER EXPRESS OR IMPLIED, THAT IT WILL BE ABLE TO SUCCESSFULLY DEVELOP, MANUFACTURE, OR COMMERCIALIZE ANY LICENSED PRODUCT OR, IF COMMERCIALIZED, THAT ANY PARTICULAR SALES LEVEL OF SUCH LICENSED PRODUCT WILL BE ACHIEVED.

12. INDEMNIFICATION

Indemnification by Coherus

. Coherus shall indemnify, defend, and hold harmless Innovent, its Affiliates, and its and their respective directors, officers, employees, agents, successors, and assigns (collectively, the "Innovent Indemnitees") from and against any and all Damages to the extent arising out of or relating to, directly or indirectly, any Third Party Claim based upon:

(a) subject to Section 9.4(e), the Development, Manufacture, or Commercialization of the Licensed Products in the Field in the Territory by Coherus, its Affiliates, or its sublicensees;

(b) the gross negligence or willful misconduct of Coherus or its Affiliates or sublicensees, or its or their respective directors, officers, employees, or agents, in connection with Coherus's performance of its obligations under this Agreement; or

(c) any material breach by Coherus of any of its representations, warranties, covenants, agreements, or obligations under this Agreement;

provided, however, that, in each case of Section 12.1(a), Section 12.1(b) or Section 12.1(c), such indemnity shall not apply to the extent Innovent has an indemnification obligation pursuant to Section 12.2(a), Section 12.2(b), Section 12.2(c) or Section 12.2(d) for such Damages.

Indemnification by Innovent

. Innovent shall indemnify and hold harmless Coherus, its Affiliates, and its and their respective directors, officers, employees, agents, successors, and assigns (collectively, the "Coherus Indemnitees"), from and against any and all Damages to the extent arising out of or relating to, directly or indirectly, any Third Party Claim based upon:

(a) the Development, Manufacture or Commercialization by Innovent, its Affiliates, contractors or licensees of any terminated or expired Licensed Product(s) after the corresponding termination in the Territory;

(b) the Development by Innovent, its Affiliates, contractors or licensees of any Innovent Combination Product in the Territory, including product liability related to such Development;

(c) the gross negligence or willful misconduct of Innovent or its Affiliates or its or their respective directors, officers, employees, or agents, in connection with Innovent's performance of its obligations under this Agreement; or

(d) any material breach by Innovent of any of its representations, warranties, covenants, agreements, or obligations under this Agreement;

provided, however, that, in each case of, and Section 12.2(a), Section 12.2(b), Section 12.2(c) or Section 12.2(d), such indemnity shall not apply to the extent Coherus has an indemnification obligation pursuant to Section 12.1(a), Section 12.1(b) or Section 12.1(c) for such Damages.

Procedure

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(a) If a Party is seeking indemnification under Section 12.1 or Section 12.2, as applicable (the "Indemnitee"), it shall inform the other Party (the "Indemnitor") of the claim giving rise to the obligation to indemnify pursuant to Section 12.1 or Section 12.2, as applicable, as soon as reasonably practicable after receiving notice of the claim (an "Indemnification Claim Notice"); provided, that any delay or failure to provide such notice shall not constitute a waiver or release of, or otherwise limit, the Indemnitee's rights to indemnification under Section 12.1 or Section 12.2, as applicable, except to the extent that such delay or failure materially prejudices the Indemnitor's ability to defend against the relevant claims.

(b) The Indemnitor shall have the right, upon written notice given to the Indemnitee within [***] ([***]) days after receipt of the Indemnification Claim Notice, to assume the defense of any such claim for which the Indemnitee is seeking indemnification pursuant to Section 12.1 or Section 12.2, as applicable. The Indemnitee shall cooperate with the Indemnitor and the Indemnitor's insurer as the Indemnitor may reasonably request, and at the Indemnitor's cost and expense. The Indemnitee shall have the right to participate, at its

own expense and with counsel of its choice, in the defense of any claim or suit that has been assumed by the Indemnitor.

(c) The Indemnitor shall not settle any claim without first obtaining the prior written consent of the Indemnitee, not to be unreasonably withheld, conditioned, or delayed; provided, however, that the Indemnitor shall not be required to obtain such consent if the settlement: (a) involves only the payment of money and shall not result in the Indemnitee (or other Innovent Indemnitees or Coherus Indemnitees, as applicable) becoming subject to injunctive or other similar type of relief; (b) does not require an admission by the Indemnitee (or other Innovent Indemnitees or Coherus Indemnitees, as applicable); and (c) does not adversely affect the Intellectual Property Rights Controlled by, or the rights or licenses granted to the Indemnitee (or its Affiliate) under this Agreement. The Indemnitee shall not settle or compromise any such claim without first obtaining the prior written consent of the Indemnitor.

(d) If the Parties cannot agree as to the application of Section 12.1 or Section 12.2, as applicable, to any claim, pending the resolution of the dispute pursuant to Section 14.6, the Parties may conduct separate defenses of such claims, with each Party retaining the right to claim indemnification from the other Party in accordance with Section 12.1 or Section 12.2, as applicable, upon resolution of the underlying claim. In each case, the Indemnitee shall reasonably cooperate with the Indemnitor and shall make available to the Indemnitor all pertinent information under the control of the Indemnitee, which information shall be subject to Article 10.

LIMITATION OF LIABILITY

. NEITHER INNOVENT NOR COHERUS, NOR ANY OF THEIR RESPECTIVE AFFILIATES, WILL BE LIABLE TO THE OTHER PARTY OR ITS AFFILIATES UNDER OR IN CONNECTION WITH THIS AGREEMENT FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL, OR PUNITIVE OR EXEMPLARY DAMAGES (INCLUDING LOST PROFITS OR LOST REVENUES), WHETHER LIABILITY IS ASSERTED IN CONTRACT, TORT (INCLUDING NEGLIGENCE AND STRICT PRODUCT LIABILITY), INDEMNITY, CONTRIBUTION, OR OTHERWISE, AND IRRESPECTIVE OF WHETHER THAT PARTY OR ANY REPRESENTATIVE OF THAT PARTY HAS BEEN ADVISED OF, OR OTHERWISE MIGHT HAVE ANTICIPATED THE POSSIBILITY OF, ANY SUCH LOSS OR DAMAGE. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 12.4 IS INTENDED TO OR SHALL LIMIT OR RESTRICT: (A) THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTION 12.1 OR SECTION 12.2, AS APPLICABLE, IN CONNECTION WITH ANY THIRD PARTY CLAIMS; OR (B) DAMAGES AVAILABLE FOR A PARTY'S GROSS NEGLIGENCE, INTENTIONAL MISCONDUCT, OR FRAUD OR FOR BREACH OF ARTICLE 10.

13. TERM AND TERMINATION

Term

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(a) With respect to the Bevacizumab Licensed Product, this Agreement shall remain in effect for ten (10) years from the Effective Date ("Bevacizumab Product Term"), which may be renewed by successive two (2) year terms prior to expiration of the then effective Bevacizumab Product Term by the mutual agreement of the Parties, unless earlier terminated.

(b) With respect to the Rituximab Licensed Product, the Agreement shall be effective from the Option Effective Date (if any) and shall remain in effect for ten (10) years from the Option Effective Date (if any) ("Rituximab Product Term"), which may be renewed by successive two (2) year terms prior to expiration of the then effective Rituximab Product Term by the mutual agreement of the Parties, unless earlier terminated.

(c) With respect to the right to exercise the Option under Section 2.3 and the obligations in Section 4.3, such right shall be effective from the Effective Date and shall remain in effect as described in Section 2.3 and Section 4.3.

(d) The term of this Agreement shall begin as of the Effective Date and expire on the later of the expiration of (i) the Bevacizumab Product Term and (ii) the Rituximab Product Term, unless earlier terminated (the "Term").

Termination for Material Breach

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(a) Material Breach. This Agreement may be terminated in its entirety or on a Licensed Product-by-Licensed Product or country-by-country basis by a Party for a material breach of a material term of this Agreement (a "Material Breach") by the other Party; provided, that the breaching Party has not cured (if curable) such breach within sixty (60) days after the date of written notice to the breaching Party of such breach (the "Cure Period"), which notice shall describe such breach in reasonable detail and shall state the non-breaching Party's intention to terminate this Agreement (in its entirety or on a Licensed Product-by-Licensed Product or country-by-country basis). Any termination of this Agreement (in its entirety or on a Licensed Product-by-Licensed Product or country-by-country basis) under this Section 13.2(a) shall become effective at the end of the Cure Period, unless the breaching Party has cured such breach prior to the expiration of such Cure Period, or, if such breach is not susceptible to cure within the Cure Period, then, except with respect to any breach of any undisputed payment obligation, such Cure Period shall be extended for an additional ninety (90) days so long as the breaching Party continues to use commercially reasonable efforts to cure such Material Breach during such extension period. Notwithstanding the foregoing, (i) a Coherus breach of any material, undisputed payment obligation payable by Coherus to Innovent under Article 8 shall be deemed a Material Breach, and (ii) Coherus shall have thirty (30) days to cure any such breach, not to be extended; *provided* that, if a government or regulatory action (or inaction) prevents Coherus from making such payment to Innovent within such thirty (30) day period, the Parties shall discuss in good faith to extend such thirty (30) day period.

(b) Disagreement as to Material Breach. Notwithstanding Section 13.2(a), if the Parties in good faith disagree as to whether there has been a Material Breach, then: (a) the Party that disputes whether there has been a Material Breach may contest the allegation by referring such matter for resolution in accordance with Section 14.6(b); (b) the relevant Cure Period with respect to such alleged Material Breach shall be tolled from the date on which the Party that disputes whether there has been a Material Breach notifies the other Party of such dispute and through the resolution of such dispute in accordance with the applicable provisions of this Agreement; (c) during the pendency of such dispute, all of the terms and conditions of this Agreement shall remain in effect and the Parties shall continue to perform all of their respective obligations hereunder; and (d) if it is ultimately determined that the breaching Party committed such Material Breach, then the breaching Party shall have the right to cure such Material Breach, after such determination, within the Cure Period (as

may be extended in accordance with Section 13.2(a)), which shall commence as of the date of such determination.

13.3 Termination for Change of Control. Coherus shall notify Innovent in writing within [***] ([***]) days after entry by Coherus into a definitive agreement with [***] ("Competitor Agreement") as the acquirer of Coherus through a merger or a sale of all of substantially all of Coherus's assets. For a period of [***] ([***]) months thereafter, Coherus shall have the right to assign this Agreement to a Third Party as an Acquirer in accordance with Section 14.4. In the event Coherus, or [***], after the closing of the Competitor Agreement does not assign this Agreement to a Third Party, then Innovent may terminate this Agreement upon written notice.

13.4 Termination for Bankruptcy.

(a) If either Party makes a general assignment for the benefit of, or an arrangement or composition generally with, its creditors, appoints or suffers appointment of an examiner or of a receiver or trustee over all or substantially all of its property, passes a resolution for its winding up, or files a petition under any bankruptcy or insolvency act or law or has any such petition filed against it which is not dismissed, discharged, bonded, or stayed within ninety (90) days after the filing thereof and seeks to reject this Agreement, the other Party may treat this Agreement as terminated by such rejection, effective immediately upon written notice to such Party.

(b) For purposes of Section 365(n) of the U.S. Bankruptcy Code (the "Code") and any similar laws in any other country, all rights and licenses granted under or pursuant to any Section of this Agreement are rights to "intellectual property" (as defined in Section 101(35A) of the Code). The Parties agree that the licensee of such rights under this Agreement will retain and may fully exercise all of its protections, rights and elections under the Code and any similar laws in any other country. Each Party hereby acknowledges that (i) copies of research data, (ii) laboratory samples, (iii) product samples, (iv) formulas, (v) laboratory notes and notebooks, (vi) data and results related to Clinical Trials, (vii) regulatory filings and approvals, (viii) rights of reference in respect of regulatory filings and approvals, (ix) pre-clinical research data and results, and (x) marketing, advertising and promotional materials, in each case, that relate to such Intellectual Property Rights, constitute "embodiments" of such Intellectual Property Rights pursuant to Section 365(n) of the Code, and that the licensee will be entitled to a complete duplicate of (or complete access to, as appropriate) any such Intellectual Property Rights and all embodiments of such Intellectual Property Rights, and the same, if not already in its possession, will be promptly delivered to it upon its written request therefor and election under Bankruptcy Code Section 365(n)(1)(B) to retain the licenses granted by Innovent to Coherus hereunder in the event of Innovent's rejection of this Agreement, unless Innovent elects to continue to perform all of its obligations under this Agreement. The provisions of this Section 13.4(b) are without prejudice to any rights the non-subject Party may have arising under the Code, laws of other jurisdictions governing insolvency and bankruptcy, or other Applicable Law. The Parties agree that they intend the following rights to extend to the maximum extent permitted by law, including for purposes of the Code and any similar laws in any other country: (A) the right of access to any Intellectual Property Rights (including all embodiments thereof) of Innovent, or any Third Party with whom Innovent contracts to perform an obligation of Innovent under this Agreement which is necessary for the Development, Manufacture or Commercialization of a Licensed Product; (B) the right to contract directly with any Third Party described in (A) to complete the contracted work, and (C) the right to cure any breach

of or default under any such agreement with a Third Party and set off the costs thereof against amounts payable to such licensor under this Agreement.

13.5 Termination by Coherus for due to Market Conditions. On a Licensed Product-by-Licensed Product basis, if the competitive, pricing or reimbursement environment for a Licensed Product makes it, in Coherus' sole discretion, commercially unreasonable for Coherus to Commercialize a Licensed Product, then, following the one-year anniversary of the First Commercial Sale of such Licensed Product, Coherus may terminate this Agreement with respect to such Licensed Product upon eighteen (18) months' advance written notice to Innovent; provided, however, that [***].

13.6 Termination by Coherus for Launch Delay. On a Licensed Product-by-Licensed Product basis, Coherus may terminate this Agreement upon written notice to Innovent any time prior to the receipt of the Regulatory Approval for the Licensed Product in the Field in the United States in the event the Regulatory Approval in the Field in the United States cannot be reasonably obtained within [***] ([***]) months from the Effective Date or the Option Effective Date, as applicable.

13.7 Termination by Coherus for Regulatory Reasons.

(a) On a Licensed Product-by-Licensed Product basis, Coherus may terminate this Agreement immediately upon receipt of [***].

(b) On a Licensed Product-by-Licensed Product basis, Coherus may terminate this Agreement immediately upon receipt of [***].

13.8 Effects of Expiration or Termination. Upon the termination or expiration of this Agreement with respect to any Licensed Product, the following provisions shall apply in relation to the terminated or expired Licensed Product:

(a) General. The licenses granted by Innovent to Coherus pursuant to Article 2 with respect to the terminated or expired Licensed Product shall terminate and Coherus shall not have any rights to use or exercise any rights under the Innovent IP with respect to such terminated or expired Licensed Product. In addition, with respect to such terminated or expired Licensed Product, the following provisions in the remainder of this Section 13.8 shall apply.

(b) Transfer of Regulatory Materials and Regulatory Approvals. Upon the expiration of this Agreement or the effective date of termination, Coherus shall and hereby does, and shall cause its Affiliates and sublicensees to assign to Innovent or, at the direction of Innovent, its Affiliate or designee (such Affiliate or designee, the "Innovent Transferee"), all rights, title and interests in and to all Regulatory Materials and Regulatory Approvals related to the terminated or expired Licensed Product in the Field in the Territory. Coherus shall use commercially reasonable efforts to [***] take [***] actions necessary to effectuate the [***] assignment of such Regulatory Materials and Regulatory Approvals, including [***], that may be necessary, required or which Innovent or the Innovent Transferee may request.

(c) Continuation of Performance. Until expiration of this Agreement or the effective date of termination, as applicable, Coherus shall continue to perform its obligations under this Agreement, except with respect to activities that Innovent elects for Coherus to discontinue.

(d) Transition Assistance. Coherus shall reasonably cooperate with Innovent to assure a smooth transition of any Clinical Trials, Development, Manufacturing, or

Commercialization activities related to the terminated or expired Licensed Product ("Transition Assistance").

(e) Return or Destruction of Confidential Information. Upon the expiration of this Agreement or the effective date of termination, each Party shall return or destroy, at the other Party's reasonable discretion, the other Party's Confidential Information in accordance with Section 10.1.

(f) Inventory.

(i) In the event of termination of this Agreement by Coherus in accordance with Section 13.5, Section 13.6, or Section 13.7 or by Innovent in accordance with Section 13.2, Section 13.3, or Section 13.4, Innovent may purchase the terminated or expired Licensed Product [***] plus [***] percent ([***]%) all of the inventory of the terminated or expired Licensed Product held by or on behalf of Coherus on the effective date of termination or expiration (including raw materials, intermediates, and finished, unfinished, or partially finished goods) in the applicable country in the Territory. Innovent shall notify Coherus within [***] ([***]) days after the effective date of termination or expiration whether Innovent wishes to purchase such inventory in accordance with this Section 13.8(f). In the event Innovent does not purchase such inventory, then Coherus shall be permitted to sell such inventory, provided that such sales occur within [***] ([***]) months after the effective date of termination or expiration and, provided further that Coherus shall remain obligated to pay royalties and report to Innovent with respect to Net Sales of such inventory in accordance with Article 8.

(ii) In the event of expiration of this Agreement or termination of this Agreement by Coherus in accordance with Section 13.2 or Section 13.4, Coherus shall be permitted to sell all of the inventory of the terminated or expired Licensed Product held by or on behalf of Coherus on the effective date of termination or expiration (including raw materials, intermediates, and finished, unfinished, or partially finished goods), provided that such sales occur within [***] ([***]) months after the effective date of termination or expiration and, provided further that Coherus shall remain obligated to pay royalties and report to Innovent with respect to Net Sales of such inventory in accordance with Article 8.

(g) Costs and Expenses.

(i) [***] shall pay for the costs and expenses related to the transfer of all Regulatory Materials in accordance with Section 13.8(b) and Transition Assistance, in each case, in the event of termination of this Agreement by Coherus in accordance with Section 13.5, Section 13.6, or Section 13.7 or by Innovent in accordance with Section 13.2, Section 13.3, or Section 13.4.

(ii) [***] shall pay for the costs and expenses related to the transfer of all Regulatory Materials in accordance with Section 13.8(b) and Transition Assistance, in each case, in the event of expiration of this Agreement or termination of this Agreement by Coherus in accordance with Section 13.2 or Section 13.4.

(h) Sublicense. In the case of termination of this Agreement in its entirety, (i) any and all sublicense agreements entered into by Coherus or any of its Affiliates with a sublicensee pursuant to this Agreement shall be deemed a direct license between such sublicensee and

Innovent on the same terms as the corresponding sublicense; and (ii) Coherus shall, upon the written request of Innovent, assign the corresponding sublicense to Innovent or its Affiliates and, upon such assignment, Innovent or its Affiliates, as applicable, shall assume such sublicense; provided that: (A) such sublicensee is not in breach of any material term of this Agreement; and (B) such sublicensee is in compliance with all terms and conditions of the corresponding sublicense.

Surviving Provisions

.

(a) Accrued Rights; Remedies. The expiration or termination of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of any Party prior to such expiration or termination, and any and all damages or remedies (whether at law or in equity) arising from any breach hereunder, each of which shall survive expiration or termination of this Agreement. Such expiration or termination shall not relieve any Party from obligations which are expressly indicated to survive expiration or termination of this Agreement. Except as otherwise expressly set forth in this Agreement, the termination provisions of this Article are in addition to any other relief and remedies available to either Party under this Agreement, at law, or in equity.

(b) Survival. Without limiting the provisions of Section 13.9(a), the rights and obligations of the Parties set forth in the following Sections and Articles of this Agreement shall survive the expiration or termination of this Agreement (to the extent in effect as of the Effective Date), in addition to those other terms and conditions that are expressly stated to survive termination or expiration of this Agreement: Article 1, Section 2.4, Section 2.7, Section 8.5, Section 8.6, Section 9.1, Section 9.2(a)(i) (solely the first sentence), Section 9.2(b) (solely with respect to any Joint Patents that have been filed prior to the date of termination or expiration of this Agreement), Section 9.3(c) (solely the first sentence), Section 9.2(d), Article 10 (other than Section 10.7, which shall not survive), Article 12, Section 13.8, this Section 13.9 and Article 14 shall survive the termination or expiration of this Agreement.

14. MISCELLANEOUS

Severability

. If one (1) or more of the terms or provisions of this Agreement is held by a court of competent jurisdiction to be void, invalid, or unenforceable in any situation in any jurisdiction, such holding shall not affect the validity or enforceability of the remaining terms and provisions hereof or the validity or enforceability of the void, invalid, or unenforceable term or provision in any other situation or in any other jurisdiction, and the term or provision shall be considered severed from this Agreement solely for such situation and solely in such jurisdiction, unless the void, invalid, or unenforceable term or provision is of such essential importance to this Agreement that it is to be reasonably assumed that the Parties would not have entered into this Agreement without the void, invalid, or unenforceable term or provision. If the final judgment of such court declares that any term or provision hereof is void, invalid, or unenforceable, the Parties agree to: (a) reduce the scope, duration, area, or applicability of the term or provision or to delete specific words or phrases to the minimum extent necessary to cause such term or provision as so reduced or amended to be enforceable; and (b) make a good-faith effort to replace any void, invalid, or unenforceable term or provision with a valid and enforceable term or provision such that the objectives contemplated by the Parties when entering this Agreement may be realized.

Notices

. Any notice required or permitted to be given by this Agreement shall be in writing and in English and shall be: (a) delivered by hand or by overnight courier with tracking capabilities; or (b) mailed postage prepaid by first class, registered, or certified mail, in each case, addressed as set forth below unless changed by notice so given:

If to Coherus:

Coherus BioSciences, Inc.
333 Twin Dolphin Drive, Suite 600
Redwood City, CA, 94065, USA
Attention: [***]

With copies to (which shall not constitute notice):

Latham & Watkins LLP
140 Scott Drive
Menlo Park, CA 94025, USA
Attn: [***]

If to Innovent:

Innovent Biologics (Suzhou) Co., Ltd.

168 Dongping Street
Suzhou Industrial Park
Suzhou 215123, China
Attn: [***]

With copies to (which shall not constitute notice):

Ropes & Gray LLP
36/F Park Place
1601 Nanjing Road West
Shanghai 200040, China
Attn: [***]

Force Majeure

. A Party shall not be liable for delay or failure in the performance of any of its obligations hereunder if such delay or failure is due to a cause beyond the reasonable control of such Party, including acts of God, fires, earthquakes, acts of war, terrorism, or civil unrest, or hurricane or other inclement weather; provided, that the affected Party: (a) promptly notifies the other Party; and (b) shall use its commercially reasonable efforts to avoid or remove such causes of non-performance and to mitigate the effect of such occurrence, and shall continue performance in accordance with the terms of this Agreement whenever such causes are removed. When such circumstances arise, the Parties shall negotiate in good faith any modifications of the terms of this Agreement that may be necessary or appropriate in order to arrive at an equitable solution.

Assignment

. Except as otherwise expressly provided in this Agreement, neither Party may assign any of its rights or delegate any of its obligations under this Agreement without the prior written consent of the other Party, such consent not to be unreasonably withheld. Subject to the other provisions of this Section 14.4, either Party may assign this Agreement, in its entirety, to (a) an Affiliate for so long as the Affiliate remains an Affiliate of such Party; (b) an acquirer ("Acquirer") in a change of control or in connection with the sale of all or substantially all of either Party's assets; or (c) an Acquirer in connection with the sale of all or substantially all of either Party's assets to which this Agreement relates by first providing to the other Party a reasonable explanation of the capabilities and financial wherewithal of the prospective Acquirer and obtaining the prior written

consent of the other Party, such consent not to be unreasonably withheld, delayed, or conditioned based on the consideration of the Licensed Products in the Field in the Territory; provided that in the event of any such transaction described in sub-section (a), (b) or (c) above, the Acquirer to which this Agreement is assigned expressly agrees in writing to assume and be bound by the obligations of the assigning Party under this Agreement. A copy of such writing shall be provided to the non-assigning Party within thirty (30) days of the assignment. Subject to the foregoing and other applicable provisions of this Section 14.4, this Agreement will inure to the benefit of and bind the Parties' successors and assigns. Any attempted assignment not in accordance with this Section 14.4 shall be void. In the event that a permitted assignment of this Agreement by a Party increases the tax liability of the other Party or any of its Affiliates over the amount of any Taxes that otherwise would have been payable in the absence of such assignment, the assigning Party shall reimburse the other Party for the amount of such increased Tax liability.

Waivers and Modifications

. The failure of any Party to insist on the performance of any obligation hereunder shall not be deemed to be a waiver of such obligation. Waiver of any breach of any provision hereof shall not be deemed to be a waiver of any other breach of such provision or any other provision on such occasion or any succeeding occasion. No waiver, modification, release, or amendment of any obligation under or provision of this Agreement shall be valid or effective unless in writing and signed by the Parties.

Choice of Law; Waiver of Jury Trial; Dispute Resolution; Jurisdiction

.

(a) Choice of Law. This Agreement and any dispute arising from the performance or breach hereof shall be governed by and interpreted in accordance with the laws of the [***], without giving effect to any choice of law rules. The provisions of the United Nations Convention on Contracts for the International Sale of Goods shall not apply to this Agreement or any subject matter hereof.

(b) Dispute Resolution.

(i) Except as otherwise set forth in this Agreement, in the event of an unresolved matter, dispute, or issue relating to the breach or alleged breach or interpretation of this Agreement ("Dispute"), the Parties shall refer the Dispute to the Senior Executives for discussion and resolution. If the Senior Executives are unable to resolve such Dispute within [***] ([***]) days of the Dispute being referred to them by either Party in writing, then the Dispute shall be resolved as provided in Section 14.6(b)(ii) or Section 14.6(b)(iii), as applicable.

(ii) Any unresolved Disputes between the Parties arising out of or in connection with this Agreement shall be resolved by final and binding arbitration. Whenever a Party decides to institute arbitration proceedings, it shall give written notice to that effect to the other Party. Arbitration shall be held in [***], according to the Rules of Arbitration of the [***] ("[***]") in effect at the Effective Date, except as they may be modified herein or by mutual agreement of the Parties. All arbitration proceedings shall be conducted by three (3) arbitrators unless otherwise mutually agreed by the Parties. The claimant and the respondent shall each nominate an arbitrator in accordance with the [***], and the third arbitrator, who shall be the president of the arbitral tribunal, shall be appointed by the two Party-appointed arbitrators in consultation with the Parties. The Parties undertake to maintain confidentiality as to the existence of the arbitration proceedings and as to all submissions, correspondence, and evidence relating to the arbitration proceedings. This Section 14.6(b)(ii) shall survive the termination of the arbitral proceedings.

No arbitrator (nor any arbitral tribunal) shall have the power to award punitive damages under this Agreement, and such award is expressly prohibited. Decisions of the arbitrator(s) shall be final and binding on the Parties. Judgment on the award so rendered may be entered in any court of competent jurisdiction. The costs of the arbitration shall be shared by the Parties during the course of such arbitration, as assessed by the International Chamber of Commerce, and shall be borne as determined by the arbitrator(s).

(iii) Notwithstanding anything to the contrary, either Party may at any time seek to obtain preliminary injunctive relief or other applicable provisional relief from a court of competent jurisdiction with respect to an issue arising under this Agreement if the rights of such Party would be prejudiced absent such relief. A request by a Party to a court of competent jurisdiction for interim measures necessary to preserve the Party's rights, including attachments or injunctions, shall not be deemed incompatible with, or a waiver of, the agreement to mediate or arbitrate contained in this Section 14.6(b)(iii), or the availability of interim measures of protection under the [***]. Notwithstanding anything to the contrary in this Section 14.6(b)(iii), any disputes regarding the scope, validity, enforceability, or inventorship of any Patents shall be submitted for final resolution by a court of competent jurisdiction.

Relationship of the Parties

. Innovent and Coherus are independent contractors under this Agreement. Nothing contained herein is intended or is to be construed so as to constitute either Party as a partner, agent, or joint venturer of the other Party. Neither Innovent nor Coherus, respectively, shall have any express or implied right or authority to assume or create any obligations on behalf of or in the name of Innovent and Coherus, respectively, or to bind Innovent and Coherus, respectively, to any contract, agreement, or undertaking with any Third Party.

Fees and Expenses

. Except as otherwise specified in this Agreement, each Party shall bear its own costs and expenses (including investment banking and legal fees and expenses) incurred in connection with this Agreement and the transactions contemplated hereby.

Third Party Beneficiaries

. There are no express or implied Third Party beneficiaries hereunder. The provisions of this Agreement are for the exclusive benefit of the Parties, and no other person or entity shall have any right or claim against any Party by reason of these provisions or be entitled to enforce any of these provisions against any Party, except for the indemnification rights of the Innovent Indemnitees pursuant to Section 12.1 and Section 12.3 and the Coherus Indemnitees pursuant to Section 12.2 and Section 12.3.

Entire Agreement

. This Agreement, together with the attached Exhibits and Schedules, contains the entire agreement by the Parties with respect to the subject matter hereof and supersedes any prior express or implied agreements, understandings, and representations, either oral or written, which may have related to the subject matter hereof in any way, including the Prior CDA and any and all term sheets relating to the transactions contemplated by this Agreement and exchanged between the Parties prior to the Effective Date; provided, that this Agreement shall not supersede the terms and provisions of the Prior CDA applicable to any period prior to the Effective Date.

Counterparts

. This Agreement may be executed in counterparts with the same effect as if both Parties had signed the same document. All such counterparts shall be deemed an original, shall be construed together, and shall constitute one (1) and the same instrument. Any such counterpart, to the extent delivered by means of facsimile by .pdf, .tif, .gif, .jpeg, or similar attachment to electronic mail (any such delivery, an "Electronic Delivery") shall be treated in all manner and respects as an

original executed counterpart and shall be considered to have the same binding legal effect as if it were the original signed version thereof delivered in person. No Party hereto shall raise the use of Electronic Delivery to deliver a signature or the fact that any signature or agreement or instrument was transmitted or communicated through the use of Electronic Delivery as a defense to the formation of a contract, and each Party forever waives any such defense, except to the extent that such defense relates to lack of authenticity.

Equitable Relief; Cumulative Remedies

. Notwithstanding anything to the contrary herein, the Parties shall be entitled to seek equitable relief, including injunction and specific performance, as a remedy for any breach of this Agreement. Such remedies shall not be deemed to be the exclusive remedies for a breach of this Agreement but shall be in addition to all other remedies available at law or in equity. The Parties further agree not to raise as a defense or objection to the request or granting of such relief that any breach of this Agreement is or would be compensable by an award of money damages. No remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under Applicable Law.

Interpretation

.

(a) Generally. This Agreement has been diligently reviewed by and negotiated by and between the Parties, and in such negotiations each of the Parties has been represented by competent (in-house or external) counsel, and the final agreement contained herein, including the language whereby it has been expressed, represents the joint efforts of the Parties and their counsel. Accordingly, in interpreting this Agreement or any provision hereof, no presumption shall apply against any Party as being responsible for the wording or drafting of this Agreement or any such provision, and ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision.

(b) Definitions; Interpretation.

(i) The definitions of the terms herein shall apply equally to the singular and plural forms of the terms defined and, where a word or phrase is defined herein, each of its other grammatical forms shall have a corresponding meaning.

(ii) Whenever the context may require, any pronoun shall include the corresponding masculine, feminine, and neuter forms.

(iii) The word “will” shall be construed to have the same meaning and effect as the word “shall.”

(iv) The words “including,” “includes,” “include,” “for example,” and “e.g.,” and words of similar import, shall be deemed to be followed by the words “without limitation.”

(v) The word “or” shall be interpreted to mean “and/or,” unless the context requires otherwise.

(vi) The words “hereof,” “herein,” and “herewith,” and words of similar import, shall, unless otherwise stated, be construed to refer to this Agreement as a whole and not to any particular provision of this Agreement.

(vii) Unless the context requires otherwise or otherwise specifically provided: (i) all references herein to Articles, Sections, or Schedules shall be construed to refer to Articles, Sections, and Schedules of this Agreement; and (ii) reference in any Section to any subclauses are references to such subclauses of such Section.

(c) Subsequent Events. Unless the context requires otherwise: (i) any definition of or reference to any agreement, instrument, or other document herein shall be construed as referring to such agreement, instrument, or other document as from time to time amended, supplemented, or otherwise modified (subject to any restrictions on such amendments, supplements, or modifications set forth herein); (ii) any reference to any Applicable Law herein shall be construed as referring to such Applicable Law as from time to time enacted, repealed, or amended; and (iii) subject to Section 14.4, any reference herein to any Person shall be construed to include the Person's successors and assigns.

(d) Headings. Headings, captions, and the table of contents are for convenience only and shall not be used in the interpretation or construction of this Agreement.

(e) Prior Drafts. No prior draft of this Agreement shall be used in the interpretation or construction of this Agreement.

Further Assurances

. Each Party shall execute, acknowledge, and deliver such further instruments, and do all such other ministerial, administrative, or similar acts, as may be reasonably necessary or appropriate in order to carry out the expressly stated purposes and the clear intent of this Agreement.

Extension to Affiliates

. Except as expressly set forth otherwise in this Agreement, each Party shall have the right to extend the rights and obligations granted in this Agreement to one or more of its Affiliates. All applicable terms and provisions of this Agreement, except this right to extend, shall apply to any such Affiliate to which this Agreement has been extended to the same extent as such terms and provisions apply to the Party extending such rights and obligations. The Party extending the rights and obligations granted hereunder shall remain primarily liable for any acts or omissions of any of its Affiliates.

[*Signature Page Follows*]

IN WITNESS WHEREOF, and intending to be legally bound hereby, the Parties have caused this License Agreement to be executed by their respective duly authorized officers as of the Effective Date.

COHERUS BIOSCIENCES, INC.	**INNOVENT BIOLOGICS (SUZHOU) CO., LTD.**
By: /s/ Denny M. Lanfear	By: /s/ Michael Yu
Name: Denny M. Lanfear	Name: Michael Yu
Title: Chairman &Chief Executive	Title: CEO

EXHIBIT A

Knowledge of a Party

Omitted pursuant to Regulation S-K, Item 601(a)(5)

Exhibit 23.1

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, 333-222700, 333-229480, and 333-236068) 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, 333-225616, 333-228274, 333-229479, 333-231329, 333-234601, and 333-236065) pertaining to the 2016 Employment Commencement Incentive Plan; of Coherus BioSciences, Inc. of our reports dated February 27, 2020, 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, 2019.

/s/ Ernst & Young LLP

Redwood City, California
February 27, 2020

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO
SECTION 13(a) OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Dennis M. Lanfear, certify that:

1. I have reviewed this Annual Report on Form 10-K of Coherus BioSciences, Inc. (the "registrant");

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 27, 2020

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

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO
SECTION 13(a) OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jean-Frédéric Viret, certify that:

1. I have reviewed this Annual Report on Form 10-K of Coherus BioSciences, Inc. (the "registrant");

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 27, 2020

/s/ Jean-Frédéric Viret
Jean-Frédéric Viret, Ph.D.
Chief Financial Officer

Exhibit 32.1

CERTIFICATIONS OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officers of Coherus BioSciences, Inc. (the "Registrant") certify that the Registrant's Annual Report on Form 10-K for the year ended December 31, 2019 (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 27, 2020

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

Date: February 27, 2020

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.