Table of Contents

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, 2020

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 the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

Indicate by check mark whether the 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, 2020 (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 $0.9 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 the registrant's common stock issued and outstanding as of January 31, 2021 was 72,793,660.

DOCUMENTS INCORPORATED BY REFERENCE

Part III incorporates by reference certain information from the registrant's definitive proxy statement for the 2021 Annual Meeting of Stockholders.

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

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 biopharmaceutical company with a mission to increase patient access to cost-effective medicines that can have a major impact on their lives and to deliver significant savings to the health care system. Our first product, UDENYCA® (pegfilgrastim-cbqv), a biosimilar to Neulasta®, a long-acting granulocyte-colony stimulating factor, was launched commercially in the United States in January 2019. Biosimilars are a class of protein-based therapeutics with high similarity to approved originator products on the basis of various structural and biologic properties, as well as in terms of safety and efficacy. We have become a leader in the biosimilar market by leveraging our team's collective expertise in key areas such as process science, analytical characterization, protein production, clinical-regulatory development and commercialization. In addition to UDENYCA®, we have a product candidate pipeline that includes biosimilars of Humira®, Avastin® and Lucentis®.

We are investing cash flows generated by our commercial biosimilars business to build a leading immuno-oncology franchise in the United States and Canada. In February 2021, we in-licensed Junshi Biosciences' toripalimab, a novel anti-PD-1 antibody, which was first approved in 2018 for second-line treatment of melanoma in China, where it is marketed by Shanghai Junshi Biosciences, Co., Ltd. ("Junshi Biosciences"). Toripalimab has been extensively evaluated in late-stage clinical trials for the treatment of multiple tumor types. We and Junshi Biosciences expect to submit the first biologic license application ("BLA") to the United States Food and Drug Administration ("FDA") in 2021 for the treatment of third-line nasopharyngeal carcinoma, an indication for which the FDA has granted toripalimab Breakthrough Therapy designation. Within the next several years, we and Junshi Biosciences anticipate submitting BLAs for multiple additional indications for rare and highly prevalent tumor types, including non-small cell lung cancer. We have also acquired options to license two pipeline immuno-oncology product candidates from Junshi Biosciences, an anti-TIGIT antibody and a next-generation engineered IL-2 cytokine, which we plan to evaluate in combination with toripalimab.

With our UDENCYA commercialization efforts, we have built a strong, oncology-focused commercial capability in the United States. We expect to leverage this commercial capability as we build our immuno-oncology franchise if we are successful with the development and registration of toripalimab and potential combination product candidates.

Our pipeline includes the following product candidates:

Oncology Pipeline

- Toripalimab, an anti-PD-1 antibody being developed in collaboration with Junshi Biosciences, a leading Chinese biotechnology company. So far, more than thirty company-sponsored clinical studies covering more than fifteen indications have been conducted globally, including in China and the United States, on toripalimab. On December 17, 2018, toripalimab obtained a conditional approval from the National Medical Products Administration of China ("NMPA") for the second-line treatment of patients with unresectable or metastatic melanoma, making it the first Chinese domestic anti-PD-1 monoclonal antibody to obtain marketing approval in China. Supplemental new drug applications ("NDAs") of toripalimab for the third-line treatment of recurrent/metastatic nasopharyngeal carcinoma and second-line treatment of metastatic urothelial carcinoma were accepted by the NMPA in April and May 2020, respectively. Both supplemental NDAs received priority review designations from the NMPA in July 2020. In December 2020, toripalimab was included in the National Reimbursement Drug List ("NRDL") for the treatment of melanoma by the China National Healthcare Security Administration ("NHSA").

  In the United States, toripalimab was granted the Breakthrough Therapy designation for the treatment of recurrent/metastatic nasopharyngeal carcinoma by the FDA in September 2020. The FDA has also granted toripalimab Fast Track designation for the treatment of mucosal melanoma and orphan drug designations for treatment of nasopharyngeal carcinoma, mucosal melanoma and soft tissue sarcoma.

  We expect the first toripalimab Biologics License Application ("BLA") to be submitted to the FDA for recurrent/metastatic nasopharyngeal carcinoma in 2021. In addition to nasopharyngeal carcinoma, we and Junshi Biosciences plan to submit BLAs

to the FDA for toripalimab within the next two years for the treatment of several rare and highly prevalent cancers, including non-small cell lung cancer.

- UDENYCA® (pegfilgrastim-cbqv). We are continuing to develop additional presentations of UDENYCA®.

- 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. 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, which is the 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 in the United States and Canada.

  We are performing a three-way pharmacokinetic ("PK") study using Avastin drug products from the United States, Avastin drug products from 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, to the FDA.

Immunology Pipeline

- CHS-1420 (our adalimumab (Humira) biosimilar candidate). We are developing CHS-1420, an anti-TNF product candidate, as an adalimumab (Humira) biosimilar. In August 2016, we announced positive data from our Phase 3 study in psoriasis patients, followed by confirmatory 24-week results in January 2017. In the fourth quarter of 2020, we submitted the 351(k) BLA, which was accepted for review by the FDA in February 2021. The user fee goal date is in December 2021. 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.

Ophthalmology Pipeline

- Ranibizumab (Lucentis) Biosimilar. On November 4, 2019, we 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. Under this agreement, Bioeq granted to us an exclusive royalty-bearing license to commercialize Bioeq's biosimilar to ranibizumab 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 requested additional manufacturing data for the equipment in its new location in the context of its review of the 351(k) BLA. As a result, Bioeq decided to withdraw its 351(k) BLA for this candidate and provide the requested data. During the first quarter of 2021, Bioeq received positive pre-BLA filing feedback from the FDA on the requested manufacturing data, and the FDA indicated support of Bioeq's current plans to proceed with the resubmission of its 351(k) BLA during 2021.

Small Molecule Pipeline

- CHS-131 (our oral, small-molecule drug candidate). CHS-131 is a novel, potential first-in-class, once-daily oral drug candidate for non-alcoholic steatohepatitis ("NASH") and other metabolic conditions. In February 2020, we announced that we are seeking strategic alternatives to finance this program externally.

Market Opportunity for Biosimilars

According to Evaluate Pharma, total U.S. annual revenues of Neulasta, Avastin, Lucentis and Humira, which are the reference drugs of our commercialized or late stage biosimilar candidates of pegfilgrastim, bevacizumab, ranibizumab, and adalimumab, respectively, and other commercial biosimilar drugs for those compounds are expected to reach approximately $22.0 billion in 2020. 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

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 2020 U.S. sales for all pegfilgrastim products represent an estimated $2.6 billion.

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 2020 U.S. sales for Avastin were $1.9 billion. In January 2020, we acquired the right to commercialize Innovent's Avastin biosimilar candidate in the United States and Canada.

Toripalimab Opportunity

In February 2021, we acquired exclusive rights in the United States and Canada for the co-development and commercialization of Junshi Biosciences' toripalimab. Toripalimab is a humanized IgG4 anti-PD-1 monoclonal antibody selected for its potential to block PD-1 interactions with its ligands, PD-(L)1 and PD-(L)2, and for its potential to provide enhanced receptor endocytosis function. PD-(L)1 and PD-(L)2 are tumor checkpoint proteins that recognize the PD-1 receptor on T cells and exhaust their anti-tumor activity. Blocking PD-1 interactions with PD-(L)1 and PD-(L)2 allows T cells to attack and kill tumor cells that display PD-(L)1 or PD-(L)2.

According to Evaluate Pharma, total anti-PD-1 antibody U.S. annual revenues in 2020 were approximately $15.0 billion and are projected to grow to approximately $30.0 billion by 2026. Non-small cell lung cancer accounted for approximately 50% of all anti-PD-1 antibody U.S. revenues in 2020 and is expected to remain the largest tumor segment in the foreseeable future.

Ophthalmology Franchise Opportunity

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. Lucentis is approved in the United States for indications including wet AMD, macular edema following retinal vein occlusion, and diabetic retinopathy.

According to Evaluate Pharma, Lucentis achieved approximately $1.5 billion in U.S. sales in 2020. In November 2019, we in-licensed U.S. commercial rights to Bioeq's ranibizumab (Lucentis) biosimilar.

Immunology Franchise Opportunity

Our biosimilar candidate, CHS-1420 (adalimumab (Humira) biosimilar) binds 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 2020 U.S. sales of Humira reached approximately $16.0 billion in 2020. 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 substantial topline sales for CHS-1420 in the United States, if approved.

Deprioritized pipeline programs

In February 2020, we announced that we would seek strategic alternatives for CHS-131, a PPARγ small molecule being evaluated for the treatment of NASH.

In February 2021, we announced discontinuation of the development of CHS-2020, a biosimilar of Eylea® as part of a realignment of research and development resources toward the development of immuno-oncology assets including toripalimab.

Sales and Marketing

Our strategy is to invest cash flows from our commercial biosimilars business to build a leading immuno-oncology franchise in the United States and Canada.

The sales call points to oncologists in the United States are highly concentrated and addressable by our relatively small commercial organization. If we are successful in gaining approval of our bevacizumab biosimilar or of toripalimab and other immuno-oncology assets, we will plan to commercialize these products alongside UDENYCA through our oncology sales and marketing team. Similarly, for our ophthalmology franchise, 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 in the United States from Amgen (“Amgen”), Viatris Inc. (“Viatris”), Mylan N.V. (“Mylan”), Sandoz International GmbH (“Sandoz”), Pfizer Inc., and may face competition from Amneal and Fresenius, each of which has announced the development of a pegfilgrastim biosimilar.

Toripalimab, if approved, will enter a competitive market in the United States where a number of anti-PD-1 or PD-(L)1 antibody drugs have been approved by the FDA including the following marketed products from several competitors: Keytruda® (pembrolizumab) from Merck & Company, Inc. (“Merck”), Opdivo® (nivolumab) from Bristol-Myers Squibb Company (“BMS”), Tecentriq® (atezolizumab) from Genentech USA, Inc. (“Genentech”), Imfinzi® (durvalumab) from AstraZeneca, Bavencio® (avelumab) from EMD Serono and Pfizer, and Libtayo® (cemiplimab-rwlc) from Regeneron Pharmaceuticals, Inc. (“Regeneron”) and Sanofi. In addition to toripalimab, multiple other competitors are seeking to develop and approve novel anti-PD-1 or PD-(L)1 antibody drugs in the United States in the coming years, including but not limited to BeiGene, Ltd. (in collaboration with Novartis), GlaxoSmithKline PLC and Innovent.

Innovent’s bevacizumab (Avastin) may face competition in the United States from Genentech, Inc. (“Genentech,” the holder of rights to Avastin), as well as Amgen (Mvasi™ (bevacizumab-awwb)) and Pfizer (Zirabev™ (bevacizumab-bvzr)), each of which have initiated the commercial launch of an Avastin biosimilar. We may also face competition from several other companies with Avastin biosimilar candidates in development or in registration, including Samsung Bioepis Co., Ltd. (Samsung Bioepis”) and Viatris.

Bioeq’s ranibizumab (Lucentis) biosimilar candidate may face competition in the United States from Genentech (the manufacturer of Lucentis). Biogen Inc. (“Biogen”) with collaborator Samsung Bioepis Co., Ltd. (Samsung Bioepis), and Xbrane Biopharma AB (in collaboration with STADA Arzneimittel AG and Bausch + Lomb) have each disclosed the development of a Lucentis 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 (Hadlima™ (adalimumab-bwwb)), Pfizer (Abrilada™ (adalimumab-afzd)), Boehringer Ingelheim GmbH ("Boehringer Ingelheim") (Cyltezo™ (adalimumab-adbm)) as well as Fujifilm, Alvotech and Fresenius, companies that have each disclosed development plans for a Humira biosimilar candidate.

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 and CHS-0214 (our etanercept (Enbrel®) biosimilar candidate, which we discontinued development) 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 twenty 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 60 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. In February 2020, the FDA requested additional manufacturing data for the equipment in its new location in the context of its review of the 351(k) BLA, and Bioeq withdrew its BLA. During the first quarter of 2021, Bioeq received positive pre-BLA filing feedback from the FDA on the requested manufacturing data, and the FDA indicated it was supportive of Bioeq's current plans to proceed with the resubmission of its 351(k) BLA during 2021.

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

On January 13, 2020, we entered into a 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 (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 and a milestone payment of $2.5 million. Additionally, we are obligated to pay Innovent an aggregate of up to $37.5 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.

License Agreement with Junshi Biosciences

On February 1, 2021, we entered into an Exclusive License and Commercialization Agreement (the "Collaboration Agreement") with Junshi Biosciences for the co-development and commercialization of toripalimab, Junshi Biosciences' anti-PD-1 antibody in the United States and Canada (the "Collaboration").

Under the terms of the Collaboration Agreement, we will pay $150.0 million upfront for exclusive rights to toripalimab in the United States and Canada, options in these territories to Junshi Biosciences' anti-TIGIT antibody and next-generation engineered IL-2 cytokine, and certain negotiation rights to two undisclosed preclinical immuno-oncology drug candidates. We will have the right to conduct all commercial activities of toripalimab in the United States and Canada. We will be obligated to pay Junshi Biosciences a 20% royalty on net sales of toripalimab and up to an aggregate $380.0 million in one-time payments for the achievement of various milestones, including up to $290.0 million for attainment of certain sales thresholds. If we exercise our options, we will be obligated to pay an option exercise fee for each of the anti-TIGIT antibody and the IL-2 cytokine of $35.0 million per program. Additionally, for each exercised option, we will

be obligated to pay Junshi Biosciences an 18% royalty on net sales and up to an aggregate $255.0 million for the achievement of various milestones, including up to $170.0 million for attainment of certain sales thresholds. Under the Collaboration Agreement, we retain the right to collaborate in the development of toripalimab and the other licensed compounds, and will pay for a portion of these co-development activities up to a maximum of $25.0 million per licensed compound per year.

Closing of the Collaboration Agreement is subject to clearance under the Hart-Scott Rodino Antitrust Improvements Act (the “HSR Act”).

In connection with the Collaboration Agreement, we entered into a stock purchase agreement (the “Stock Purchase Agreement”) with Junshi Biosciences agreeing, subject to customary conditions, to acquire certain equity interests in the Company. Pursuant to the Stock Purchase Agreement, we have agreed to issue 2,491,988 unregistered shares of our common stock, at a price per share of $20.0643, for an aggregate value of approximately $50.0 million, to Junshi Biosciences as a portion of the consideration for the Collaboration.

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. 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 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 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 (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by such physicians and their immediate family members. Beginning in 2022, these reporting obligations will extend to include payments and transfers of value made during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and anesthesiologist assistants, and certified nurse midwives. 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. Further, the California Privacy Rights Act ("CPRA") recently passed in California. The CPRA will impose additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. The CCPA and the CPRA 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. The U.S. Supreme Court is currently reviewing the case, although it is unclear how the Supreme Court will rule. It is also unclear how other efforts, if any, 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, which was temporarily suspended from May 1, 2020 through March 31, 2021, 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 and Human Capital Resources

As of December 31, 2020, we had 317 employees. We believe we have good relations with our employees. Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. The principal purposes of our equity incentive plans are to attract, retain and motivate selected employees, consultants and directors through the granting of equity awards and cash-based performance bonus awards.

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.”

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 Factor Summary

Below is a summary of the principal factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading “Risk Factors” and should be carefully considered, together with other information in this Annual

Report on Form 10-K, including our financial statements and related notes thereto, before making investment decisions regarding our common stock.

- Our business, financial condition, results of operations and growth could be harmed by the effects of the COVID-19 pandemic.

- We have a limited operating history in an emerging regulatory environment on which to assess our business and we have a limited history of profitability.

- 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.

- UDENYCA® and our other product candidates, even if approved, will remain subject to regulatory scrutiny.

- 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 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.

- If an improved version of an originator product, such as Neulasta, Humira, 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.

- 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 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 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.

- 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.

- 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.

- 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.

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 COVID-19

Our business, financial condition, results of operations and growth could be harmed by the effects of the COVID-19 pandemic.

We are subject to risks related to public health crises such as the global pandemic associated with the novel coronavirus and the associated disease ("COVID-19"). In December 2019, a novel strain of coronavirus, SARS-CoV-2, was reported to have surfaced in Wuhan, China. Since then, SARS-CoV-2, and the resulting disease COVID-19, has spread to most countries, and all 50 states within the United States. As a result of the COVID-19 outbreak, we have experienced and may continue to experience disruptions that could severely impact our business, clinical trials and preclinical studies, including, but not limited to:

- decreased sales of UDENYCA®;
- our ability to maintain or expand the commercial use of UDENYCA® due to, among other factors, healthcare providers, payers and patients not utilizing or adopting UDENYCA® due to resources being strained or otherwise focused on the COVID-19 pandemic and our sales team efficacy in selling UDENYCA® being limited due to such strained resources or other factors such as travel restrictions;
- fewer individuals undertaking or completing cancer treatments, whether due to contracting COVID-19, self-isolating or quarantining to lower the risk of contracting COVID-19 or being unable to access care as a result of healthcare providers tending to COVID-19 patients;
- our third-party contract manufacturers and logistics providers not being able to maintain adequate (in amount and quality) supply to support the commercial sale of UDENYCA® or the clinical development of our product candidates due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- delays and difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff, as well as delays or difficulties in enrolling patients or maintaining enrolled patients in our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures (particularly any procedures that may be deemed non-essential), which may impact the integrity of subject data and clinical study endpoints;
- interruption or delays in the operations of the U.S. Food and Drug Administration and comparable foreign regulatory agencies, which may impact regulatory review and approval timelines; and
- limitations on our employee resources, and those of our business partners, that would otherwise be focused on the conduct of our business in all aspects, including because of sickness of employees or their families.

These and other factors arising from the COVID-19 pandemic could result in us not being able to maintain UDENYCA®'s market position or increase its penetration against all Neulasta's dosage forms, and could result in our inability to meet development milestones for our product candidates, each of which would harm our business, financial condition, results of operations and growth.

Numerous state and local jurisdictions have imposed, and others in the future may impose, "shelter-in-place" orders, quarantines, executive orders and similar government orders and restrictions for their residents to control the spread of COVID-19. Starting in mid-March 2020, the governor of California, where our headquarters and laboratory facilities are located, issued a "shelter-in-place" order restricting non-essential activities, travel and business operations for an indefinite period of time, subject to certain exceptions for necessary activities. Such orders or restrictions, have resulted in our headquarters closing, slowdowns and delays,

travel restrictions and cancellation of events, among other effects, thereby negatively impacting our operations. Such orders or restrictions may be extended or re-instated, thereby causing additional negative impact on our operations.

While the long-term economic impact and the duration of the COVID-19 pandemic may be difficult to assess or predict, the widespread pandemic has resulted in, and may continue to result in, significant disruption of global financial markets, which could reduce our ability to access capital and could negatively affect our liquidity and the liquidity and stability of markets for our common stock and the notes. In addition, a recession, further market correction or depression resulting from the spread of COVID-19 could materially affect our business and the value of our notes and our common stock.

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 a limited history of profitability.

We are a biopharmaceutical company with a limited operating history in an emerging regulatory environment. We incurred net losses in each year from our inception in September 2010 through December 31, 2018, including net losses of $209.4 million for the year ended December 31, 2018. However, while we did generate net income of $132.2 million and $89.8 million for the year ended December 31, 2020 and 2019, respectively, it is uncertain that we will remain profitable every quarter or every year going forward as research and development is expensive and risky. The amount of our future net losses or net income will depend, in part, on the amount of our future expenditures offset by the amount of future product sales. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk.

For example, as of December 31, 2020, we had an accumulated deficit of $762.8 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.

For example, we completed several clinical studies with our lead product, UDENYCA® (pegfilgrastim-cbqv), before the FDA approved UDENYCA® as a biosimilar to Neulasta on November 2, 2018. We have completed several clinical studies with CHS-1420 (our adalimumab (Humira) biosimilar candidate), which is still investigational. We also completed several clinical studies for CHS-0214 (our etanercept (Enbrel) biosimilar candidate), which we then subsequently discontinued.

We have not yet initiated clinical trials for toripalimab or any other future products which may be developed. 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 loss 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 $132.2 million and $89.8 million for the years ended December 31, 2020 and 2019, respectively, 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 income or net loss will depend, in part, on the level of sales of UDENYCA® in the United States 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 be 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, 2020, our cash and cash equivalents were $541.2 million. We expect that our existing cash and cash equivalents and cash collected from our UDENYCA® sales will be sufficient to fund our current operations for the foreseeable future. We have financed our operations primarily through the sale of equity securities, convertible notes, credit facilities, license agreements and 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 Neulasta, Neulasta Onpro® and new and existing commercial pegfilgrastim biosimilar products;
- 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.

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 United States and E.U., and we have no products approved in any other territories.

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:

- Toripalimab;
- Bioeq's ranibizumab (Lucentis) biosimilar candidate;
- Innovent's bevacizumab (Avastin) biosimilar candidate;
- CHS-1420 (our adalimumab (Humira) 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 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 unavailable, 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 United States, 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 United States, 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 United States and abroad to control healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for 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 United States and requirements of comparable foreign regulatory authorities.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA, and comparable foreign regulatory authority, requirements, including ensuring that quality control and manufacturing procedures conform to current Good Manufacturing Practices ("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.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, the results of the 2020 U.S. Presidential Election may impact our business and industry. Namely, the Trump administration took 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 whether or how these executive actions will be implemented, or whether they will be rescinded and replaced under the Biden administration. The policies and priorities of a new administration are unknown and could materially impact the regulations governing our product candidates.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, or approved or commercialized in a timely manner or at all, 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, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the FDA 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 biologics or modifications to approved biologics to be reviewed and/or approved by necessary 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.

Separately, in response to the COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most foreign inspections of manufacturing facilities and products through April 2020, and on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, on July 10, 2020, the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities 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," a subsidiary of Mundipharma), 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) and aflibercept (Eylea).

UDENYCA® faces competition in the United States from Amgen, Mylan (with partner Biocon Ltd.), Sandoz, Pfizer, and may face completion from 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 United States from Genentech (the manufacturer of Lucentis). Biogen Inc. ("Biogen") with collaborator Samsung Bioepis Co., Ltd. (Samsung Bioepis), and Xbrane Biopharma AB (in collaboration with STADA Arzneimittel AG and Bausch + Lomb) have each disclosed the development for a Lucentis biosimilar candidate.

Our bevacizumab (Avastin) biosimilar candidate licensed from Innovent may face competition in the United States from Genentech (the manufacturer of Avastin) as well as Amgen and Pfizer, each of which have initiated the commercial launch of an Avastin 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 United States and Fujifilm and Fresenius are companies that have each disclosed development plans for a Humira biosimilar candidate. As a result of number of potential adalimumab (Humira) biosimilar competitors, we may not be able to achieve substantial topline sales for CHS-1420 in the United States, if approved.

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) or adalimumab (Humira), 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 or Humira. If other biosimilars 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 United States 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, 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, 2020, we had 317 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® and CHS-1420, 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.

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, and potentially exacerbated by climate change.

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, including due to sudden or long-term changes in weather patterns, 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, 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.

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 United States Patent and Trademark Office (“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 and Regeneron, 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-licensed 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 United States and abroad that is relevant or necessary to the commercialization of our product candidates. Moreover, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents covering our product candidates. With respect to products we are evaluating for inclusion in our future biosimilar product pipeline, our freedom to operate analyses, including our research on the timing of potentially relevant patent expirations, are ongoing.

There may also be patent applications that have been filed but not published and if such applications issue as patents, they could be asserted against us. For example, in most cases, a patent filed today would not become known to industry participants for at least 18 months given patent rules applicable in most jurisdictions, which do not require publication of patent applications until 18 months after filing. 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 United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Also in proceedings before courts in Europe, the burden of proving invalidity of the patent usually rests on the party alleging invalidity. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on us. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

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

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, our 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 our motion 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 our 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, we 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, we filed our Reply Brief with the District Court. On November 30, 2020, the District Court issued an order denying the Company's motion.

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 United States 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.

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

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

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.

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 United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including but not limited to lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could include an allegation that someone involved in the prosecution of the patent withheld relevant or material information related to the patentability of the

invention from the USPTO or made a misleading statement during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable.

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

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

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

We employ individuals, retain independent contractors and consultants and members on our board of directors or scientific advisory board who were previously employed at universities or other pharmaceutical companies, including our competitors or potential competitors. For example, our Chief Executive Officer, Dennis M. Lanfear is a former employee of Amgen. Mr. Lanfear was employed at Amgen during periods when Amgen's operations included the development and commercialization of Neulasta and Enbrel. 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 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 certain vendors (pertaining to mammalian cell lines) 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 United States may be significantly delayed or prevented by the BPCIA patent dispute resolution mechanism.

The Biologics Price Competition and Innovation Act of 2009, Title VII, Subtitle A of the Patent Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119, Sections 7001-02 signed into law March 23, 2010, and codified in 42 U.S.C. §262, (the “BPCIA”), created an elaborate and complex patent dispute resolution mechanism for biosimilars that, if we choose to implement it, could prevent us from launching our product candidates in the United States or could substantially delay such launches. However, even if we elect not to implement this mechanism, the launch of our products in the United States 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.

Under the complex, and uncertain rules of the BPCIA patent provisions, coupled with the inherent uncertainty surrounding the legal interpretation of any originator patents that might be asserted against us in this new process, we see substantial risk that the BPCIA process may significantly delay or defeat our ability to market our products in the United States, 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 has completed Phase 3 clinical trials or other 351(k) BLA-enabling clinical development. Other than certain PK bridging studies, we have not yet initiated phase 3 clinical trials for toripalimab and any other product in our pipeline. 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 United States, 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 United States, 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 United States 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) biosimilar, 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 United States, the EEA or elsewhere;
- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical studies;
- the population studied in the clinical program may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from analytical and bioanalytical studies, nonclinical studies or clinical studies;
- we may be unable to demonstrate to the FDA or comparable foreign regulatory authorities that a product candidate's risk-benefit ratio for its proposed indication is acceptable;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications or facilities of 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 United States 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.

In addition, disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, or conducting our planned clinical trials. 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 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 United States, 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 United States is unclear. Numerous states are considering or have already enacted laws that regulate or restrict the substitution by state pharmacies of biosimilars for originator products already licensed by the FDA. Market success of biosimilar products will depend on demonstrating to patients, physicians, 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 FDA. 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.

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

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

We are marketing UDENYCA® in the United States, and subject to product approvals and relevant patent expirations, we intend to market our other biosimilar products in the United States 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 United States 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 in any market. 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

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

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, (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 ACA, and we expect there will be additional challenges and amendments to the ACA 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 ACA. 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 ACA'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 ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. 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. The U.S. Supreme Court is currently reviewing the case, although it is unclear how the Supreme Court will rule. In addition, there may be other efforts to challenge, repeal or replace the ACA. At this time, the full effect that the ACA and any subsequent changes would have on our business remains unclear.

In addition, other legislative changes have been proposed and adopted in the United States 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 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2021, unless additional Congressional action is taken. In addition, 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 United States 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 United States, 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 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 United States 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.

Risks Related to Ownership of Our Common Stock

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

The market price of our common stock has been highly volatile since our Initial Public Offering ("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 19, 2021 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; 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, 2020, our executive officers, directors, five percent stockholders and their affiliates beneficially owned approximately 62.6% 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, 2020, there were approximately 72.5 million 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, 2020, approximately 23.3 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, 2020, we reserved for future issuance under the 2016 Plan a total of 0.2 million 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 "2022 Convertible Notes"). The holders may convert their 2022 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 2022 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.

In April 2020, we issued and sold $230.0 million aggregate principal amount of our 1.5% senior convertible notes due April 2026 (the "2026 Convertible Notes"). The holders may convert their 2026 Convertible Notes at their option at any time prior to the close of business on the second scheduled trading day immediately before April 15, 2016. Upon conversion of the 2026 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 51.9224 shares of common stock per $1,000 principal amount of convertible notes, which is equivalent to an initial conversion price of approximately $19.26 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.

General Risk Factors

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

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

We 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.

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. On July 1, 2020, the U.S. Court of Appeals for the Federal Circuit issued a decision that affirmed the lower court's decision upholding the validity of these patents. As a result, we discontinued the development of CHS-0214 (our etanercept (Enbrel®) biosimilar candidate).

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 United States market.

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

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

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

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

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

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

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

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

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

In addition, 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 United States and most other countries are confidential for a period of time, typically for 18 months after filing, we cannot be certain that we were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our patents or patent applications. Furthermore, for applications filed before March 16, 2013 or patents issuing from such applications, an interference proceeding can be provoked by a third party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications and patents. As of March 16, 2013, the 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 United States and globally, covering our biosimilar product candidates 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 United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Further, licensing partners 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 United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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

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

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time consuming and inherently uncertain. In addition, the U.S. has recently enacted and is currently implementing wide-ranging patent reform legislation.

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 United States and the EU, 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.

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.

Our internal computer systems, or those used by our third-party CROs or other contractors or consultants, may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer, server, and other information technology systems as well as those of our third-party collaborators, consultants, contractors, suppliers, and service providers, may be vulnerable to damage from physical or electronic break-ins, computer viruses, "phishing" attacks, malware, ransomware, denial of service and other cyber-attacks or disruptive incidents that could result in unauthorized access to, use or disclosure of, corruption of, or loss of sensitive, and/ or proprietary data, including health-related information or other personal information, and could subject us to significant liabilities and regulatory and enforcement actions, and reputational damage. If we or any of our third-party collaborators were to experience any material failure or security breach, it could result in a material disruption of our development programs, reputation, and business operations. For example, the loss of clinical study data from completed or ongoing clinical studies could result in delays in any regulatory approval or clearance efforts and significantly increase our costs to recover or reproduce the data, and subsequently commercialize the product. If we or our third-party collaborators, consultants, contractors, suppliers, or service providers were to suffer an attack or breach, for example, that resulted in the unauthorized access to or use or disclosure of personal information, including health-related information, we may have to notify individuals, collaborators, government authorities, and the media, and may be subject to investigations, civil penalties, administrative and enforcement actions, and litigation, any of which could harm our business and reputation. Likewise, we rely on our third-party CROs and other third parties to conduct clinical studies, and similar events relating to their computer systems could also have a material adverse effect on our business. The COVID-19 pandemic is generally increasing the attack surface available to criminals, as more companies and individuals work online and work remotely, and as such, the risk of a cybersecurity incident potentially occurring, and our investment in risk mitigations against such an incident, is increasing. For example, there has been an increase in phishing and spam emails as well as social engineering attempts from "hackers" hoping to use the recent COVID-19 pandemic to their advantage. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or systems, or inappropriate or unauthorized access to or disclosure or use of confidential, proprietary, or other sensitive, personal information, including health-related information, we could incur liability and suffer reputational harm, and the development and commercialization of our products could be delayed. Our insurance policies may not be adequate to compensate us for the potential losses arising from such disruptions, failure, or security breach. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and defending a suit, regardless of its merit, could be costly, divert management attention, and harm our reputation.

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 United States, 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 may be subject to diverse laws and regulations relating to data privacy and security, including, in the United States, HIPAA and CCPA (defined below), and, in the E.U. and 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 United States, we and our partners may be subject to numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws and regulations, that govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our partners. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of 1996, as amended, or HIPAA. Depending on the facts and circumstances, we could be subject to criminal penalties if we knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

Even when HIPAA does not apply, according to the Federal Trade Commission ("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. 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.

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. Further, the CPRA recently passed in California, which will impose additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. The CCPA and the CPRA 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. The GDPR is applicable in each EEA member state and applies to companies established in the EEA as well as companies that collect and use personal data to offer goods or services to, or monitor the behavior of, individuals in the EEA, including, for example, through the conduct of clinical trials. GDPR introduces more stringent data protection obligations for processors and controllers of personal data. Among other things, the GDPR requires the establishment of a lawful basis for the processing of data, includes requirements relating to the consent of the individuals to whom the personal data relates, including detailed notices for clinical trial subjects and investigators, as well as requirements regarding the security of personal data and notification of data processing obligations or security incidents to appropriate data protection authorities or data subjects. Recent legal developments in Europe have created complexity and uncertainty regarding transfers of personal data from the EEA to the United States. For example, on July 16, 2020, the Court of Justice of the European Union ("CJEU") invalidated the EU-US Privacy Shield Framework ("Privacy Shield") under which personal data could be transferred from the EEA to United States entities that had self-certified under the Privacy Shield scheme. While the CJEU upheld the adequacy of the standard contractual clauses (a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism, and potential alternative to the Privacy Shield), it made clear that reliance on them alone may not necessarily be sufficient in all circumstances. Use of the standard contractual clauses must now be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, in particular applicable surveillance laws and rights of individuals and additional measures and/or contractual provisions may need to be put in place, however, the nature of these additional measures is currently uncertain. 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, as of January 1, 2021, we have to comply with the GDPR and the GDPR as implemented in the United Kingdom, 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 with respect 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.

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 laboratory is located in Camarillo, California under a lease that expires 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 we 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 United States 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, our 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, 2019, Judge Stark of the District Court adopted the U.S. Magistrate Judge's Report and Recommendation to grant our motion 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 2019, Amgen filed a Notice of Appeal in the U.S. Court of Appeals for the Federal Circuit. The parties 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 our 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, we 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, we filed our Reply Brief with the District Court. On November 30, 2020, the District Court issued an order denying the Company's motion.

On January 24, 2019, we filed suit against Amgen in the United States District Court of Delaware alleging that the manufacture of Amgen's Humira biosimilar, Amgevita™, infringes our U.S. patents 10,155,039; 10,159,732; and 10,159,733. Each of our asserted 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 our 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, we filed our Answering Brief in Opposition to Amgen's motion. On January 21, 2020, Amgen filed its Reply Brief. On June 11, 2020, the Court issued an order denying Amgen's motion.

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, 2019 through December 31, 2020.

	Price Range	
	High	Low
Year ended December 31, 2020		
1st Quarter	$ 23.03	$ 10.86
2nd Quarter	19.72	14.12
3rd Quarter	20.73	17.03
4th Quarter	19.12	16.26
Year ended December 31, 2019		
1st Quarter	$ 15.62	$ 8.32
2nd Quarter	22.17	12.95
3rd Quarter	23.91	16.16
4th Quarter	22.08	15.50

On February 19, 2021, the closing sale price of our common stock was $17.27.

Common Stockholders

As of January 31, 2021, 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.

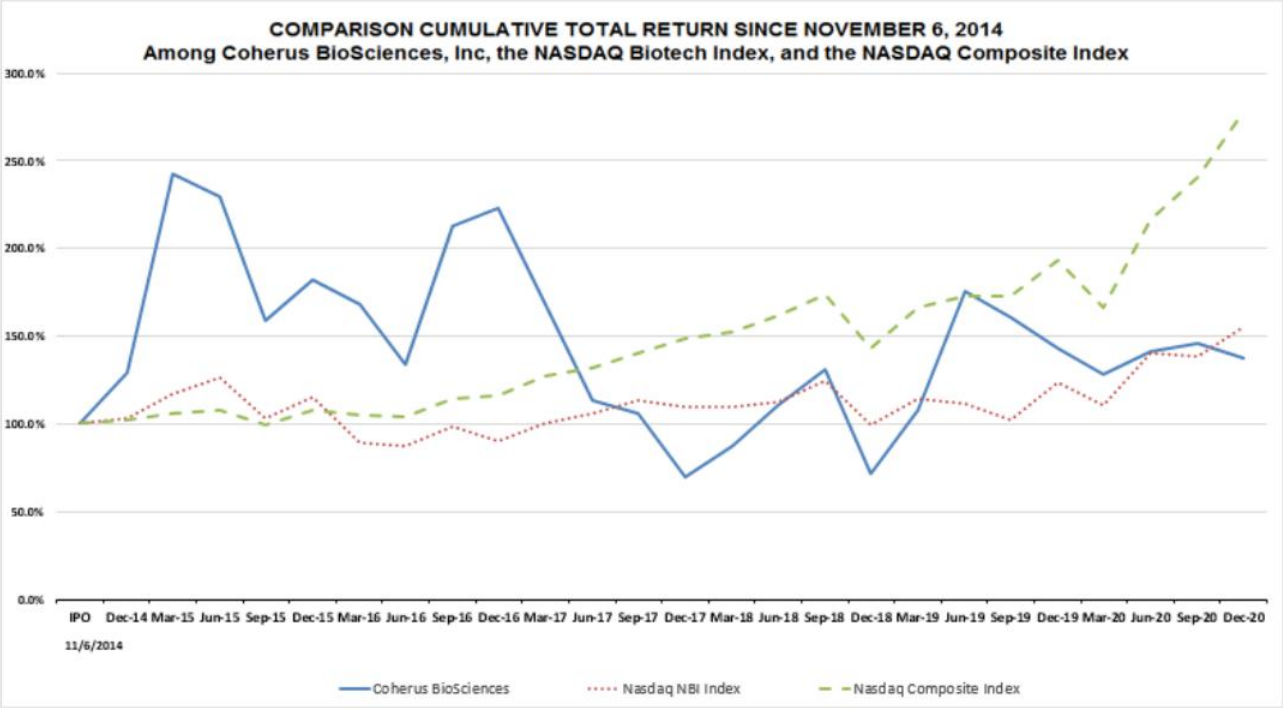
Dividend Policy

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. We entered into 8.2% senior convertible notes in February 2016 and 1.5% convertible notes in April 2020, each of 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, 2020 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, 2020 through December 31, 2020, 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, 2020.

Item 6. *Selected Financial Data*

Not required.

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 biopharmaceutical company with a mission to increase patient access to cost-effective medicines that can have a major impact on their lives and to deliver significant savings to the health care system. We have become a leader in the biosimilar market by leveraging our team's collective expertise in key areas such as process science, analytical characterization, protein production, clinical-regulatory development and commercialization. We began selling UDENYCA® (pegfilgrastim-cbqv), a biosimilar to Neulasta, a long-acting granulocyte-colony stimulating factor, in the United States in January 2019.

On February 1, 2021, we entered into an Exclusive License and Commercialization Agreement (the "Collaboration Agreement") with Shanghai Junshi Biosciences, Co., Ltd. ("Junshi Biosciences"), for the co-development and commercialization of toripalimab, Junshi Biosciences' anti-PD-1 antibody, in the United States and Canada. Under the Collaboration Agreement, we will also be granted options to Junshi Biosciences' TIGIT-targeted antibody and next generation engineered IL-2 cytokine for evaluation as potential combination therapies with toripalimab, as well as certain negotiation rights to two early-stage checkpoint inhibitor antibodies (the "Collaboration"). The Collaboration expands our late-stage pipeline into the rapidly growing checkpoint inhibitor market, which is expected to exceed $25.0 billion in the United States by 2025, and provides us a PD-1 backbone for potential long-term growth with next-generation immuno-oncology combinations. Closing of the Collaboration Agreement is subject to clearance under the HSR Act.

Our pre-commercial pipeline includes the following product candidates:

Oncology Pipeline

- Toripalimab, an anti-PD-1 antibody being developed in collaboration with Junshi Biosciences.
- A bevacizumab (Avastin) biosimilar candidate in collaboration with Innovent.

Immunology Pipeline

- CHS-1420 (our adalimumab (Humira) biosimilar candidate).

Opthalmology Pipeline

- A ranibizumab (Lucentis) biosimilar candidate in collaboration with Bioeq;

On January 3, 2019, we initiated the U.S. sales of UDENYCA®, our first commercial product. While we have been profitable for the years ended December 31, 2020 and 2019, we anticipate that we may experience lower profitability and annual losses in the near term as a result of incurring expenses associated with upfront and milestone payments under our collaboration with Junshi Biosciences, if cleared under the HSR Act. Our net income was $132.2 million and $89.8 million for the year ended December 31, 2020 and 2019, respectively, and our net loss was $209.4 million for the year ended December 31, 2018. As of December 31, 2020, we had an accumulated deficit of $762.8 million.

In February 2016, we issued and sold $100.0 million aggregate principal amount of our 8.2% Convertible Senior Notes due in March 2022 (the "2022 Convertible Notes"). These 2022 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 2022 Convertible Notes at a rate of up to 0.50% per annum in the aggregate. The holders of the 2022 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 2022 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 2022 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 2022 Convertible Notes were issued), subject to adjustment in certain events. Upon conversion of the 2022 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 2022 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 2022 Convertible Notes. At maturity or redemption, if not earlier converted, we will pay 109% of the principal amount of the 2022 Convertible Notes, together with accrued and unpaid interest, in cash. In April 2020, we amended the 2022 Convertible Notes purchase agreement in connection with the issuance and sale of our 2026 Convertible Notes (as defined below).

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 (the "ATM Offering Program"). In the first quarter of 2019, we sold 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. Following such sales, the ATM Offering Program terminated as all shares authorized thereunder had been sold.

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). Pursuant to the terms of the Term Loan, the interest rate was reduced to 6.75% per annum plus LIBOR as of January 1, 2020 as the consolidated net sales (customarily defined) for UDENYCA® for the fiscal year ending December 31, 2019, were in excess of $250.0 million. 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 April 2020, we amended the Term Loan in connection with the issuance and sale of our 2026 Convertible Notes (as defined below).

In April 2020, we issued and sold $230.0 million aggregate principal amount of 1.5% convertible senior subordinated notes due in 2026 (the “2026 Convertible Notes”) in a private offering to qualified institutional buyers pursuant to Rule 144A under the Securities Act. In connection with the pricing of the 2026 Convertible Notes, we entered into privately negotiated capped call transactions with one or more of the initial purchasers or their respective affiliates and/or other financial institutions (the “Option Counterparties”). The cap price of the capped call transactions will initially be $25.9263 per share, which represents a premium of approximately 75.0% over the last reported sale price of our common stock of $14.815 per share on April 14, 2020, and is subject to certain adjustments under the terms of the capped call transactions. The 2026 Convertible Notes are general unsecured obligations and will be subordinated to our designated senior indebtedness. The 2026 Convertible Notes accrue interest at a rate of 1.5% per annum, payable semi-annually in arrears on April 15 and October 15 of each year, beginning on October 15, 2020, and will mature on April 15, 2026, unless earlier repurchased or converted. At any time before the close of business on the second scheduled trading day immediately before the maturity date, holders may convert their 2026 Convertible Notes at their option into shares of our common stock, together, if applicable, with cash in lieu of any fractional share, at the then-applicable conversion rate. The initial conversion rate is 51.9224 shares of common stock per $1,000 principal amount of 2026 Convertible Notes, which represents an initial conversion price of approximately $19.26 per share of common stock. The initial conversion price represents a premium of approximately 30.0% over the last reported sale of $14.815 per share of our common stock on the Nasdaq Global Market on April 14, 2020. The conversion rate and conversion price will be subject to customary adjustments upon the occurrence of certain events. If a “make-whole fundamental change” (as defined in the indenture for the 2026 Convertible Notes) occurs, we will, in certain circumstances, increase the conversion rate for a specified period of time for holders who convert their 2026 Convertible Notes in connection with that make-whole fundamental change. The 2026 Convertible Notes are not redeemable at our election before maturity. If a “fundamental change” (as defined in the indenture for the 2026 Convertible Notes) occurs, then, subject to a limited exception, holders may require us to repurchase their 2026 Convertible Notes for cash. The repurchase price will be equal to the principal amount of the 2026 Convertible Notes to be repurchased, plus accrued and unpaid interest, if any, to, but excluding, the applicable repurchase date. The net proceeds from the offering were $222.2 million, net of the initial purchasers’ fees and the offering expenses. We used approximately $18.2 million of the net proceeds to fund the cost of entering into the capped call transactions.

COVID-19 Update

As a result of the COVID-19 outbreak, we have experienced and may continue to experience disruptions that could severely impact our business, clinical trials and preclinical studies. See “Risk Factors ”. These and other factors arising from the COVID-19 pandemic could result in us not being able to maintain UDENYCA®’s market position or increase its penetration against all Neulasta’s dosage forms, and could result in our inability to meet development milestones for our product candidates, each of which would harm our business, financial condition, results of operations and growth. We expect the COVID-19 pandemic to have some adverse impact on our sales growth on a year-over-year basis.

While the long-term economic impact and the duration of the COVID-19 pandemic may be difficult to assess or predict, the widespread pandemic has resulted in, and may continue to result in, significant disruption of global financial markets, which could reduce our ability to access capital and could negatively affect our liquidity and the liquidity and stability of markets for our common stock and our convertible notes. In addition, a recession, further market correction or depression resulting from the spread of COVID-19 could materially affect our business and the value of our notes and our common stock.

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 $475.8 million and $356.1 million for the years ended December 31, 2020 and 2019, respectively.

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 licensing 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 2021 to be substantially higher than in 2020 due to the incurrence of the $150.0 million upfront payment as well as additional potential milestone payments to Junshi Biosciences and other additional increased development costs.

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, 2020	Year ended December 31, 2020	2019	2018
			(in thousands)	
External costs incurred by product candidate:				
UDENYCA®	Approved	$ 14,008	$ 9,047	$ 42,975
CHS-1420	Completed	25,048	9,039	5,989
CHS-2020	Phase 3	19,249	5,024	878
CHS-131	Phase 2	1,470	4,789	1,181
Bevacizumab (Avastin) biosimilar product candidate licensed from Innovent		3,523	—	—
Upfront and milestone based license fees		7,500	11,075	—
Other research and development expenses (1)		9,635	3,654	7,139
Internal costs		62,326	51,560	52,077
Total research and development expenses		$142,759	$94,188	$110,239

(1) 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. Our selling, general and administrative expense in 2020 was lower than expected as certain sales and marketing activities were decreased due to the COVID-19 pandemic. We expect our selling, general and administrative expense in 2021 to be higher than in 2020 as a result of anticipated increased commercial activities to support UDENYCA® sales and as a result of initiating our ophthalmology and immuno-oncology commercial activities.

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, 2020, 2019 and 2018.

Other Income, Net

Other income, net for the years ended December 31, 2020, 2019 and 2018, 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.

Significant Transactions

1.5% Convertible Senior Subordinated Notes due 2026

In April 2020, we issued and sold $230.0 million aggregate principal amount of 1.5% convertible senior subordinated notes due 2026 (the “2026 Convertible Notes”) in a private offering to qualified institutional buyers pursuant to Rule 144A under the Securities Act. The 2026 Convertible Notes are general unsecured obligations and will be subordinated to our designated senior indebtedness. The 2026 Convertible Notes accrue interest at a rate of 1.5% per annum, payable semi-annually in arrears on April 15 and October 15 of each year, beginning on October 15, 2020, and will mature on April 15, 2026, unless earlier repurchased or converted.

At any time before the close of business on the second scheduled trading day immediately before the maturity date, noteholders may convert their 2026 Convertible Notes at their option into shares of our common stock, together, if applicable, with cash in lieu of any

fractional share, at the then-applicable conversion rate. The initial conversion rate is 51.9224 shares of common stock per $1,000 principal amount of the 2026 Convertible Notes, which represents an initial conversion price of approximately $19.26 per share of common stock. The initial conversion price represents a premium of approximately 30.0% over the last reported sale of $14.815 per share of our common stock on the Nasdaq Global Market on April 14, 2020. The conversion rate and conversion price will be subject to customary adjustments upon the occurrence of certain events. If a "make-whole fundamental change" (as defined in the indenture for the 2026 Convertible Notes) occurs, we will, in certain circumstances, increase the conversion rate for a specified period of time for noteholders who convert their 2026 Convertible Notes in connection with that make-whole fundamental change. The 2026 Convertible Notes are not redeemable at our election before maturity. If a "fundamental change" (as defined in the indenture for the 2026 Convertible Notes) occurs, then, subject to a limited exception, noteholders may require us to repurchase their 2026 Convertible Notes for cash. The repurchase price will be equal to the principal amount of the 2026 Convertible Notes to be repurchased, plus accrued and unpaid interest, if any, to, but excluding, the applicable repurchase date.

In connection with the pricing of the 2026 Convertible Notes, we entered into privately negotiated capped call transactions with one or more of the Option Counterparties. The cap price of the capped call transactions will initially be $25.9263 per share, which represents a premium of approximately 75.0% over the last reported sale price of our common stock of $14.815 per share on April 14, 2020, and is subject to certain adjustments under the terms of the capped call transactions.

The net proceeds from the offering were $222.2 million, net of the initial purchasers' discounts and commissions and the offering expenses. We used approximately $18.2 million of the net proceeds to fund the cost of entering into the capped call transactions.

The 2026 Convertible Notes are accounted for in accordance with ASC 470-20, *Debt with Conversion and Other Options* ("ASC 470-20") and ASC 815-40, *Contracts in Entity's Own Equity* ("ASC 815-40"). Under ASC 815-40, to qualify for equity classification (or nonbifurcation, if embedded) the instrument (or embedded feature) must be both (1) indexed to the issuer's stock and (2) meet the requirements of the equity classification guidance. We determined that the 2026 Convertible Notes do contain embedded features indexed to our own stock, but do not meet the requirements for bifurcation, and therefore do not need to be separately accounted for as an equity component. Since the embedded conversion feature meets the equity scope exception from derivative accounting, and also since the embedded conversion option does not need to be separately accounted for as an equity component under ASC 470-20, the proceeds received from the issuance of the convertible debt were recorded as a liability on the consolidated balance sheet. We evaluated the capped call transactions under ASC 815-10 and determined that it should be accounted as a separate transaction from the 2026 Convertible Notes and that the capped calls should be classified as equity instruments. Therefore, the capped call premium paid in the amount of $18.2 million was recorded as a reduction to additional paid-in capital. The capped calls will not be subsequently re-measured as long as the conditions for equity classification continue to be met.

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.

Net Product Revenue

We account for sales of UDENYCA® under Topic *606 Revenue from Contracts with Customers*. 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.

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, 2020, our total net deferred tax assets, net of gross deferred tax liabilities, were $200.9 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, stock-based compensation expenses and sales related accruals. 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

For a description of the impact of recent accounting pronouncements, see “Note 2. Basis of Presentation and Summary of Significant Accounting Policies” in the “Notes to Consolidated Financial Statements” contained in Part II, Item 8 of this Annual Report on Form 10-K.

Results of Operations

Comparison of Years Ended December 31, 2020, 2019 and 2018

Revenue

	Year Ended December 31,			2020 vs 2019 Change	2019 vs 2018 Change
	2020	2019	2018		
	(in thousands)			*(in thousands)*	
Revenue:					
Net product revenue	$475,824	$356,071	$ —	$ 119,753	$ 356,071

Net product revenue for the year ended December 31, 2020 was $475.8 million compared to $356.1 million for the year ended December 31, 2019, an increase of $119.8 million. The increase was primarily due to an increase in the number of units of UDENYCA® sold, which was partially offset by an increase in discounts and allowances incurred during the year ended December 31, 2020.

During the second quarter of 2020, we identified that certain of our commercial payer invoices were erroneously overstated and we received a refund of $7.5 million from these payers related to fiscal year 2019 which resulted in an increase in net product revenue by the same amount for 2020.

We expect our net product revenue to decline during 2021, as a result of COVID-19 impact and new market entrants.

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.

Cost of Goods Sold

	Year Ended December 31,			2020 vs 2019 Change	2019 vs 2018 Change
	2020	2019	2018		
	(in thousands)			*(in thousands)*	
Cost of goods sold	$37,667	$17,078	$ —	$ 20,589	$ 17,078
Gross margin	92 %	95 %	— %	(3)%	95 %

The cost of goods sold was $37.7 million for the year ended December 31, 2020 compared to $17.1 million for the year ended December 31, 2019. 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 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 $3.3 million and $24.9 million at December 31, 2020 and December 31, 2019, respectively, with estimated associated sales value of approximately $44.8 million and $367.5 million, respectively, based on our current average net selling price for the three months ended December 31, 2020. The cost basis of product sold that was expensed prior to approval, was approximately $21.1 million and $17.0 million for the year ended December 31, 2020 and 2019, respectively. 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 to utilize the inventory expensed prior to approval of UDENYCA® 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.

Cost of goods sold for the year ended December 31, 2019 included a write-down of 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.

We expect our gross margin to decrease during 2021 as a result of decreasing net revenue per unit sold.

Research and Development Expense

	Year Ended December 31,			2020 vs 2019 Change	2019 vs 2018 Change
	2020	2019	2018		
	(in thousands)			*(in thousands)*	
Research and development	$142,759	$94,188	$110,239	$ 48,571	$ (16,051)

Research and development expense for the year ended December 31, 2020 was $142.8 million compared to $94.2 million for the same period in 2019, an increase of $48.6 million. The increase in research and development expense was primarily due to:

- an increase of $16.0 million in costs for CHS-1420 related to the preparation of our BLA submission and activities related to inspection readiness;
- an increase of $14.2 million in costs for CHS-2020 as we initiated the manufacturing scale-up to produce drug substance and drug product for clinical trial supply;
- an increase of $7.7 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 $6.0 million related to right of first negotiation fees cost in connection with potential future strategic licensing transactions;

- an increase of $5.0 million related to the on-body device development for UDENYCA®;
- an increase of $3.5 million in costs incurred to support opening an IND application with the FDA and continued development of bevacizumab (Avastin) biosimilar product candidate licensed from Innovent in 2020; and
- an increase of $3.0 million in facilities, supplies and materials and other infrastructure to support our research and development programs.

The increase in research and development expense for the year ended December 31, 2020 was partially offset by:

- a decrease of $3.6 million in upfront and milestone-based license fee primarily attributable to $11.1 million of upfront and milestone payments to Bioeq in 2019 partially offset by $7.5 million of upfront and milestone payments to Innovent in 2020;
- a decrease of $3.3 million in CHS-131 related costs incurred in 2019 in connection with opening an IND application with the FDA and the initiation of a clinical program.

We expect our research and development expense in 2021 to be substantially higher than in 2020 due to the incurrence of $150.0 million upfront payment as well as additional potential milestone payments to Junshi Biosciences and other additional increased development costs.

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.

Selling, General and Administrative Expense

	Year Ended December 31,			2020 vs 2019 Change	2019 vs 2018 Change
	2020	2019	2018		
	(in thousands)			*(in thousands)*	
Selling, general and administrative	$139,079	$137,037	$94,177	$ 2,042	$ 42,860

Selling, general and administrative expense for the year ended December 31, 2020 was $139.1 million compared to $137.0 million for the same period in 2019, an increase of $2.0 million. The increase was primarily due to the following:

- a net increase of $12.8 million for personnel, consulting, professional services, marketing, advertising and other related expenses due to an increase in sales force personnel and related commercial functions to support the continued growth in UDENYCA® sales, which was partially offset by a decrease of $3.8 million in travel expenses as a result of shelter-in-place response to COVID-19; and

- an increase of $2.1 million in facilities, supplies and materials and other infrastructure related expenses to support our growing commercial infrastructure for UDENYCA®.

These increases were partially offset by a decrease of $9.0 million in legal costs related to entering into a legal settlement with Amgen in May 2019.

We expect our selling, general and administrative expense in 2021 to be higher than in 2020 as a result of anticipated increased commercial activities to support UDENYCA® sales and as a result of initiating our ophthalmology and immuno-oncology commercial activities.

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.

Interest Expense

	Year Ended December 31,			2020 vs 2019 Change	2019 vs 2018 Change
	2020	2019	2018		
	(in thousands)			*(in thousands)*	
Interest expense	$21,166	$17,601	$9,684	$ 3,565	$ 7,917

Interest expense for the year ended December 31, 2020 was $21.2 million compared to $17.6 million for the same period in 2019, an increase of $3.6 million. The increase in interest expense was primarily due to the interest related to our 2026 Convertible Notes that were issued in April 2020.

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.

Other income, net

	Year Ended December 31,			2020 vs 2019 Change	2019 vs 2018 Change
	2020	2019	2018		
	(in thousands)			(in thousands)	
Other income, net	$ 554	$ 2,608	$ 4,691	$ (2,054)	$ (2,083)

Other income, net for the year ended December 31, 2020 was $0.6 million compared to $2.6 million for the year ended December 31, 2019, a decrease of $2.1 million. The decrease in other income, net was primarily due to decrease of $1.3 million in interest income due to lower portfolio yields as a result of decrease in interest rates in 2020 and a decrease of $0.6 million due to fluctuations in foreign exchange rates.

Other income, net was higher in 2018 compared to that of 2019 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,			2020 vs 2019 Change	2019 vs 2018 Change
	2020	2019	2018		
	(in thousands)			(in thousands)	
Income tax provision	$ 3,463	$ 2,942	$ —	$ 521	$ 2,942

Income tax provision for the year ended December 31, 2020 was $3.5 million compared to $2.9 million for the same period in 2019, an increase of $0.5 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. The income tax provision differed from the U.S. federal statutory rate of 21% primarily due to the effect of change in the valuation allowance against our federal deferred tax assets, which reduced our net tax expense. We maintain a full valuation allowance against our net deferred tax assets due to our history of losses.

There was no income tax provision for the year ended December 31, 2018 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 years ended December 31, 2020 and 2019, we previously generated significant operating losses since our inception. We funded our operations primarily through the equity financing, sales of our convertible preferred stock, sales of UDENYCA® units, issuance of debt 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 resulted 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 April 2020, we issued and sold $230 million aggregate principal amount of 1.5% convertible senior subordinated notes due 2026 (the "2026 Convertible Notes") in a private offering to qualified institutional buyers pursuant to Rule 144A under the Securities Act. In connection with the pricing of the 2026 Convertible Notes, we entered into privately negotiated capped call transactions with one or more of the Option Counterparties. The cap price of the capped call transactions will initially be $25.9263 per share, which represents a premium of approximately 75.0% over the last reported sale price of our common stock of $14.815 per share on April 14, 2020, and is subject to certain adjustments under the terms of the capped call transactions. The 2026 Convertible Notes are general unsecured obligations and will be subordinated to our designated senior indebtedness. The 2026 Convertible Notes accrue interest at a rate of 1.5% per annum, payable semi-annually in arrears on April 15 and October 15 of each year, beginning on October 15, 2020, and will mature on April 15, 2026, unless earlier repurchased or converted. At any time before the close of business on the second scheduled trading day immediately before the maturity date, holders may convert their 2026 Convertible Notes at their option into shares of our common stock, together, if applicable, with cash in lieu of any fractional share, at the then-applicable conversion rate. The initial conversion rate is 51.9224 shares of common stock per $1,000 principal amount of 2026 Convertible Notes, which represents an initial conversion price of approximately $19.26 per share of common stock. The initial conversion price represents a premium of approximately 30.0% over the last reported sale of $14.815 per share of our common stock on the Nasdaq Global Market on April 14, 2020. The conversion rate and conversion price will be subject to customary adjustments upon the occurrence of certain events. If a "make-whole fundamental change" (as defined in the indenture for the 2026 Convertible Notes) occurs, we will, in certain circumstances, increase the conversion rate for a specified period of time for holders who convert their 2026 Convertible Notes in connection with that make-whole fundamental change. The 2026 Convertible Notes are not redeemable at our election before maturity. If a "fundamental change" (as defined in the indenture for the 2026 Convertible Notes) occurs, then, subject to a limited exception, holders may require us to repurchase their 2026 Convertible Notes for cash. The repurchase price will be equal to the principal amount of the 2026 Convertible Notes to be repurchased, plus accrued and unpaid interest, if any, to, but excluding, the applicable repurchase date. The net proceeds from the offering were $222.2 million, net of the initial purchasers' fees and the offering expenses. We used approximately $18.2 million of the net proceeds to fund the cost of entering into the capped call transactions.

In 2020, 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, 2020, we had an accumulated deficit of $762.8 million and cash and cash equivalents of $541.2 million. We had $132.2 million in net income for the year ended December 31, 2020. 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,		
	2020	2019	2018
	(in thousands)		
Net cash provided by (used in) operating activities	$154,145	$ 28,355	$(159,266)
Net cash used in investing activities	(14,401)	(12,732)	(1,188)
Net cash provided by financing activities	223,946	89,370	105,421
Effect of exchange rate changes in cash, cash equivalents and restricted cash	—	(276)	468
Net increase in cash, cash equivalents and restricted cash	$363,690	$104,717	$ (54,565)

Net cash provided by (used in) operating activities

Cash provided by operating activities was $154.1 million for the year ended December 31, 2020, which was primarily due to the following:

- net income of $132.2 million;
- an increase in accrued rebates, fees and reserve of $30.4 million as a result of continued growth in UDENYCA® sales;
- upfront and milestone-based license fee payments of $7.5 million to Innovent are being reclassified to investing activities to provide better alignment between the cash flows and the underlying nature of the transactions;
- non-cash charges related to stock-based compensation of $38.2 million and depreciation and amortization of property and equipment of $2.9 million, non-cash interest expense from amortization of debt issuance discounts of $3.5 million, non-cash operating lease expense of $2.1 million, other non-cash adjustments of $0.4 million;
- an increase in accrued compensation of $6.2 million primarily due to increase in headcount and vacation accrual for 2020, partially offset by the settlement of 2019 bonus payout;
- an increase in accrued and other liabilities of $5.5 million primarily related to contract manufacturing accruals; and
- An increase in other non-current liabilities of $0.9 million primarily due to deferral of certain payroll tax liabilities under the CARES act.

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

- an increase in inventory of $36.2 million primarily due to continued growth in UDENYCA® sales and to maintain adequate supplies in order to meet future demand for UDENYCA®;
- an increase in trade receivables of $15.2 million primarily due to the timing of payment from our customers;
- an increase in prepaid manufacturing and other assets, non-current of $12.6 million to secure drug production runs scheduled for 2020 and 2021; and

- a decrease in accounts payable of $9.8 million primarily due to the timing of receiving and processing invoices from our vendors.

- a decrease in lease liabilities of $1.4 million due to the lease payments for 2020.

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;

- a 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 RSUs 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®.

Net cash used in investing activities

Cash used in investing activities of $14.4 million for the year ended December 31, 2020 was primarily due to purchases of investments in marketable securities of $273.8 million, upfront and milestone-based license fee payments of $7.5 million to Innovent and purchases of property and equipment of $7.2 million partially offset by the proceeds from maturities of investments in marketable securities of $274.0 million.

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.

Net cash provided by financing activities

Cash provided by financing activities of $223.9 million for the year ended December 31, 2020 was primarily due to $222.2 million in proceeds from the issuance of 2026 Convertible Notes, net of issuance costs, $17.4 million proceeds from the exercise of stock options and $3.8 million proceeds from purchases under the Employee Stock Purchase Plan (“ESPP”) partially offset by $18.2 million of capped call option purchases related to 2026 Convertible Notes, $0.9 million in tax payments related to net share settlement of bonus payout in RSUs and $0.4 million in principal payments for finance lease obligations.

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.

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, 2020 were as follows:

	As of December 31, 2020		
Contractual Obligations	**Total**	**Short Term**	**Long Term**
		(in thousands)	
Long-term debt obligations - 2026 Convertible notes (1)	$248,975	$ 3,450	$245,525
Long-term debt obligations - 2022 Convertible notes (1)	119,250	8,200	111,050
Long-term debt obligations - Term loan (1)	100,675	7,034	93,641
Non-cancelable purchase commitments (2)	66,662	40,963	25,699
Operating lease obligations (3)	13,744	3,425	10,319
Finance lease obligations (4)	1,537	626	911
Contingent payments to InteKrin Stockholders	102	—	102
Total contractual liabilities	$550,945	$ 63,698	$487,247

(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 CMOs.
(3) These amounts are comprised of future minimum rent payment on our facility leases.
(4) These amounts are comprised of future minimum rent payment on our vehicle leases.

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, 2020, we had cash and cash equivalents of $541.2 million. A portion of our cash equivalents, which are in money market funds, may be subject to interest rate risk and could fall in value if market interest rates increase. However, because our cash equivalents are primarily short-term in duration, we believe that our exposure to interest rate risk is not significant and a 1% movement in market interest rates would not have a significant impact on the total value of our portfolio.

We are exposed to market risk related to changes in foreign exchange rates. We contract with CROs and contract manufacturers globally and thus we face foreign exchange risk as a result of entering into transactions denominated in currencies other than U.S. dollars. Due to the uncertain timing of expected payments in foreign currencies, we do not utilize any forward exchange contracts. All foreign transactions settle on the applicable spot exchange basis at the time such payments are made. An adverse movement in foreign exchange rates could have a material effect on payments made to foreign suppliers and for license agreements. A hypothetical 10% change in foreign exchange rates during any of the periods presented would not have had a material impact on our financial statements. We 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, 2020 and 2019, 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, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020, 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, 2020, 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 25, 2021 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 Matter

The 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 Chargebacks 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 $40.0 million at December 31, 2020. Estimated rebates are presented within accrued rebates, fees and reserves on the consolidated balance sheet and totaled $54.1 million at December 31, 2020.

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, 2020, 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 for 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 25, 2021

Coherus BioSciences, Inc.

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

	December 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 541,158	$ 177,668
Trade receivables, net	157,046	141,992
Inventory	44,233	9,807
Prepaid manufacturing	19,429	8,578
Other prepaid and other assets	5,613	4,964
Total current assets	767,479	343,009
Property and equipment, net	10,108	5,840
Inventory, non-current	47,956	45,264
Operating lease right-of-use assets	9,956	10,649
Intangible assets	2,620	2,620
Goodwill	943	943
Restricted cash, non-current	440	240
Other assets, non-current	2,147	362
Total assets	$ 841,649	$ 408,927
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 15,201	$ 25,985
Accrued rebates, fees and reserve	81,529	51,120
Accrued compensation	22,244	18,410
Accrued liabilities	22,818	17,258
Other current liabilities	3,861	2,196
Total current liabilities	145,653	114,969
Contingent consideration, non-current	102	102
Convertible notes due 2022	79,885	78,542
Convertible notes due 2022 - related parties	26,628	26,181
Convertible notes due 2026	223,029	—
Term loan	74,481	73,663
Lease liabilities, non-current	9,948	10,256
Other liabilities, non-current	949	—
Total liabilities	560,675	303,713
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Common stock ($0.0001 par value; shares authorized: 300,000,000; shares issued and outstanding: 72,513,348 and 70,366,661 at December 31, 2020 and 2019, respectively)	7	7
Additional paid-in capital	1,043,991	1,000,763
Accumulated other comprehensive loss	(270)	(558)
Accumulated deficit	(762,754)	(894,998)
Total stockholders' equity	280,974	105,214
Total liabilities and stockholders' equity	$ 841,649	$ 408,927

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,		
	2020	2019	2018
Revenue:			
Net product revenue	$ 475,824	$ 356,071	$ —
Operating expenses:			
Cost of goods sold	37,667	17,078	—
Research and development	142,759	94,188	110,239
Selling, general and administrative	139,079	137,037	94,177
Total operating expenses	319,505	248,303	204,416
Income (loss) from operations	156,319	107,768	(204,416)
Interest expense (includes related party expense of $2,498, $2,457 and $2,421 for the years ended December 31, 2020, 2019 and 2018, respectively)	(21,166)	(17,601)	(9,684)
Other income, net	554	2,608	4,691
Net income (loss) before income taxes	135,707	92,775	(209,409)
Income tax provision	3,463	2,942	—
Net income (loss)	132,244	89,833	(209,409)
Net loss attributable to non-controlling interest	—	—	70
Net income (loss) attributable to Coherus	$ 132,244	$ 89,833	$ (209,339)
Net income (loss) per share attributable to Coherus:			
Basic	$ 1.85	$ 1.29	$ (3.22)
Diluted	$ 1.62	$ 1.23	$ (3.22)
Weighted-average number of shares used in computing net income (loss) per share attributable to Coherus:			
Basic	71,411,705	69,679,916	65,034,827
Diluted	83,491,898	73,185,943	65,034,827

See accompanying notes to consolidated financial statements.

Coherus BioSciences, Inc.

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

	Year Ended December 31,		
	2020	2019	2018
Net income (loss)	$ 132,244	$ 89,833	$ (209,409)
Other comprehensive income (loss):			
Foreign currency translation adjustments, net of tax	288	(276)	468
Comprehensive income (loss)	132,532	89,557	(208,941)
Comprehensive loss attributable to non-controlling interest	—	—	70
Comprehensive income (loss) attributable to Coherus	$ 132,532	$ 89,557	$ (208,871)

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, 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 RSUs	39,765	—	—	—	—	—	—	—
Issuance of common stock under the 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
Issuance of common stock upon exercise of stock options	1,704,764	—	17,061	—	—	17,061	—	17,061
Issuance of common stock upon vesting of RSUs	89,668	—	—	—	—	—	—	—
Issuance of common stock under the ESPP	267,772	—	3,801	—	—	3,801	—	3,801
Issuance of common stock upon 2019 bonus payout in RSUs	134,099	—	2,378	—	—	2,378	—	2,378
Taxes paid related to net share settlement of bonus payout in RSUs	(49,616)	—	(880)	—	—	(880)	—	(880)
Stock-based compensation expense	—	—	39,038	—	—	39,038	—	39,038
Purchase of capped call options related to convertible notes due 2026	—	—	(18,170)	—	—	(18,170)	—	(18,170)
Cumulative translation adjustment	—	—	—	288	—	288	—	288
Net income attributable to Coherus	—	—	—	—	132,244	132,244	—	132,244
Balances at December 31, 2020	72,513,348	$ 7	$1,043,991	$ (270)	$ (762,754)	$ 280,974	$ —	$ 280,974

See accompanying notes to consolidated financial statements.

Coherus BioSciences, Inc.

Consolidated Statements of Cash Flows
(in thousands)

	Years Ended December 31,		
	2020	2019	2018
Operating activities			
Net income (loss)	$ 132,244	$ 89,833	$ (209,409)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Depreciation and amortization	2,888	3,259	3,235
Remeasurement of fair-value contingent consideration	—	42	(3,230)
Stock-based compensation expense	38,160	33,591	34,797
Non-cash accretion of discount on marketable securities	(155)	(165)	(301)
Non-cash interest expense from amortization of debt discount	3,481	2,339	1,484
Impairment of property and equipment	—	110	3,861
Excess and obsolete inventory	—	410	—
Other non-cash adjustments	426	—	—
Non-cash operating lease expense	2,081	1,789	—
Upfront and milestone based license fee payments	7,500	11,075	—
Changes in operating assets and liabilities:			
Trade receivables, net	(15,218)	(141,992)	—
Inventory	(36,188)	(48,184)	(5,484)
Prepaid manufacturing	(10,851)	(672)	7,063
Other prepaid and current assets	(235)	(2,126)	1,146
Other assets, non-current	(1,785)	(348)	(1)
Accounts payable	(9,820)	9,893	(301)
Accounts payable - related parties	—	—	(233)
Accrued rebates, fees and reserve	30,409	51,120	—
Accrued compensation	6,212	10,035	8,466
Accrued and other liabilities	5,486	10,386	69
Lease liabilities	(1,439)	(2,010)	—
Other liabilities, non-current	949	(30)	(428)
Net cash provided by (used in) operating activities	154,145	28,355	(159,266)
Investing activities			
Purchases of property and equipment	(7,231)	(1,822)	(789)
Proceeds from disposal of property and equipment	175	—	—
Purchases of investments in marketable securities	(273,845)	(20,235)	(42,869)
Proceeds from maturities of investments in marketable securities	274,000	20,400	43,170
Upfront and milestone based license fee payments	(7,500)	(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	(14,401)	(12,732)	(1,188)
Financing activities			
Proceeds from common stock offering, net of underwriters discounts, commissions and offering costs	—	8,153	101,748
Proceeds from issuance of Convertible Notes due 2026, net of issuance costs	222,156	—	—
Purchase of capped call options related to Convertible Notes due 2026	(18,170)	—	—
Proceeds from term loan, net of issuance costs	—	72,955	—
Proceeds from issuance of common stock upon exercise of stock options	17,428	5,558	2,082
Proceeds from purchase under the employee stock purchase plan	3,801	3,519	1,591
Taxes paid related to net share settlement of bonus payout in RSUs	(880)	(815)	—
Principal payments for finance lease obligations	(389)	—	—
Net cash provided by financing activities	223,946	89,370	105,421
Effect of exchange rate changes in cash, cash equivalents and restricted cash	—	(276)	468
Net increase (decrease) in cash, cash equivalents and restricted cash	363,690	104,717	(54,565)
Cash, cash equivalents and restricted cash at beginning of period	177,908	73,191	127,756
Cash, cash equivalents and restricted cash at end of period	$ 541,598	$ 177,908	$ 73,191
Supplemental disclosure of cash flow information			
Cash paid for interest	$ 16,959	$ 15,263	$ 8,200
Cash paid for income taxes	3,953	1,732	—
Right-of-use assets obtained in exchange for lease obligations related to operating leases	1,388	5,267	—
Right-of-use assets obtained in exchange for lease obligations related to finance leases	1,817	—	—
Supplemental disclosures of non-cash investing and financing activities			
Purchase of property and equipment in accounts payable and accrued liabilities	109	999	272
Non-cash non-controlling interest reflected in additional paid in capital	—	—	1,359
Non-cash employee bonuses settled in common stock	1,498	1,350	—
Common stock offering costs in accounts payable and accrued liabilities	—	—	75

See accompanying notes to consolidated financial statements.

Coherus BioSciences, Inc.

Notes to Consolidated Financial Statements

1. Organization and Operations

Description of the Business

Coherus BioSciences, Inc. (the "Company" or "Coherus") is a commercial-stage biotherapeutics company, focused on the biosimilar and immuno-oncology market primarily in the United States. The Company's headquarters and laboratories are located in Redwood City, California and in Camarillo, California, respectively. The Company's product pipeline comprises of four drugs, CHS-1420 (an adalimumab (Humira) biosimilar), a ranibizumab (Lucentis) biosimilar in-licensed for U.S. and Canadian commercial rights from Bioeq AG, a bevacizumab (Avastin) biosimilar in-licensed for U.S. commercial rights from Innovent Biologics (Suzhou) Co., Ltd. and toripalimab, an anti-PD-1 antibody being developed in collaboration with Shanghai Junshi Biosciences Co., Ltd.

The Company commercializes UDENYCA® (pegfilgrastim-cbqv), a biosimilar to Neulasta, a long-acting granulocyte-colony stimulating factor, in the United States.

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, 2020: 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, 2020, the Company had an accumulated deficit of $762.8 million and cash and cash equivalents of $541.2 million. The Company had $132.2 million in net income for the year ended December 31, 2020. 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 determining 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.

During the second quarter of 2020, the Company identified that certain of its commercial payer invoices were erroneously overstated. The Company received a refund of $7.5 million from these payers related to fiscal year 2019 which resulted in an increase in net product revenue of $7.5 million for the year ended December 31, 2020. The refund adjustment resulted in an increase in basic and diluted net income per share of $0.11 and $0.09, respectively, during the year ended December 31, 2020. Accrued commercial payer rebates of $27.9 million and $14.0 million were recorded in accrued rebates, fees and reserve as of December 31, 2020 and December 31, 2019, respectively, in the consolidated balance sheet.

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, 2020, 2019 and 2018, the foreign exchange gains and losses recorded in other income, net in the consolidated statements of operations were a net loss of $333,000, net gain of $239,000 and a net loss of $571,000, 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. All revenue is generated in the United States of America and all Long-lived assets are primarily maintained in the United States of America.

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,		
	2020	2019	2018
Cash and cash equivalents	$541,158	$177,668	$ 72,356
Restricted cash	—	—	50
Restricted cash - non-current	440	240	785
Total cash, cash equivalents and restricted cash	$541,598	$177,908	$ 73,191

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

The Company classifies the up-front and milestone payments related to licensing arrangements as cash flows from investing activities in its consolidated statements of cash flows.

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 investment and reevaluates such designation as of each balance sheet date. The Company's investment policy requires that it only invests in highly-rated securities and limit its exposure to any single issuer. 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 reported as a component of accumulated comprehensive income (loss), with the exception of unrealized losses believed to be related to credit losses, which, if any, are recognized through earnings in the period the impairment occurs. Impairment assessments are made at the individual security level each reporting period. When the fair value of an investment is less than its cost at the balance sheet date, a determination is made as to whether the impairment is related to a credit loss and, if it is, the portion of the impairment relating to credit loss is recorded as an allowance through net income. 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, net, based on the specific identification method. For the years ended December 31, 2020, 2019 and 2018, interest income from marketable securities was $0.6 million, $1.6 million and $1.4 million, respectively.

Trade Receivables

Trade receivables are recorded net of allowances for chargebacks, chargeback prepayments, cash discounts for prompt payment and credit losses. The Company estimates an allowance for expected credit losses by considering factors such as historical experience, credit quality, the age of the accounts receivable balances, and current economic conditions that may affect a customer's ability to pay. The corresponding expense for the credit loss allowance is reflected in selling, general and administrative expenses. The credit loss allowance was immaterial as of December 31, 2020.

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, 2020.

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. There were no impairments recorded during the year ended December 31, 2020. For the years ended December 31, 2019 and 2018, the Company recorded an impairment of property and equipment of $0.1 million and $3.9 million, respectively, in research and development within the statement of operations.

The intangible assets of $2.6 million as of December 31, 2020 and 2019 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, 2020, 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, 2020.

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 and manufacturing 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.

Net Product Revenue

The Company accounts for sales of UDENYCA® under Topic *606 Revenue from Contracts with Customers*. 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.

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. There were no material inventory write-offs recorded during the years ended December 31, 2020 and 2018.

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, upfront and milestone payments under the licensing 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.

Costs associated with the development, validation and scaling of manufacturing processes at new third party suppliers and regulatory registration of new third-party manufacturing facilities are recognized as research and development expenses. These costs generally comprise of all costs incurred in such activities prior to the process performance qualification ("PPQ") production commencement stage at new manufacturing facilities. Costs incurred after the PPQ production commencement at new manufacturing facilities are capitalized as inventory as the regulatory approval at that point becomes probable and the net realizable value of the batches produced during this stage of the process is recoverable.

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 $3.8 million, $4.5 million and $2.8 million for the years ended December 31, 2020, 2019 and 2018, 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.

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, 2020 and 2019.

Operating and Finance Leases

The Company adopted ASU 2016-02, *Leases* on January 1, 2019. 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 years ended December 31, 2020 and 2019 are presented under Topic 842, and the results for the year ended December 31, 2018 are presented in accordance with the prior lease

guidance, ASC Topic 840: *Leases*. 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 and vehicle leases. The Company did not elect to apply the hindsight expedient.

The Company determines if an arrangement is a lease at inception. Operating leases are included in operating lease right-of-use assets, other current liabilities, and lease liabilities, non-current in the consolidated balance sheets. The Lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise any such options. The Company recognizes operating lease expense for these leases on a straight-line basis over the term of the lease.

In 2019, the Company entered into a vehicle lease agreement, pursuant to which it currently leases 42 vehicles. Delivery of the vehicles commenced during the first quarter of 2020. The term of each leased vehicle commences upon the delivery of the vehicle and is for a period of 36 months. The vehicles leased under this arrangement were classified as finance leases. Assets acquired under finance leases are included in property and equipment, net, other current liabilities, and lease liabilities, non-current in the consolidated balance sheets and are depreciated to operating expenses on a straight-line basis over their estimated useful lives.

With the exception of initial adoption of the new lease standard, where the Company's incremental borrowing rate used was the rate on the adoption date (January 1, 2019), the operating and finance lease ROU assets and the lease liabilities are recognized based on the present value of lease payments over the lease term at the lease commencement date. The Company uses its incremental borrowing rate based on the information available at the commencement date in determining the lease liabilities, as the Company's leases generally do not provide an implicit rate.

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 14).

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 foreign currency translation adjustments for the years ended December 31, 2020, 2019 and 2018.

Recent Accounting Pronouncements

The following are the recent accounting pronouncements adopted by the Company in 2020:

Effective January 1, 2020, the Company adopted ASU No. 2016-13, Financial Instruments — Credit Losses, *(Topic 326): Measurement of Credit Losses on Financial Instruments* (ASU 2016-13), which changed the impairment model for most financial assets and certain other instruments. For trade receivables and other instruments, the Company uses a new forward-looking expected loss model that generally results in the earlier recognition of allowances for losses. The Company is exposed to credit losses primarily through receivables from customers. The Company's expected loss allowance methodology for the receivables is developed using historical collection experience, current and future economic market conditions, a review of the current aging status and financial condition of the entities. Specific allowance amounts are established to record the appropriate allowance for customers that have a higher probability of default. ASU 2016-13 also eliminates the concept of "other-than-temporary" impairment when evaluating available-for-sale debt securities and instead focuses on determining whether any impairment is a result of a credit loss or other factors. An entity will recognize an allowance for credit losses on available-for-sale debt securities, rather than an other-than-temporary impairment that reduces the cost

basis of the investment. The adoption of the new guidance did not have a material impact on the Company's 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. The Company adopted this accounting standard as of January 1, 2020. The adoption did not have a material impact on the Company's 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. The Company adopted this accounting standard as of January 1, 2020. The adoption did not have a material impact on the Company's consolidated financial statements.

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

In August 2020, the FASB issued ASU No. 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging Contracts in Entity's Own Equity (Subtopic 815-40)* ("ASU 2020-06"), which reduces the number of accounting models for convertible debt instruments and convertible preferred stock as well as amends the derivatives scope exception for contracts in an entity's own equity. ASU 2020-06 is effective for the Company on January 1, 2022, with early adoption permitted. The Company is currently evaluating the potential impact that this standard may have on its consolidated financial statements and related disclosures.

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

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.

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

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, 2020			
	Total	Level 1	Level 2	Level 3
Financial Assets:				
Money market funds	$ 538,673	$ 538,673	$ —	$ —
Restricted cash (money market funds)	440	440	—	—
Total financial assets	$ 539,113	$ 539,113	$ —	$ —
Financial Liabilities:				
Contingent consideration	$ 102	$ —	$ —	$ 102

	Fair Value Measurements December 31, 2019			
	Total	Level 1	Level 2	Level 3
Financial Assets:				
Money market funds	$ 155,523	$ 155,523	$ —	$ —
Restricted cash (money market funds)	240	240	—	—
Total financial assets	$ 155,763	$ 155,763	$ —	$ —
Financial Liabilities:				
Contingent consideration	$ 102	$ —	$ —	$ 102

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, 2020 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, 2020, 2019 and 2018, the Company recognized a loss of $0, a loss of $42,000 and a gain of $3.2 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
Change in fair value of the contingent consideration liability	—
Balance as of December 31, 2020	$ 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.

1.5% Convertible Notes due 2026

The estimated fair value of the 1.5% Convertible Notes due 2026, which the Company issued in April 2020 (see Note 8) is influenced by interest rates, the Company's stock price and stock price volatility and is determined by prices observed in market trading. The market for trading of the Convertible Notes due 2026 is not considered to be an active market and therefore the estimate of fair value is based on Level 2 inputs. The estimated fair value of the Convertible Notes due 2026 was approximately $269.1 million (par value $230.0 million) as of December 31, 2020.

8.2% Convertible Notes due 2022

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 $113.7 million (par value $100.0 million) as of December 31, 2020 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.

Term Loan

The principal amount outstanding under the Company's Term Loan (see Note 8) of $75 million as of December 31, 2020 is subject to variable interest rate, which is based on a fixed percentage plus three month LIBOR ("LIBOR"), and as such, the Company believes the carrying amount of these obligations approximates fair value.

4. Inventory

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

	December 31, 2020	December 31, 2019
Raw Materials	$ 5,205	$ 5,089
Work in process	43,952	43,446
Finished goods	43,032	6,536
Total	$ 92,189	$ 55,071

Balance sheet classification (in thousands):

	December 31, 2020	December 31, 2019
Inventory	$ 44,233	$ 9,807
Inventory, non-current	47,956	45,264
Total	$ 92,189	$ 55,071

Inventory expected to be sold in periods more than twelve months from the balance sheet date is classified as inventory, non-current on the consolidated balance sheets. As of December 31, 2020 and 2019, the non-current portion of inventory consisted of raw materials and a portion of work in process.

Prepaid manufacturing of $19.4 million as of December 31, 2020 includes prepayments of $8.9 million 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; and prepayments of $10.5 million to various CMOs for other research and development pipeline programs. Prepaid manufacturing of $8.6 million as of December 31, 2019 includes prepayments of $7.2 million to a CMO for manufacturing services for UDENYCA®; and prepayments of $1.4 million to various CMOs for other research and development pipeline programs.

Other Assets, non-current of $2.1 million on the consolidated balance sheet as of December 31, 2020 primarily includes prepayments of $1.3 million made to a CMO for manufacturing services for UDENYCA®, which the Company expects to be converted into inventory after twelve months. The other assets, non current balance was immaterial as of December 31, 2019.

5. Balance Sheet Components

Property and Equipment, Net

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

	December 31, 2020	December 31, 2019
Machinery and equipment	$ 13,301	$ 12,611
Computer equipment and software	3,996	2,923
Furniture and fixtures	1,268	714
Leasehold improvements	5,830	4,388
Finance lease right of use assets	1,451	—
Construction in progress	312	1,500
Total property and equipment	26,158	22,136
Accumulated depreciation and amortization	(16,050)	(16,296)
Property and equipment, net	$ 10,108	$ 5,840

Depreciation and amortization expense was $2.9 million, $3.3 million and $3.2 million for the years ended December 31, 2020, 2019 and 2018, respectively. During the year ended December 31, 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. There were no material impairments of property and equipment for the years ended December 31, 2020 and 2019.

Accrued Liabilities

Accrued liabilities are as follows (in thousands):

	December 31, 2020	December 31, 2019
Accrued clinical and manufacturing	$ 11,365	$ 7,106
Accrued other	11,453	10,152
Accrued liabilities	$ 22,818	$ 17,258

6. Revenue

The Company initiated U.S. sales of UDENYCA® on January 3, 2019. The Company recorded net product revenue of $475.8 million and $356.1 million during the years ended December 31, 2020 and 2019, respectively. There was no product revenue during the year ended December 31, 2018.

Revenue by significant Customer was distributed as follows:

	Year Ended December 31, 2020 Percent of Total	Year Ended December 31, 2019 Percent of Total
McKesson	38 %	42 %
AmeriSource-Bergen Corp	37 %	33 %
Cardinal	23 %	23 %
Others	2 %	2 %
Total revenue	100 %	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):

	Year Ended December 31, 2020			
	Chargebacks and Discounts for Prompt Payment	Rebates	Other Fees, Co-pay Assistance and Returns	Total
Balance at December 31, 2019	$ 35,159	$ 27,494	$ 24,494	$ 87,147
Provision related to sales made in:				
Current period	462,328	115,864	114,372	692,564
Prior period	(1,336)	(3,438)	(6,288)	(11,062)
Payments and customer credits issued	(455,571)	(85,862)	(103,818)	(645,251)
Balance at December 31, 2020	$ 40,580	$ 54,058	$ 28,760	$ 123,398

	Year Ended December 31, 2019			
	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. Licensing Arrangements

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 accounted for 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. As of December 31, 2020 and 2019, the Company did not have any outstanding obligations for milestones and royalties to Bioeq.

Innovent Biologics (Suzhou) Co., Ltd.

On January 13, 2020, 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 "Innovent 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 an Innovent 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 Innovent 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 Innovent Licensed Products in the Territory and, upon completion of such technology transfer, the Company will have the exclusive right to manufacture the Innovent Licensed Products in the Territory.

Under the agreement, the Company committed to pay Innovent a $5.0 million upfront payment and 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 Innovent Licensed Products with Innovent in the mid-teens to low twenty percent range. If the Company exercises its option to acquire Innovent's biosimilar version of rituximab (Rituxan®), it would be required to pay a 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 Innovent Licensed Products, it would be required to pay up to $10.0 million for fees related thereto. The Company accounted for the licensing transaction as an asset acquisition under the relevant accounting rules. The Company recorded research and development expense of $7.5 million during the year ended December 31, 2020 related to an upfront payment and a milestone payment for the bevacizumab Licensed Product. As of December 31, 2020 the Company did not have any outstanding milestone or royalty payment obligations to Innovent.

The additional milestone payments, option fee for licensing of rituximab (Rituxan®), manufacturing technology transfer fee and royalties are contingent upon future events and, therefore, will be recorded when it is probable that a milestone will be achieved, option fee or manufacturing technology transfer fee will be incurred or when royalties are due.

8. Debt Obligations

1.5% Convertible Senior Subordinated Notes due 2026

In April 2020, the Company issued and sold $230.0 million aggregate principal amount of its 1.5% convertible senior subordinated notes due 2026 (the "2026 Convertible Notes") in a private offering to qualified institutional buyers pursuant to Rule 144A under the Securities Act. The net proceeds from the offering were $222.2 million after deducting initial purchasers' fees and offering expenses. The 2026 Convertible Notes are general unsecured obligations and will be subordinated to the Company's designated senior indebtedness (as defined in the indenture for the 2026 Convertible Notes) and structurally subordinated to all existing and future indebtedness and other liabilities, including trade payables. The 2026 Convertible Notes accrue interest at a rate of 1.5% per annum, payable semi-annually in arrears on April 15 and October 15 of each year, beginning on October 15, 2020, and will mature on April 15, 2026, unless earlier repurchased or converted.

At any time before the close of business on the second scheduled trading day immediately before the maturity date, noteholders may convert their 2026 Convertible Notes at their option into shares of the Company's common stock, together, if applicable, with cash in lieu of any fractional share, at the then-applicable conversion rate. The initial conversion rate is 51.9224 shares of common stock per $1,000 principal amount of the 2026 Convertible Notes, which represents an initial conversion price of approximately $19.26 per share of common stock. The initial conversion price represents a premium of approximately 30.0% over the last reported sale of $14.815 per share of the Company's common stock on the Nasdaq Global Market on April 14, 2020. The conversion rate and conversion price will be subject to customary adjustments upon the occurrence of certain events. If a "make-whole fundamental change" (as defined in the indenture for the 2026 Convertible Notes) occurs, the Company will, in certain circumstances, increase the conversion rate for a specified period of time for noteholders who convert their 2026 Convertible Notes in connection with that make-whole fundamental change. The 2026 Convertible Notes are not redeemable at the Company's election before maturity. If a "fundamental change" (as defined in the indenture for the 2026 Convertible Notes) occurs, then, subject to a limited exception, noteholders may require the Company to repurchase their 2026 Convertible Notes for cash. The repurchase price will be equal to the principal amount of the 2026 Convertible Notes to be repurchased, plus accrued and unpaid interest, if any, to, but excluding, the applicable repurchase date.

The 2026 Convertible Notes will have customary provision relating to the occurrence of "events of default" (as defined in the Indenture for the 2026 Convertible Notes). The occurrence of such events of default could result in the acceleration of all amounts due under the 2026 Convertible Notes.

As of December 31, 2020, the Company was in full compliance with these covenants and there were no events of default under the 2026 Convertible Notes.

The 2026 Convertible Notes are accounted for in accordance with ASC 470-20, *Debt with Conversion and Other Options* ("ASC 470-20") and ASC 815-40, *Contracts in Entity's Own Equity* ("ASC 815-40"). Under ASC 815-40, to qualify for equity classification (or nonbifurcation, if embedded) the instrument (or embedded feature) must be both (1) indexed to the issuer's stock and (2) meet the

requirements of the equity classification guidance. The Company determined that the 2026 Convertible Notes do contain embedded features indexed to its own stock, but do not meet the requirements for bifurcation, and therefore do not need to be separately accounted for as an equity component. Since the embedded conversion feature meets the equity scope exception from derivative accounting, and also since the embedded conversion option does not need to be separately accounted for as an equity component under ASC 470-20, the proceeds received from the issuance of the convertible debt were recorded as a liability on the consolidated balance sheet.

Capped Call Transactions

In connection with the pricing of the 2026 Convertible Notes, the Company also paid $18.2 million to enter into privately negotiated capped call transactions with one or more of the Option Counterparties. The capped call transactions are generally expected to reduce the potential dilution upon conversion of the 2026 Convertible Notes in the event that the market price per share of the Company's common stock, as measured under the terms of the capped call transactions, is greater than the strike price of the capped call transactions, which initially corresponds to the conversion price of the 2026 Convertible Notes, and is subject to anti-dilution adjustments generally similar to those applicable to the conversion rate of the 2026 Convertible Notes. The cap price of the capped call transactions will initially be $25.9263 per share, which represents a premium of approximately 75.0% over the last reported sale price of the Company's common stock of $14.815 per share on April 14, 2020, and is subject to certain adjustments under the terms of the capped call transactions.

The Company evaluated the capped call transactions under ASC 815-10 and determined that it should be accounted as a separate transaction from the 2026 Convertible Notes and that the capped calls should be classified as equity instruments. Therefore, the capped call premium paid in the amount of $18.2 million was recorded as a reduction to additional paid-in capital. The capped calls will not be subsequently re-measured as long as the conditions for equity classification continue to be met.

The Company incurred $0.9 million of debt issuance costs relating to the issuance of the 2026 Convertible Notes, which were recorded as a reduction to the notes on the consolidated balance sheet. The debt issuance costs is being amortized and recognized as additional interest expense over the six-year contractual term of the notes using the effective interest rate method.

The following table summarizes information about the components of the 2026 Convertible Notes (in thousands):

	December 31, 2020
Principal amount of the 2026 Convertible Notes	$ 230,000
Unamortized debt discount and debt issuance costs	(6,971)
Total 2026 Convertible Notes	$ 223,029

If the 2026 Convertible Notes were to be converted on December 31, 2020, the holders of the 2026 Convertible Notes would receive common shares with an aggregate value of $207.6 million based on the Company's closing stock price of $17.38 as of December 31, 2020.

The following table presents the components of interest expense related to 2026 Convertible Notes (in thousands):

	Year Ended December 31, 2020
Stated coupon interest	$ 2,434
Accretion of debt discount and debt issuance costs	873
Total interest expense	$ 3,307

The remaining unamortized debt discount and debt offering costs related to the Company's 2026 Convertible Notes of approximately $7.0 million as of December 31, 2020, will be amortized using the effective interest rate over the remaining term of the 2026 Convertible Notes of 5.3 years. The annual effective interest rate is 2.11% for the 2026 Convertible Notes.

Future payments on the 2026 Convertible Notes as of December 31, 2020 are as follows (in thousands):

Year ending December 31,	
2021	3,450
2022	3,450
2023	3,450
2024	3,450
2025 and beyond	235,175
Total minimum payments	248,975
Less amount representing interest	(18,975)
2026 Convertible Notes, principal amount	230,000
Less debt discount and debt issuance costs on 2026 Convertible Notes	(6,971)
Net carrying amount of 2026 Convertible Notes	$ 223,029

8.2% Convertible Notes due 2022

On February 29, 2016, the Company issued and sold $100.0 million aggregate principal amount of its 8.2% Convertible Senior Notes (the "2022 Convertible Notes") and received total net proceeds of approximately $99.2 million, after deducting issuance costs of $0.8 million. The 2022 Convertible Notes constitute general, senior unsubordinated obligations of the Company and are guaranteed by certain subsidiaries of the Company. The 2022 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 2022 Convertible Notes at a rate of up to 0.50% per annum in the aggregate. The 2022 Convertible Notes also bear a premium of 9% of their principal amount, which is payable when the 2022 Convertible Notes mature or are repurchased or redeemed by the Company.

The 2022 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 2022 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 2022 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 2022 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 2022 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 2022 Convertible Notes. At maturity or redemption, if not earlier converted, the Company will pay 109% of the principal amount of the 2022 Convertible Notes maturing or being redeemed, together with accrued and unpaid interest, in cash.

The 2022 Convertible Notes contain customary events of default (as defined in the 2022 Convertible Note purchase agreement), the occurrence of which could result in the acceleration of all amounts due under the 2022 Convertible Notes. These events of default include, among others, certain failures to pay amounts due on the 2022 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 2022 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, 2020, the Company was in full compliance with these covenants and there were no events of default under the 2022 Convertible Notes.

The 2022 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 2022 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 2022 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 2022 Convertible Notes.

On April 13, 2020, the Company entered into an amendment (the "Second Amendment") to the 2022 Convertible Note Purchase Agreement, dated as of February 29, 2016 (the "Note Purchase Agreement"), which amended the definition of Restricted Payment to exclude any payment (including a premium) to a counterparty under a Permitted Bond Hedge Transaction (as defined in the Note Purchase Agreement). The Second Amendment also added to the Note Purchase Agreement a definition of Permitted Bond Hedge Transaction, with such definition including any capped call option (or substantively equivalent derivative transaction) relating to the Company's common stock purchased by it in connection with any issuance of indebtedness or convertible indebtedness.

The following table summarizes information about the components of the 2022 Convertible Notes as of December 31, 2020 and 2019 (in thousands):

	December 31, 2020	December 31, 2019
Principal amount of the 2022 Convertible Notes	$ 81,750	$ 81,750
Unamortized debt discount and debt issuance costs	(1,865)	(3,208)
2022 Convertible Notes	$ 79,885	$ 78,542
Principal amount of the 2022 Convertible Notes - related parties	$ 27,250	$ 27,250
Unamortized debt discount and debt issuance costs - related parties	(622)	(1,069)
2022 Convertible Notes - related parties	$ 26,628	$ 26,181
Total 2022 Convertible Notes	$ 106,513	$ 104,723

If the 2022 Convertible Notes were converted on December 31, 2020, the holders of the 2022 Convertible Notes would receive common shares with an aggregate value of $77.8 million based on the Company's closing stock price of $17.38.

The following table presents the components of interest expense of the 2022 Convertible Notes for the years ended December 31, 2020, 2019 and 2018 (in thousands):

	Year Ended December 31,		
	2020	2019	2018
Stated coupon interest	$ 6,150	$ 6,150	$ 6,150
Accretion of debt discount and debt issuance costs	1,343	1,223	1,113
Interest expense	$ 7,493	$ 7,373	$ 7,263
Stated coupon interest - related parties	$ 2,050	$ 2,050	$ 2,050
Accretion of debt discount and debt issuance costs - related parties	448	407	371
Interest expense - related parties	$ 2,498	$ 2,457	$ 2,421
Total interest expense	$ 9,991	$ 9,830	$ 9,684

The remaining unamortized debt discount and debt offering costs related to the Company's 2022 Convertible Notes of approximately $2.5 million as of December 31, 2020, will be amortized using the effective interest rate over the remaining term of the 2022 Convertible Notes of 1.25 years. The annual effective interest rate is 9.48% for the 2022 Convertible Notes.

Future payments on the 2022 Convertible Notes as of December 31, 2020 are as follows (in thousands):

Year ending December 31,	
2021	8,200
2022	111,050
Total minimum payments	119,250
Less amount representing interest	(10,250)
2022 Convertible Notes, principal amount	109,000
Less debt discount and debt issuance costs on 2022 Convertible Notes	(2,487)
Net carrying amount of 2022 Convertible Notes	$ 106,513

Term Loan

On January 7, 2019 (“the “Term Loan Closing Date”), the Company 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”). The obligations of the Company under the loan documents are guaranteed by the Company’s material domestic U.S. subsidiaries.

The Borrowings under the Term Loan bear interest through maturity at 7.00% per annum plus three month LIBOR. Pursuant to the terms of the Term Loan, the interest rate was reduced to 6.75% per annum plus LIBOR as of January 1, 2020 as the consolidated net sales for UDENYCA® for the fiscal year ending December 31, 2019 were in excess of $250.0 million. 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, 2020, the effective interest rate is 10.47%.

The Company is 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.

The Company is 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 the Company 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 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, the Company 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), it 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 Term Loan are secured by a lien on substantially all of the Company’s and its 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 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 Lender under the Term Loan to declare the Borrowings, together with accrued interest and fees, to be immediately due and payable.

On April 13, 2020, the Company entered into an amendment to the Term Loan, which amended the Term Loan's indebtedness covenant such that the Company could incur Convertible Bond Indebtedness (as defined in the credit agreement governing the Term Loan) in an amount not to exceed the greater of $230.0 million or 20% of the Company's market capitalization.

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

	December 31, 2020	December 31, 2019
Principal amount of the Term Loan	$ 75,000	$ 75,000
Unamortized debt discount and debt issuance costs	(519)	(1,337)
Term Loan	$ 74,481	$ 73,663

The following table presents the components of interest expense:

	Year Ended	
	December 31, 2020	December 31, 2019
Stated coupon interest	$ 7,053	$ 7,063
Accretion of debt discount and debt issuance costs	818	709
Interest expense	$ 7,871	$ 7,772

The remaining unamortized debt discount and debt offering costs related to the Term Loan of approximately $0.5 million as of December 31, 2020, will be amortized using the effective rate over the remaining term of the Term Loan of 4 years.

Future payments on the Term Loan as of December 31, 2020 are as follows (in thousands):

Year ending December 31,	
2021	7,034
2022	7,034
2023	39,187
2024	36,072
2025	11,348
Total minimum payments	100,675
Less amount representing interest	(22,675)
Term Loan, gross	78,000
Less debt discount and debt issuance costs on Term Loan	(3,519)
Net carrying amount of Term Loan	$ 74,481

9. Commitments and Contingencies

Purchase Commitments

The Company entered into agreements with a vendor to secure raw materials and a CMO to manufacture its commercial supply of UDENYCA®. As of December 31, 2020, the Company's contractual obligations under the terms of the agreements are as follows (in thousands):

Years ending December 31,	
2021	40,963
2022	15,946
2023	9,753
Total obligations	$ 66,662

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.

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 47,789 square feet. The Lease Agreement, provides for certain limited rent abatement and contains annual scheduled rent increases over the lease term. The lease terminates in September 2024 and contains a one-time option to extend the lease term for five years.

The Company also leases laboratory facilities in Camarillo, California. 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 in Camarillo, California as the current Camarillo

leases terminated 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 commenced in January 2020 and terminates in May 2027, and contains a one-time option to extend the lease term for five years.

The Company determined that the above facility leases were operating leases. The options to extend the lease terms for these leases were not included as part of the right-of-use asset or lease liability as the Company was not reasonably certain it would exercise those options.

In 2019, the Company entered into a vehicle lease agreement, pursuant to which it currently leases 42 vehicles. Delivery of the vehicles commenced during the first quarter of 2020. The term of each leased vehicle commences upon the delivery of the vehicle and is for a period of 36 months. The vehicles leased under this arrangement were classified as finance leases.

In determining the present value of the lease payments, the Company used the incremental borrowing rate based on the information available on January 1, 2019 (adoption date of ASC 842) for the leases that commenced prior to that date. For all other leases, the Company used the incremental borrowing rate on the lease commencement or the lease modification date, as applicable.

The supplemental information related to Company's leases is as follows (in thousands):

Assets	Balance Sheet Classification	December 31, 2020	December 31, 2019
Operating lease	Operating lease right-of-use assets	$ 9,956	$ 10,649
Finance lease	Property and equipment, net	1,451	—
Total leased assets		$ 11,407	$ 10,649

Liabilities	Balance Sheet Classification	December 31, 2020	December 31, 2019
Operating lease liabilities, current	Other current liabilities	$ 2,573	$ 2,196
Operating lease liabilities, non-current	Lease liabilities, non-current	9,073	10,256
Total operating lease liabilities		$ 11,646	$ 12,452
Finance lease liabilities, current	Other current liabilities	$ 560	$ —
Finance lease liabilities, non-current	Lease liabilities, non-current	875	—
Total finance lease liabilities		$ 1,435	$ 0

Operating lease costs were $3.1 million, $2.4 million and $2.2 million for the years ended December 31, 2020, 2019 and 2018, respectively. Cash paid for amounts included in the measurement of the operating lease liabilities for the years ended December 31, 2020 and 2019 was $3.2 million and $2.7 million, respectively, and was included in net cash used in operating activities in the consolidated statements of cash flows. Finance lease costs and cash paid for amounts included in the measurement of finance lease liabilities were immaterial during the years ended December 31, 2020 and 2019.

As of December 31, 2020, the maturities of the operating lease liabilities were as follows (in thousands):

Years ending December 31,	Operating leases	Finance leases
2021	3,425	626
2022	3,293	626
2023	3,438	285
2024	2,889	—
2025 and beyond	699	—
Total lease payments	13,744	1,537
Less imputed interest	(2,098)	(102)
Operating lease liabilities	$ 11,646	$ 1,435

As of December 31, 2020 and 2019, the weighted average remaining lease term for operating leases was 4.1 years and 4.7 years, respectively. The weighted average discount rate used to determine the operating lease liabilities was 8.1% and 8.2% as of December 31, 2020 and 2019, respectively. The weighted average remaining lease term for finance leases was 2.4 years as of December 31, 2020. The weighted average discount rate used to determine the finance lease liabilities was 5.8% as of December 31, 2020.

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, 2020, the Company had 240,467 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, 2020, the Company had 238,589 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, 2019	17,811,671	$ 14.582
Granted - at fair value	4,535,550	17.890
Exercised	(1,704,764)	10.008
Forfeited/Cancelled	(1,627,622)	18.926
Balances at December 31, 2020	19,014,835	$ 15.409

Additional information related to the status of options as of December 31, 2020 is summarized as follows:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Terms (Years)	Aggregate Intrinsic Value (in thousands)
Options outstanding	19,014,835	15.409	6.60	72,425,719
Options vested and exercisable	11,866,172	14.974	5.54	58,173,433

During the years ended December 31, 2020, 2019 and 2018, the estimated weighted-average grant-date fair value of options granted was $10.94, $9.52 and $7.77 per share, respectively, and the aggregate intrinsic value of options exercised was $14.6 million, $10.3 million and $4.9 million, respectively.

The Company recognized stock-based compensation expenses of $30.3 million, $31.4 million and $33.3 million for the years ended December 31, 2020, 2019 and 2018, respectively, related to stock options. As of December 31, 2020, total unrecognized stock-based compensation expenses related to unvested employee stock options was $68.5 million, which is expected to be recognized on a straight-line basis over a weighted-average period of approximately 2.6 years.

Restricted Stock Units

In August 2017, the Compensation Committee of the Company's board of directors approved the granting of restricted stock units ("RSUs") to its employees. RSUs are share awards that entitle the holder to receive freely tradable shares of our common stock upon vesting. The RSUs cannot be transferred and are subject to forfeiture if the holder's employment terminates prior to the release of the vesting restrictions. The Company's RSUs generally vest 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, 2019	104,750	$ 19.544
RSUs granted	1,186,124	17.860
RSUs vested	(223,767)	18.380
RSUs cancelled	(57,450)	17.969
Balances at December 31, 2020	1,009,657	$ 17.913

The total fair value of RSUs vested was $4.1 million, $2.7 million and $1.0 million during the years ended December 31, 2020, 2019 and 2018 respectively. The total estimated grant date fair value of RSUs was $21.2 million, $4.3 million and $78,000 granted during the years ended December 31, 2020, 2019 and 2018, respectively. The estimated weighted-average grant-date fair value per share of RSUs granted during the years ended December 31, 2020, 2019 and 2018 was $17.86, $15.11 and $15.60, respectively.

The Company recognized stock-based compensation expense related to RSUs of $6.5 million, $0.8 million and $0.7 million for the years ended December 31, 2020, 2019 and 2018, respectively. As of December 31, 2020, total unrecognized stock-based compensation expenses related to unvested RSUs was $12.6 million, which is expected to be recognized on a straight-line basis over a weighted-average period of approximately 1.8 years.

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 2,752,449 shares of common stock available for future issuance as of December 31, 2020. 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 $1.4 million, $1.3 million and $0.8 million for the years ended December 31, 2020, 2019 and 2018, respectively. As of December 31, 2020, there was $0.7 million of unrecognized compensation expense associated with the ESPP, which is expected to be recognized over an estimated weighted-average period of 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,		
	2020	2019	2018
Cost of goods sold (1)	$ 583	$ 108	$ —
Research and development	13,837	12,912	15,339
Selling, general and administrative	23,740	20,571	19,458
Stock-based compensation expense	$38,160	$33,591	$34,797
Capitalized stock-based compensation expense into inventory	$ 1,460	$ 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, 2020, 2019 and 2018:

	Year Ended December 31,		
	2020	2019	2018
Expected term (years)			
Stock options	6.10	6.00	6.00
ESPP	0.50	0.50	0.50
Expected volatility			
Stock options	68 %	69 %	71 %
ESPP	58 %	61 %	71 %
Risk-free interest rate			
Stock options	1.09 %	2.29 %	2.77 %
ESPP	0.13 %	1.89 %	2.40 %
Expected dividend yield			
Stock options	—%	—%	—%
ESPP	—%	—%	—%

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 years ended December 31, 2020 and 2019 is based on the Company's historical stock price volatility. The expected volatility for the year ended December 31, 2018 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 90% of their annual compensation or the statutorily prescribed annual limit allowable under Internal Revenue Service regulations. The Company made matching contributions of 50% of the first $6,000 of each participant's contributions into the 401(k) Plan during the years ended December 31, 2020 and 2019. The Company recorded compensation expense related to the match of $0.8 million for each of the years ended December 31, 2020 and 2019.

13. Income Taxes

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

	Year Ended December 31,		
	2020	2019	2018
Domestic	$133,615	$92,584	$(208,843)
Foreign	2,092	190	(496)
Total	$135,707	$92,774	$(209,339)

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

	Year Ended December 31,		
	2020	2019	2018
Current			
Federal	$ —	$ —	$ —
State	3,463	2,942	—
Foreign	—	—	—
Subtotal	$ 3,463	$ 2,942	$ —
Deferred			
Federal	$ —	$ —	$ —
State	—	—	—
Foreign	—	—	—
Subtotal	$ —	$ —	$ —
Provision for income taxes	$ 3,463	$ 2,942	$ —

Income tax provision for the years ended December 31, 2020 and 2019 of $3.5 million and $2.9 million, respectively, primarily relates to state taxes in jurisdictions outside of California, for which the Company has a limited operating history. There was no income tax provision for the year ended December 31, 2018 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,		
	2020	2019	2018
Percent of pre-tax income:			
U.S. federal statutory income tax rate	21.00 %	21.00 %	21.00 %
State taxes, net of federal benefit	1.95	1.51	0.16
Foreign rate differences	(0.32)	(0.04)	(0.05)
Permanent items	0.36	(0.64)	0.15
Research and development credit	(4.76)	(4.77)	2.61
Stock based compensation costs	1.31	1.26	(0.84)
Other	(0.28)	(0.71)	3.07
Change in valuation allowance	(16.71)	(14.44)	(26.10)
Effective income tax rate	2.55 %	3.17 %	— %

Significant components of the Company's net deferred tax assets as of December 31, 2020 and 2019 consist of the following (in thousands):

	December 31,	
	2020	2019
Net operating loss carryforwards	$ 94,043	$ 138,663
Research and development credits	49,965	43,879
Depreciation and amortization	9,672	7,230
Stock-based compensation	25,983	22,807
Sales related accruals	16,404	7,137
Other accruals	8,013	6,927
Gross deferred tax assets	204,080	226,643
Right-of-use asset	(2,566)	(2,396)
In-process research and development	(589)	(589)
Gross deferred tax liabilities	(3,155)	(2,985)
Total net deferred tax asset	200,925	223,658
Less valuation allowance	(200,925)	(223,658)
Net deferred tax assets	$ —	$ —

ASC 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 $22.7 million and $13.4 million during the years ended December 31, 2020 and 2019, respectively and increased by $54.6 million during the year ended December 31, 2018.

As of December 31, 2020, the Company had federal net operating loss carryforwards of approximately $430.3 million, which will start to expire beginning in 2036, and various state net operating loss carryforwards of approximately $44.6 million, which have various expiration dates beginning in 2031.

As of December 31, 2020, the Company had federal research and development credit carryforwards for federal income tax purposes of approximately $48.2 million, which will start to expire in 2031, and state research and development credit carryforwards of approximately $18.0 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, 2020 and 2019. 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, 2020, 2019 and 2018 is as follows (in thousands):

	Year Ended December 31,		
	2020	2019	2018
Balance at beginning of year	$11,603	$18,115	$15,682
Additions based on tax positions related to current year	1,749	1,206	1,276
Additions (reductions) for tax positions of prior years	(109)	(7,718)	1,157
Balance at end of year	$13,243	$11,603	$18,115

As of December 31, 2020, 2019 and 2018, the Company had approximately $13.2 million, $11.6 million and $18.1 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, 2020, 2019 and 2018 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.

14. 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,		
	2020	2019	2018
Basic net income (loss) per share			
Numerator:			
Net income (loss) attributable to Coherus	$ 132,244	$ 89,833	$ (209,339)
Denominator:			
Weighted-average common shares outstanding	71,411,705	69,679,916	65,034,827
Basic net income (loss) per share attributable to Coherus	$ 1.85	$ 1.29	$ (3.22)
Diluted net income (loss) per share			
Numerator:			
Net income (loss) attributable to Coherus	$ 132,244	$ 89,833	$ (209,339)
Add interest expense on 2026 convertible notes, net of tax	3,307	—	—
Numerator for diluted (loss) net income per share attributable to Coherus	135,551	89,833	(209,339)
Denominator:			
Denominator for basic net income (loss) per share attributable to Coherus	71,411,705	69,679,916	65,034,827
Add effect of potential dilutive securities:			
Stock options, including purchases from contributions to ESPP	3,455,646	3,491,272	—
Restricted stock units	167,597	14,755	—
Shares issuable upon conversion of 2026 Convertible Notes	8,456,950	—	—
Denominator for diluted net income (loss) per share attributable to Coherus	83,491,898	73,185,943	65,034,827
Diluted net income (loss) per share attributable to Coherus	$ 1.62	$ 1.23	$ (3.22)

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,		
	2020	2019	2018
Stock options, including purchases from contributions to ESPP	9,521,403	10,412,471	14,743,547
Restricted stock units	7,689	22,068	44,387
Shares issuable upon conversion of 2022 Convertible Notes	4,473,871	4,473,871	4,473,871
Total	14,002,963	14,908,410	19,261,805

15. 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 during year ended December 31, 2018 for services rendered by Medpace within research and development expense in the consolidated statements of operations.

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.

16. Subsequent Events

On February 1, 2021, the Company entered into an Exclusive License and Commercialization Agreement (the "Collaboration Agreement") with Junshi Biosciences for the co-development and commercialization of toripalimab, Junshi Biosciences' anti-PD-1 antibody in the United States and Canada.

Under the terms of the Collaboration Agreement, the Company will pay $150.0 million upfront for exclusive rights to toripalimab in the United States and Canada, options in these territories to Junshi Biosciences' anti-TIGIT antibody and next-generation engineered IL-2 cytokine, and certain negotiation rights to two undisclosed preclinical immuno-oncology drug candidates. The Company will have the right to conduct all commercial activities of toripalimb in the United States and Canada. The Company will be obligated to pay Junshi Biosciences a 20% royalty on net sales of toripalimab and up to an aggregate $380.0 million in one-time payments for the achievement of various milestones, including up to $290.0 million for attainment of certain sales thresholds. If the Company exercise its options, it will be obligated to pay an option exercise fee for each of the anti-TIGIT antibody and the IL-2 cytokine of $35.0 million per program. Additionally, for each exercised option, the Company will be obligated to pay Junshi Biosciences an 18% royalty on net sales and up to an aggregate $255.0 million for the achievement of various milestones, including up to $170.0 million for attainment of certain sales thresholds. Under the Collaboration Agreement, the Company retains the right to collaborate in the development of toripalimab and the

other licensed compounds, and will pay for a portion of these co-development activities up to a maximum of $25.0 million per licensed compound per year.

Closing of the Collaboration Agreement is subject to clearance under the Hart-Scott Rodino Antitrust Improvements Act (the “HSR Act”).

In connection with the Collaboration Agreement, the Company entered into a stock purchase agreement (the “Stock Purchase Agreement”) with Junshi Biosciences agreeing, subject to customary conditions, to acquire certain equity interests in the Company. Pursuant to the Stock Purchase Agreement, the Company has agreed to issue 2,491,988 unregistered shares of its common stock, at a price per share of $20.0643, for an aggregate value of approximately $50.0 million, to Junshi Biosciences as a portion of the consideration for the Collaboration.

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, 2020. 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, 2020, 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, 2020, 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, 2020 and 2019, 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, 2020, and the related notes and our report dated February 25, 2021 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 Annual 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 25, 2021

Changes in Internal Control Over Financial Reporting.

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended December 31, 2020 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 (the “Proxy Statement”) with the Securities and Exchange Commission within 120 days after the end of our year ended December 31, 2020.

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	11/18/2020	3.1	
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.	10-K	2/27/2020	4.3	
4.4	Indenture, dated April 17, 2020, by and between Coherus BioSciences, Inc. and U.S. Bank National Association.	8-K	4/17/2020	4.1	
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	

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
10.11†	Master Services Agreement, effective January 23, 2012, by and between Medpace, Inc. and BioGenerics, Inc.	S-1	9/25/2014	10.15	
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, by and 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, by and 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)	

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
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)	
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.	10-Q	11/06/2017	10.2	
10.25	Credit Agreement, dated as of January 7, 2019, by and among 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.	10-Q	11/8/2019	10.2	
10.29††	License Agreement, dated November 4, 2019, by and between Coherus BioSciences, Inc. and Bioeq IP AG	10-K	2/27/2020	10.29	
10.30††	License Agreement, dated January 13, 2020, by and between Coherus BioSciences, Inc. and Innovent Biologics (Suzhou) Co., Ltd.	10-K	2/27/2020	10.30	
10.31	Second Amendment to Senior Convertible Note Purchase Agreement, dated April 13, 2020, by and among Coherus Biosciences, Inc., the Guarantors party thereto and HealthCare Royalty Partners III, L.P.	8-K	4/14/2020	10.1	
10.32	First Amendment to Credit Agreement, dated as of April 13, 2020, by and among Coherus Biosciences, Inc. and affiliates of Healthcare Royalty Partners.	8-K	4/14/2020	10.2	
10.34††	Form of Confirmation for Base Capped Call Transactions under the Indenture.	8-K	4/17/2020	10.1	
10.36	Separation Agreement, dated as of August 23, 2019, by and between Coherus BioSciences, Inc. and Darlene Horton.	10-Q	5/7/2020	10.4	
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

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
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
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, 2020 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 25, 2021

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

POWER OF ATTORNEY

KNOW ALL PERSONS 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 25, 2021
/s/ Jean-Frédéric Viret, Ph.D. Jean-Frédéric Viret, Ph.D.	Chief Financial Officer *(Principal Financial and Accounting Officer)*	February 25, 2021
/s/ James I. Healy, M.D., Ph.D. James I. Healy, M.D., Ph.D.	Director	February 25, 2021
/s/ V. Bryan Lawlis, Ph.D. V. Bryan Lawlis, Ph.D.	Director	February 25, 2021
/s/ Samuel R. Nussbaum Samuel R. Nussbaum, M.D.	Director	February 25, 2021
/s/ Ali J. Satvat Ali J. Satvat	Director	February 25, 2021
/s/ Alan C. Mendelson Alan C. Mendelson	Director	February 25, 2021
/s/ Mark D. Stolper Mark D. Stolper	Director	February 25, 2021
/s/ Mary T. Szela Mary T. Szela	Director	February 25, 2021
/s/ Kimberly J. Tzoumakas Kimberly J. Tzoumakas	Director	February 25, 2021
/s/ Mats Wahlström Mats Wahlström	Director	February 25, 2021

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, 333-236068, and 333-251876) 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, 333-236065, and 333-251877) pertaining to the 2016 Employment Commencement Incentive Plan; of Coherus BioSciences, Inc. of our reports dated February 25, 2021, 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, 2020.

/s/ Ernst & Young LLP

Redwood City, California
February 25, 2021

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO
SECTION 13a-14(a) OR 15d-14(a) 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(s) 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(s) 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 25, 2021

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

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO
SECTION 13a-14(a) OR 15d-14(a) 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(s) 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(s) 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 25, 2021

/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, 2020 (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 25, 2021

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

Date: February 25, 2021

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.