

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, 2022

OR

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

For the transition period from _____ to _____

Commission File Number: 001-36721

Coherus BioSciences, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

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

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

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

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

Title of each class	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	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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.

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b).

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, 2022 (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 \$443,562,973. 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 February 28, 2023 was 79,609,789.

DOCUMENTS INCORPORATED BY REFERENCE

Part III incorporates by reference certain information from the registrant's definitive proxy statement for the 2023 Annual Meeting of Stockholders.

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

	<u>Page</u>
<u>PART I</u>	
<u>ITEM 1.</u> Business	3
<u>ITEM 1A.</u> Risk Factors	22
<u>ITEM 1B.</u> Unresolved Staff Comments	70
<u>ITEM 2.</u> Properties	70
<u>ITEM 3.</u> Legal Proceedings	70
<u>ITEM 4.</u> Mine Safety Disclosures	70
<u>PART II</u>	
<u>ITEM 5.</u> Market for Registrant’s Common Equity, Related Stockholder Matters, and Issuer Purchases of Equity Securities	70
<u>ITEM 6.</u> [Reserved]	71
<u>ITEM 7.</u> Management’s Discussion and Analysis of Financial Condition and Results of Operations	71
<u>ITEM 7A.</u> Quantitative and Qualitative Disclosures About Market Risk	86
<u>ITEM 8.</u> Financial Statements and Supplementary Data	87
<u>ITEM 9.</u> Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	125
<u>ITEM 9A.</u> Controls and Procedures	125
<u>ITEM 9B.</u> Other Information	128
<u>ITEM 9C.</u> Disclosure Regarding Foreign Jurisdictions that Prevent Inspections	128
<u>PART III</u>	
<u>ITEM 10.</u> Directors, Executive Officers and Corporate Governance	129
<u>ITEM 11.</u> Executive Compensation	129
<u>ITEM 12.</u> Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	129
<u>ITEM 13.</u> Certain Relationships and Related Transactions, and Director Independence	129
<u>ITEM 14.</u> Principal Accounting Fees and Services	129
<u>PART IV</u>	
<u>ITEM 15.</u> Exhibits and Financial Statement Schedules	130
<u>ITEM 16.</u> Form 10-K Summary	130
Signatures	134

UDENYCA®, YUSIMRY™ and CIMERLI®, whether or not appearing in large print or with the trademark symbol, are trademarks of Coherus, its affiliates, related companies or its licensors or joint venture partners, unless otherwise noted. Trademarks and trade names of other companies appearing in this Annual Report on Form 10-K are, to the knowledge of Coherus, the property of their respective owners.

[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. These forward-looking statements include, but are not limited to, statements about:

- *whether we will be able to continue to maintain or increase sales for our products;*
- *our expectations regarding our ability to develop and commercialize toripalimab, CHS-006 and our other product candidates in the United States and Canada, including whether the trial results, data package or biologics license application ("BLA") for toripalimab will be sufficient to support regulatory approval;*
- *our ability to address comments raised in the complete response letter for the original BLA for toripalimab and timing of the review of the original BLA resubmission for toripalimab;*
- *our ability to receive marketing authorization for the on-body injector presentation of UDENYCA®, including the timing of receiving such marketing authorization, if approved;*
- *our ability to maintain regulatory approval for our products and our ability to obtain and maintain regulatory approval of our product candidates, if and when approved;*
- *our expectations regarding government and third-party payer coverage and reimbursement;*
- *our ability to manufacture our product candidates in conformity with regulatory requirements and to scale up manufacturing capacity of these products for commercial supply;*
- *our reliance on third-party contract manufacturers to supply our product candidates and products for us;*
- *our expectations regarding the potential market size and the size of the patient populations for our products and product candidates, if approved for commercial use;*
- *our expectations about making required future interest and principal payments as they become due in connection with our debt obligations;*
- *our financial performance, including, but not limited to, projected future performance of our gross margins, research and development expenses and selling and general administrative expenses;*
- *the implementation of strategic plans for our business, products and product candidates;*
- *the initiation, timing, progress and results of future preclinical and clinical studies and our research and development programs;*
- *the scope of protection we are able to establish and maintain for intellectual property rights covering our products and product candidates;*
- *our ability to finalize the Definitive Agreements or close on the transactions contemplated by them;*
- *our expectations regarding the scope or enforceability of third-party intellectual property rights, or the applicability of such rights to our products and product candidates;*
- *the cost, timing and outcomes of litigation involving our products and product candidates;*

[Table of Contents](#)

- *our reliance on third-party contract research organizations to conduct clinical trials of our product candidates;*
- *the benefits of the use of our products and product candidates;*
- *the rate and degree of market acceptance of our current or any future products product candidates;*
- *our ability to compete with companies currently producing competitor products, including Neulasta, Humira and Lucentis and other biosimilar products made by other companies;*
- *developments and projections relating to our competitors, our market opportunity and our industry; and*
- *the potential impact of COVID-19 and the continuation of the war in Ukraine on our business and prospects.*

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, market opportunity estimates 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, publicly filed reports and similar sources.

PART I

Item 1. *Business*

Overview

We are a commercial-stage biopharmaceutical company focused on the research, development and commercialization of innovative cancer treatments and the commercialization of our portfolio of approved biosimilars. Our strategy is to build a leading immuno-oncology franchise funded with cash generated through net sales of our diversified portfolio of U.S. Food and Drug Administration (“FDA”)-approved therapeutics.

Our commercial portfolio includes three FDA-approved biosimilar products. Our first product, UDENYCA® (pegfilgrastim-cbqv), a biosimilar to Neulasta®, a long-acting granulocyte-colony stimulating factor (“G-CSF”), was launched commercially in the United States in January 2019. Our second product, CIMERLI® (ranibizumab-eqrn), a biosimilar to Lucentis®, was approved by the FDA in August 2022 as a biosimilar product interchangeable with Lucentis for the treatment of neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema, diabetic retinopathy, and myopic choroidal neovascularization. The FDA also granted CIMERLI 12 months of first interchangeable exclusivity. We launched CIMERLI commercially in the United States on October 3, 2022. In December 2021, the FDA-approved YUSIMRY™ (adalimumab-aqvh), a biosimilar to Humira®, which we plan to launch in the United States on or after July 1, 2023, pursuant to the terms of an agreement with Humira’s manufacturer, AbbVie Inc. (“AbbVie”).

In addition to our three FDA-approved biosimilar products, we also have an original biologic license application submitted under Section 351(a) of the Public Health Service Act (“original BLA”) under review by the FDA for toripalimab. Toripalimab is being developed for its ability to block PD-1 interactions with its ligands, PD-L1 and PD-L2 by binding to the FG loop on the PD-1, and for enhanced PD-1 receptor internalization (endocytosis function). We believe blocking PD-1 interactions with PD-L1 and PD-L2 have the potential to promote the immune system’s ability to attack and kill tumor cells. The original BLA for toripalimab is for the use of toripalimab in combination with gemcitabine and cisplatin for first-line treatment of adults with metastatic or recurrent locally advanced nasopharyngeal carcinoma (“NPC”), and for use as a monotherapy in the second- or later-line treatment of patients with recurrent unresectable or metastatic NPC that have progressed on or after a platinum-containing chemotherapy. On April 29, 2022, we received a complete response letter (“CRL”) from the FDA for the original BLA for toripalimab requesting certain manufacturing process changes that we and our partner Shanghai Junshi Biosciences Co., Ltd. (“Junshi Biosciences”) believe are readily addressable. On July 6, 2022, we announced that the FDA accepted the resubmission of the original BLA for toripalimab and announced that the FDA set a Prescription Drug User Fee Act (“PDUFA”) action date for December 23, 2022. On December 24, 2022, we announced that we did not receive an action letter from the FDA by the PDUFA action date. The FDA previously communicated that on-site inspections, including Junshi Biosciences’ manufacturing facility for toripalimab, are required before the FDA can approve the original BLA; however, they were unable to conduct the inspection by December 23, 2022 due to the impact of COVID-19 related restrictions on travel in China. The BLA for toripalimab remains under review, and we and Junshi Biosciences are engaged in ongoing discussions with the FDA about the pre-approval inspection plans. Since the decision in February 2022 by the FDA to not approve the BLA for sintilimab, the FDA’s current stance is to reject most product candidates that do not have data that is reflective of U.S. medical practice and/or the U.S. patient population and in particular with clinical trials conducted in a single country such as China. However, we believe that our original BLA for toripalimab for NPC is a distinct case because there are no approved immunotherapies for NPC in the United States and the FDA has stated that NPC warrants regulatory flexibility with respect to the sufficiency of single country clinical data. We plan to launch toripalimab in the United States in the third quarter of 2023, if approved by July 1, 2023. In January 2023, we and Junshi Biosciences acted to reduce the scope of the ongoing development plan for toripalimab in the United States that is used as part of the calculation for reimbursable research and development expense under the Exclusive License and Collaboration Agreement dated February 1, 2021 between us and Junshi Biosciences (the “Collaboration Agreement”).

In May 2022, we discontinued development of CHS-305, an Avastin biosimilar candidate.

We have built an experienced and robust oncology and ophthalmology market access, key account management and medical affairs capability in the United States, which have supported the successful commercialization of UDENYCA and CIMERLI. We expect to leverage these capabilities as we build and launch our immuno-oncology franchise, continue to grow our ophthalmology product portfolio and launch the commercialization of other biosimilar products.

On January 9, 2023, we announced that we entered into a binding term sheet (the “Term Sheet”) with Klinge Biopharma GmbH (“Klinge Biopharma”) for the exclusive commercialization rights to FYB203, a biosimilar candidate to Eylea® (aflibercept), in the United States. The parties to the Term Sheet expect to execute the definitive agreements contemplated by the Term Sheet (the “Definitive Agreements”) and complete the transaction in the first half of 2023. Under the Term Sheet, we will make a total upfront payment of

[Table of Contents](#)

approximately €30 million, comprised of cash and our common stock, thirty days after the execution of the Definitive Agreements. We also agreed to make other regulatory and launch milestone payments and to make royalty payments based on approximately equal sharing of profits from the sale of FYB203 in consideration for the commercialization rights to FYB203 in the United States.

The material terms of the transaction with Klinge Biopharma will be set forth in the Definitive Agreements, which we will include in a subsequent filing when such Definitive Agreements are executed.

Products and Product Candidates

Our portfolio includes the following products and product candidates:

Oncology

- UDENYCA is a biosimilar to Neulasta, a long-acting G-CSF. We launched UDENYCA commercially in the United States in January 2019. In 2022, 2021 and 2020, we recorded UDENYCA net product sales of \$203.8 million, \$326.5 million and \$475.8 million, respectively. In addition to the currently marketed pre-filled syringe (“PFS”) presentation, we are also developing additional presentations of UDENYCA, such as a proprietary on-body injector (“OBI”) and an autoinjector (“AI”). In October 2021, we announced positive results from a randomized, open-label, crossover study assessing the pharmacokinetic (“PK”) and pharmacodynamic bioequivalence of UDENYCA administered via OBI compared to our currently marketed UDENYCA PFS. We are planning a 2023 launch of UDENYCA OBI, if approved by the FDA. We submitted a prior approval supplement to the FDA for UDENYCA AI in 2022. The FDA approved the prior approval supplement for UDENYCA AI on March 3, 2023. Commercial availability of UDENYCA AI is planned for the second quarter of 2023.
- Toripalimab is being developed for its ability to block PD-1 interactions with its ligands, PD-L1 and PD-L2, by binding to the FG loop on the PD-1, and for enhanced PD-1 receptor internalization (endocytosis function). We believe blocking PD-1 interactions with PD-L1 and PD-L2 can help to promote the immune system’s ability to attack and kill tumor cells. More than thirty company-sponsored toripalimab clinical studies covering more than fifteen indications have been conducted by our partner Junshi Biosciences, including in China, the United States, Southeast Asia, and European countries.

Together with Junshi Biosciences, in the third quarter of 2021 we completed the submission of the original BLA for toripalimab to the FDA seeking approval for the use of toripalimab in combination with gemcitabine and cisplatin for first-line treatment of adults with metastatic or recurrent locally advanced NPC, and for use as a monotherapy in the second- or later-line treatment of patients with recurrent unresectable or metastatic NPC that have progressed on or after a platinum-containing chemotherapy. The FDA issued a CRL for the original BLA for toripalimab requesting certain manufacturing process changes. On July 6, 2022, we announced that the FDA accepted the resubmission of the original BLA for toripalimab and announced that the FDA set a PDUFA action date for December 23, 2022. On December 24, 2022, we announced that we did not receive an action letter from the FDA by the PDUFA action date. The FDA previously communicated that an on-site inspection of Junshi Biosciences’ manufacturing facility for toripalimab is required before the FDA can approve the original BLA; however, they were unable to conduct the inspection by December 23, 2022 due to the impact of COVID-19 related restrictions on travel in China. The BLA for toripalimab remains under review, and we and Junshi Biosciences are still engaged in ongoing discussions with the FDA about the pre-approval inspection plans. We plan to launch toripalimab in the United States in the third quarter of 2023, if approved by July 1, 2023. We believe there is potentially a high unmet need in NPC based on the current FDA-approved treatment alternatives and the lack of any approved immunotherapies.

The FDA has granted Breakthrough Therapy designation to toripalimab for the treatment of patients with recurrent or metastatic NPC with disease progression on or after platinum-containing chemotherapy and for toripalimab in combination with chemotherapy (gemcitabine and cisplatin) for the first-line treatment of recurrent or metastatic NPC.

- CHS-006 is an investigational recombinant humanized IgG4k monoclonal antibody designed to act specifically against human TIGIT that we are developing in collaboration with Junshi Biosciences. A number of third-party preclinical and clinical studies have demonstrated that activation of the TIGIT pathway could be a crucial underlying mechanism for tumor immune evasion and resistance to PD-1 blockade therapy in some tumor types. Combination of TIGIT and PD-1/PD-L1 antibodies showed a synergistic potential to enhance antitumor response, to overcome anti-PD-1 resistance and possibly broaden the cancer patient population that can benefit from immunotherapy.

[Table of Contents](#)

A dose escalation, dose expansion clinical trial (clinicaltrials.gov identifier# NCT05061628) evaluating the safety, tolerability and pharmacokinetic properties of CHS-006 as monotherapy and in combination with PD-1 inhibitor toripalimab in patients with advanced solid tumors is ongoing in China. The FDA has allowed clinical trials for CHS-006 to proceed in the United States under an investigational new drug application (“IND”), and we plan to advance toripalimab in combination with CHS-006 in a clinical trial in North America in the second quarter of 2023.

- We are pursuing an early-stage development candidate designed to improve anti-PD-1 clinical benefit by transforming an unfavorable tumor microenvironment (“TME”) to a more favorable TME. We expect to submit an IND to the FDA in 2023 for CHS-1000, an antibody targeting ILT4.

Immunology

- YUSIMRY, a biosimilar of Humira (adalimumab), is a monoclonal antibody that can bind to tumor necrosis factor (“TNF”). YUSIMRY provides certain therapeutic benefits for treatment of patients with certain inflammatory diseases characterized by increased production of TNF in the body, including rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn’s disease, psoriasis and ulcerative colitis. In December 2021, the FDA approved YUSIMRY, which we plan to launch in the United States on or after July 1, 2023, pursuant to the terms of an agreement with Humira’s manufacturer, AbbVie Inc. Based on our current review, we believe the adalimumab market will be very competitive when we are able to launch on July 1, 2023.

Ophthalmology

- CIMERLI is a Lucentis biosimilar. In November 2019, we entered into a license agreement (the “Bioeq Agreement”) with Bioeq AG (“Bioeq”) for the commercialization of CIMERLI in certain dosage forms in both a vial and PFS presentation. Under the Bioeq Agreement, Bioeq granted to us an exclusive royalty-bearing license to commercialize CIMERLI in the field of ophthalmology (and any other approved labelled indication) in the United States.

On August 2, 2022, the FDA approved CIMERLI as a biosimilar product interchangeable with Lucentis for the treatment of neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema, diabetic retinopathy, and myopic choroidal neovascularization. The FDA also granted CIMERLI 12 months of first interchangeable exclusivity. On October 3, 2022, we launched CIMERLI commercially in the United States in both 0.3 mg and 0.5 mg dosage forms.

Market Opportunity for our Oncology Franchise

Toripalimab Opportunity

According to Evaluate Pharma, total anti-PD-L1 antibody United States annual revenues in 2022 were approximately \$21.6 billion and are projected to grow to approximately \$30.3 billion by 2025.

Immuno-oncology agents, and the PD-1/PD-L1 class in particular, have shifted the treatment paradigm across a broad range of tumors, and across the continuum of cancer settings (metastatic to early stage). Clinical adoption of PD-1/PD-L1 therapies has been driven by the proven versatility of certain therapies within the class to be used as a monotherapy, as well as combination therapy with targeted agents such as tyrosine kinase inhibitors, chemotherapy, or other immunotherapy agents to achieve durable tumor responses and improved survival benefits, with acceptable toxicity profiles. The improved safety profile observed for approved PD-L1 therapies versus chemotherapy, enables these therapies to be used as a backbone therapy in a broad array of combination regimens.

UDENYCA Biosimilar

We initiated United States sales of UDENYCA in January 2019, and in 2022 we recorded UDENYCA net product sales of \$203.8 million. According to Evaluate Pharma, the 2022 United States net sales for all pegfilgrastim products was estimated to be \$1.3 billion. UDENYCA is currently approved by the FDA in both a PFS presentation and an AI presentation. PFS products currently account for approximately 54% of the overall pegfilgrastim market. The remaining 46% is held by Neulasta Onpro®, an OBI presentation of pegfilgrastim owned by Amgen Inc. and Amgen USA Inc. (collectively “Amgen”). We are planning a 2023 launch of UDENYCA OBI, if approved by the FDA. If approved, an OBI presentation could potentially expand the UDENYCA market opportunity to the remaining pegfilgrastim market. We

[Table of Contents](#)

submitted a prior approval supplement to the FDA for UDENYCA AI in 2022. The FDA approved the prior approval supplement for UDENYCA AI on March 3, 2023. Commercial availability of UDENYCA AI is planned for the second quarter of 2023.

CHS-006 Opportunity

TIGIT-targeted antibodies have emerged as promising novel immuno-oncology agents that can potentially be used in combination with PD-1/PD-L1 therapies, with the potential to improve upon the durable clinical antitumor activity of current PD-1/PD-L1 regimens. Moreover, a TIGIT-targeted antibody and PD-1/PD-L1 combination, if successfully developed and approved, could be practice-changing in numerous tumor settings by providing a chemotherapy free option, potentially improving upon the safety profile of current regimens. Our current hypothesis is that the TIGIT class of agents could be effective in some of the same tumor types and settings where PD-1/PD-L1 therapies have proven efficacy, but with a potentially better safety profile than chemotherapy containing PD-1/PD-L1 regimens, and as such, the market potential for this class of agents could be significant.

Ophthalmology Franchise Market Opportunity

CIMERLI

United States net revenues of Lucentis were reported to be approximately \$1.1 billion in 2022.

On August 2, 2022, the FDA approved CIMERLI as a biosimilar product interchangeable with Lucentis for the treatment of neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema, diabetic retinopathy, and myopic choroidal neovascularization. The FDA also granted CIMERLI 12 months of first interchangeable exclusivity. On October 3, 2022, we launched CIMERLI commercially in the United States in both 0.3 mg and 0.5 mg dosage forms.

Immunology Franchise Market Opportunity

YUSIMRY

United States net revenues of Humira were reported by AbbVie to be approximately \$18.6 billion in 2022. Our settlement and license agreements with AbbVie grant us global, non-exclusive worldwide rights under AbbVie's intellectual property to manufacture and commercialize YUSIMRY starting on July 1, 2023. Based on our current review, we believe the adalimumab market will be very competitive when we are able to launch on July 1, 2023.

Deprioritized pipeline programs

We are currently seeking strategic alternatives for CHS-131, a peroxisome proliferator-activated receptor gamma ("PPAR γ ") small molecule clinical candidate being evaluated for the treatment of nonalcoholic steatohepatitis ("NASH").

In January 2020, we entered into a license agreement (the "Innovent 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 in the United States and Canada. On May 3, 2022, we provided notice of termination of the Innovent Agreement to Innovent to discontinue development of CHS-305, a bevacizumab (Avastin) biosimilar candidate, because regulatory approval of the licensed product could not be reasonably obtained within the agreed time period.

In October 2022, we discontinued development of our preclinical immuno-oncology program, CHS-3318, an antibody targeting CCR8.

Sales and Marketing

Our strategy is to build a leading immuno-oncology franchise funded with cash generated through net sales of our diversified portfolio of FDA-approved therapeutics.

If we are successful in gaining approval of toripalimab and our other immuno-oncology assets, we believe we have the potential to efficiently integrate these new products into our existing oncology commercial infrastructure. For example, we project that our current field footprint is sufficiently organized to successfully launch toripalimab, if approved, in NPC and can scale as needed as new indications are approved.

[Table of Contents](#)

For the ophthalmology franchise, the customer base is significantly concentrated with approximately 80% of the ranibizumab market coming from almost 450 practices. We invested in a dedicated sales organization to support the CIMERLI launch. Separately, market access and our Coherus Complete™ patient services hub are supported by our payor and field reimbursement managers to meet CIMERLI customers' needs.

For the planned launch of YUSIMRY, we believe that payor coverage policies and formularies will dictate provider access to both Humira and adalimumab biosimilars and that a combination of factors will influence formulary decision making. Examples of these include but are not limited to, list price, discounts and rebates, product formulation, supply guarantees, and timing of market entry. We intend to leverage our deep and established commercial experience in market segmentation, pricing and contracting, market access (dedicated payor team, key account teams, field-based reimbursement specialists, and Coherus Complete patient services hub) to compete upon market entry. We are also scaling our digital and remote-based selling capabilities in order to drive share of voice and product pull-through in markets where formulary acceptance is achieved.

For a discussion of risks related to sales and marketing, please see "Risk Factors—Risks Related to Launch and Commercialization of our Products and our 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

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. We operate in a highly competitive environment. Such competition includes larger and better-funded pharmaceutical, generic pharmaceutical, specialty pharmaceutical and biotechnology companies commercializing and developing immuno-oncology and biosimilar products that would compete with our products and the product candidates in our pipeline.

Toripalimab, if approved, will enter a competitive market in the United States where a number of anti-PD-1 or PD-L1 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, Inc. ("Genentech"), Imfinzi® (durvalumab) from AstraZeneca plc ("AstraZeneca"), Bavencio® (avelumab) from EMD Serono Inc. and Pfizer Inc. ("Pfizer"), and Libtayo® (cemiplimab-rwlc) from Regeneron Pharmaceuticals, Inc. ("Regeneron") and Sanofi S.A. ("Sanofi"), and Jemperli (dostarlimab-gxly) from GlaxoSmithKline plc ("GlaxoSmithKline"). In addition to toripalimab, multiple other competitors are seeking to develop and approve novel anti-PD-1 or PD-L1 antibody drugs in the United States in the coming years, including but not limited to BeiGene, Ltd. (in collaboration with Novartis International AG ("Novartis")). We believe there is potentially a high unmet need for toripalimab for treatment for NPC based on the current FDA-approved treatment alternatives and the lack of any approved immunotherapies.

UDENYCA faces competition in the United States from Amgen, Viatris Inc. ("Viatris"), Sandoz International GmbH ("Sandoz"), Pfizer and Spectrum Pharmaceuticals, Inc. ("Spectrum"), and is expected to face competition from Amneal Pharmaceuticals, Inc. ("Amneal") and Fresenius Medical Care AG & Co. KGaA ("Fresenius"), each of which has announced the approval of a pegfilgrastim biosimilar.

CIMERLI faces competition in the United States from F. Hoffman-La Roche Ltd. ("Roche")/Genentech (the manufacturer of Lucentis, Vabysmo and Susvimo™). Biogen Inc. ("Biogen") with collaborator Samsung Bioepis, Xbrane Biopharma AB ("Xbrane") (in collaboration with STADA Arzneimittel AG ("STADA") and Bausch & Lomb Incorporated ("Bausch & Lomb")) have each disclosed the development of a Lucentis biosimilar candidate.

YUSIMRY, following our planned launch, may face competition in the United States from AbbVie (the holder of rights to Humira), Amgen (Amjevita™ (adalimumab-atto)), Sandoz (Hyrimoz™ (adalimumab-adaz)), Samsung Bioepis Co., Ltd. ("Samsung Bioepis") (Hadlima™ (adalimumab-bwwd)), Pfizer (Abrilada™ (adalimumab-afzb)), Boehringer Ingelheim GmbH ("Boehringer Ingelheim") (Cyltezo™

[Table of Contents](#)

(adalimumab-adbm)) as well as Viatrix / Biocon ("Biocon") (Hulio® (adalimumab-fkjp)), Alvotech Holdings S.A. and Fresenius, each a company that has 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. ("Orox")

In December 2012, we entered into a distribution agreement with 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 YUSIMRY and CHS-0214 (our etanercept (Enbrel®) biosimilar candidate, for which we discontinued development in 2020) in Latin America, except Brazil. Under this agreement, Orox has an option, exercisable within a defined time period, to obtain an exclusive license to commercialize certain additional biosimilar products in the same field and territory. We are obligated to manufacture and supply licensed products to Orox.

We are obligated to develop licensed products and achieve regulatory approval for such products outside of the Caribbean and Latin American countries covered by the agreement by specified dates in order to support Orox's activities under the agreement in its licensed territory. We are eligible to receive from Orox a share of gross profits in the low 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 Agreement with Selexis SA ("Selexis")

In June 2012, we entered into a license agreement with Selexis, under which Selexis granted to us royalty-bearing, non-exclusive, sublicensable licenses under Selexis's intellectual property rights to manufacture, use and commercialize YUSIMRY using Selexis cell lines. In consideration for the rights granted to us under the agreement, 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 product, totaling up to €210,000 for this product. 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 this agreement at any time upon 60 days written notice to Selexis. Either we or Selexis may terminate the 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 agreement with Selexis terminates 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

In January 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 YUSIMRY. The global settlements resolve all pending disputes between the parties related to YUSIMRY. Under the United States settlement, our license period in the United States commences on July 1, 2023.

Settlement and License Agreements with Pfizer

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

In November 2019, we entered into the Bioeq 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. Bioeq will manufacture and supply the Bioeq Licensed Products to us in accordance with terms and conditions specified in the Bioeq Agreement and a manufacturing and supply agreement between us and Bioeq dated as of September 29, 2022 (the "Bioeq Manufacturing Agreement"). The Bioeq Manufacturing Agreement will remain in force until the first to occur of the following: (1) the termination of the Bioeq Agreement; (2) the exercise of a right to termination by us or Bioeq for a material breach of the other party that is not cured in accordance with the Bioeq Manufacturing Agreement; and (3) the exercise of a right to termination by Bioeq if invoices are not paid in full in accordance with the Bioeq Manufacturing Agreement. Additionally, we must commit certain post-launch resources to the commercialization of the Bioeq Licensed Products for a limited time as specified in the Bioeq 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 Bioeq Agreement.

We paid Bioeq an upfront payment of €5.0 million and a milestone payment of €5.0 million in 2019. In 2022, we paid Bioeq a €2.5 million milestone payment related to the FDA approval of the CIMERLI Section 351(k) BLA. 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, which occurred on October 3, 2022, 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 if Bioeq receives certain adverse regulatory feedback from the FDA for the Bioeq Licensed Products.

The FDA approval of CIMERLI occurred on August 2, 2022, and we commercially launched CIMERLI in the United States on October 3, 2022.

License Agreement with Bioeq and Genentech

On June 22, 2022, we entered into a license agreement with Genentech, Inc. ("Genentech") and our partner Bioeq (the "Genentech Agreement"). Under the agreement, Genentech granted us and Bioeq a non-exclusive, royalty-bearing, license under certain of its patent rights to commercially launch and sell CIMERLI in the United States which started on the launch date on October 3, 2022. Pursuant to the terms of the Genentech Agreement, the royalty is a low single-digit percentage of net sales of CIMERLI that must be paid through the end of 2023. In addition, we obtained the right to make non-binding offers to sell and engage in manufacturing and stockpiling activities during specified time periods prior to the launch date pursuant to the terms of the Genentech Agreement. The term of the Genentech Agreement will expire when all of the valid claims in the patent rights licensed under the agreement expire. The agreement may be terminated by either party if a party materially breaches one or more of its material obligations, subject to customary cure period. If we, Bioeq or either party's respective affiliates initiate, participate, or assist any other person in bringing or prosecuting any challenge to the validity of any patent rights licensed under the Genentech Agreement, Genentech may terminate the licenses granted under such

[Table of Contents](#)

licensed patent rights or terminate the Genentech Agreement in its entirety, unless we, Bioeq, or the applicable affiliates withdraw all such challenges or stop assisting in any such challenges. Genentech may also terminate the agreement in the event of our insolvency.

License Agreement with Junshi Biosciences

On February 1, 2021, we entered into 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 paid \$150.0 million upfront for exclusive rights to toripalimab in the United States and Canada, an option in these territories to Junshi Biosciences' anti-TIGIT antibody CHS-006, an option in these territories to a next-generation engineered IL-2 cytokine, and certain negotiation rights to two undisclosed preclinical immunology 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 regulatory and sales milestones.

In March 2022, we paid \$35.0 million for the exercise of our option to license CHS-006. We and Junshi Biosciences are jointly developing CHS-006 with each party responsible for the associated development costs as set forth in the Collaboration Agreement. If we exercise our remaining option for the IL-2 cytokine, we will be obligated to pay an additional option exercise fee of \$35.0 million. Additionally, for each exercised option, we will be obligated to pay Junshi Biosciences an 18% royalty on net sales, up to \$85.0 million for the achievement of certain regulatory approvals, and up to \$170.0 million for the 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, including CHS-006, and will pay for a portion of these co-development activities up to a maximum of \$25.0 million per licensed compound per year. Additionally, we are responsible for certain associated regulatory and technology transfer costs for toripalimab and other licensed compounds and will reimburse Junshi Biosciences for such costs.

We accounted for the licensing transaction as an asset acquisition under the relevant accounting rules. The \$35.0 million payment for the option to license CHS-006 was reflected in our first quarter of 2022 financial statements. We recorded research and development expense of \$145.0 million during the first quarter of 2021, related to an upfront payment for exclusive rights to toripalimab in the United States and Canada. We had entered into a Right of First Negotiation agreement with Junshi Biosciences and paid a fee of \$5.0 million which was expensed as research and development expense in the fourth quarter of 2020. The Right of First Negotiation fee was fully credited against the total upfront license fee obligation under the Collaboration Agreement. As of December 31, 2022, we did not have any outstanding milestone or royalty payment obligations to Junshi Biosciences. The additional milestone payments, option fee for the IL-2 cytokine and royalties are contingent upon future events and, therefore, will be recorded if and when it becomes probable that a milestone will be achieved, or when an option fee or royalties are incurred.

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 us. Pursuant to the Stock Purchase Agreement, on April 16, 2021, we issued 2,491,988 unregistered shares of our common stock to Junshi Biosciences, at a price per share of \$20.06, for an aggregate amount of approximately \$50.0 million in cash. Under the terms of the Stock Purchase Agreement, Junshi Biosciences is not permitted to sell, transfer, make any short sale of, or grant any option for the sale of the common stock for the two years period following its effective date. The Collaboration Agreement and the Stock Purchase Agreement were negotiated concurrently and were therefore evaluated as a single agreement. We used the "Finnerty" and "Asian put" valuation models and determined the fair value for the discount for lack of marketability ("DLOM") to be \$9.0 million at the date the shares were issued. The fair value of the DLOM was attributable to the Collaboration Agreement and was included as an offset against the research and development expense in the consolidated statement of operations for the year ended December 31, 2021.

License Agreement with Innovent

In January 2020, we entered into 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. On May 3, 2022, we provided notice of termination of the Innovent Agreement with Innovent to discontinue development of CHS-305, a bevacizumab (Avastin) biosimilar candidate, because regulatory approval of the licensed product could not be reasonably obtained within the agreed time period.

Term Sheet with Klinge Biopharma

On January 9, 2023, we announced that we entered into the Term Sheet with Klinge Biopharma for the exclusive commercialization rights to FYB203, a biosimilar candidate to Eylea® (aflibercept), in the United States. The parties to the Term Sheet expect to execute the Definitive Agreements contemplated by the Term Sheet and complete the transaction in the first half of 2023. Under the Term Sheet, we will make a total upfront payment of approximately €30 million, comprised of cash and our common stock, thirty days after the execution of the Definitive Agreements. We also agreed to make other regulatory and launch milestone payments and to make royalty payments based on approximately equal sharing of profits from the sale of FYB203 in consideration for the commercialization rights to FYB203 in the United States.

The material terms of the transaction with Klinge Biopharma will be set forth in the Definitive Agreements, which we will include in a subsequent filing when such Definitive Agreements are executed.

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 United States and international patent applications on these technologies, inventions and improvements that are important to our business. We also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary position.

The term of individual patents depends upon the legal term of the patents in countries in which they are obtained. In most countries, including the United States, the patent term is generally 20 years from the earliest date of filing a non-provisional patent application in the applicable country. In the United States, a patent's term may, in certain cases, be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the United States Patent and Trademark Office ("USPTO") 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. Each patent family includes United States patent applications and/or issued patents, and some include foreign counterparts to certain of the United States 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.

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 United States, the E.U. 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, 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 E.U., have similar regulatory structures.

FDA Approval Process for Drugs and Biologics

Our products and product candidates are subject to regulation in the United States by the FDA as biological products or as drug product candidates. 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 United States requirements may subject a company to a variety of administrative or judicial sanctions,

[Table of Contents](#)

such as FDA refusal to approve a pending BLA or NDA, 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 United States is long, expensive and inherently uncertain. Biologic and drug development in the United States typically involves the completion of preclinical laboratory and animal tests in accordance with good laboratory practices (“GLP”), the submission to the FDA of an IND, 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 PHS Act (“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, when applicable, animal studies 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, pharmacokinetic, pharmacology and pharmacodynamic characteristics of the product along with other information, including information about product chemistry, manufacturing and controls and a proposed clinical trial protocol. Long-term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

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

Clinical trials involve the administration of the investigational new drug or biologic to healthy volunteers or patients with the condition under investigation, all under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with 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 United States 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, the FDA may mandate the performance of such “Phase 4” clinical trials.

[Table of Contents](#)

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 current Good Manufacturing Practices ("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 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. The FDA's goal is to review standard applications within ten months after the filing date, or, if the application qualifies for Priority Review, six months after the FDA accepts the application for filing. A BLA or NDA is eligible for Priority Review if the product or the product candidate has the potential to provide a significant improvement in the treatment, diagnosis or prevention of a serious disease or condition compared to marketed products. In both standard and Priority Reviews, the review process may also be extended by FDA requests for additional information or clarification.

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.

[Table of Contents](#)

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 any inspections in the U.S. or internationally that it deems necessary, the FDA may issue an approval letter or a CRL. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A CRL indicates that the review cycle of the application is complete and the application is not ready for approval. A CRL may require additional clinical data and/or an additional clinical 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 Section 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 an FDA-licensed reference biological product. The BPCIA attempts to minimize duplicative testing and thereby lower development costs and increase patient access to affordable treatments. 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 Section 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.

[Table of Contents](#)

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, a 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 United States. 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 Section 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 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 Section 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 the 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).

FDA Regulation of Combination Products

Certain products or product candidates, such as the OBI presentation of UDENYCA we are developing, may be composed of components, such as drug components and device components that would normally be regulated under different types of regulatory

[Table of Contents](#)

authorities, and frequently by different centers at the FDA. These products are known as combination products. Specifically, under regulations issued by the FDA, a combination product may be:

- a product composed of two or more regulated components that are physically, chemically, or otherwise combined or mixed and produced as a single entity;
- two or more separate products packaged together in a single package or as a unit and composed of drug and device products, device and biological products, or biological and drug products;
- a drug, or device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, or device, or biological product where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, e.g., to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose; or
- any investigational drug, or device, or biological product packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect.

Under the FFDCa and its implementing regulations, the FDA is charged with assigning a center with primary jurisdiction, or a lead center, for review of a combination product. The designation of a lead center generally eliminates the need to receive approvals from more than one FDA component for combination products, although it does not preclude consultations by the lead center with other components of the FDA. The determination of which center will be the lead center is based on the “primary mode of action” of the combination product. Thus, if the primary mode of action of a drug-device combination product is attributable to the drug product, the FDA center responsible for premarket review of the drug product would have primary jurisdiction for the combination product. The FDA has also established an Office of Combination Products to address issues surrounding combination products and provide more certainty to the regulatory review process. That office serves as a focal point for combination product issues for agency reviewers and industry. It is also responsible for developing guidance and regulations to clarify the regulation of combination products, and for assignment of the FDA center that has primary jurisdiction for review of combination products where the jurisdiction is unclear or in dispute.

A combination product with a biologic primary mode of action generally would be reviewed and approved pursuant to the biologic licensure processes under the PHSA. In reviewing the BLA or Section 351(k) BLA for such a product, however, FDA reviewers in the drug center could consult with their counterparts in the device center to ensure that the device component of the combination product met applicable requirements regarding safety, purity, potency, durability and performance. In addition, under FDA regulations, combination products are subject to cGMP requirements applicable to both drugs and devices, including the Quality System regulations applicable to medical devices.

Advertising and Promotion

Once an NDA, original BLA, or Section 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.

[Table of Contents](#)

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 United States 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

[Table of Contents](#)

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, chiropractors, certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and anesthesiologist assistants, and certified nurse midwives) and teaching hospitals, as well as ownership and investment interests held by such physicians and their immediate family members. Failure to submit required information may result in significant civil monetary penalties for any payments, transfers of value or ownership or investment interests that are not timely, accurately and completely reported in an annual submission, and additional penalties for "knowing failures." Certain states also mandate implementation of commercial compliance programs, impose restrictions on pharmaceutical manufacturer marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to physicians.

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

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.

Data Privacy and Security

Numerous state, federal and foreign laws, regulations and standards govern the collection, use, access to, confidentiality and security of health-related and other personal information, and could apply now or in the future to our operations or the operations of our partners. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws and consumer protection laws and regulations govern the collection, use, disclosure and protection of health-related and other personal information. In addition, certain foreign laws govern the privacy and security of personal data, including health-related data. Privacy and security laws, regulations and other obligations are constantly evolving, may conflict with each other to

[Table of Contents](#)

complicate compliance efforts and can result in investigations, proceedings or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

Pharmaceutical Coverage, Pricing and Reimbursement

In the United States and other countries, sales of UDENYCA, CIMERLI, YUSIMRY and any other 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 United States 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. A significant portion of our sales are subject to substantial discounts to list price, including rebates we may be required to pay to Medicaid agencies or discounts we may be required to pay to 340B covered entities. Decreases in third-party reimbursement for UDENYCA, CIMERLI or other products for which we receive regulatory approval or a decision by a third-party payer to not cover our products could reduce physician utilization of our products and have a material adverse effect on our sales, results of operations and financial condition.

Government Price Reporting

Medicaid is a joint federal and state program for low income and disabled beneficiaries. Medicare is a federal program that is administered by the federal government covering individuals age 65 and over as well as those with certain disabilities. Under the Medicaid Drug Rebate Program ("MDRP"), as a condition of having federal funds available for our covered outpatient drugs under Medicaid and under Medicare Part B, we must enter into, and have entered into, an agreement with the Secretary of Health and Human Services to pay a rebate to state Medicaid programs for each unit of our covered outpatient drugs dispensed to a Medicaid beneficiary and paid for by the state Medicaid program. Medicaid rebates are based on pricing data that we are required to report on a monthly and quarterly basis to the U.S. Centers for Medicare & Medicaid Services ("CMS"), the federal agency that administers the MDRP and Medicare programs. For the MDRP, these data include the average manufacturer price ("AMP") for each drug and, in the case of innovator products, the Best Price, which represents the lowest price available from us to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity in the United States in any pricing structure, calculated to include all applicable sales and associated rebates, discounts and other price concessions. In connection with Medicare Part B, we must provide CMS with Average Sales Price ("ASP") information on a quarterly basis. CMS uses this information to compute Medicare Part B payment rates, which consist of ASP plus a specified percentage. If we become aware that our MDRP submissions for a prior period were incorrect or have changed as a result of recalculation of the pricing data, we must resubmit the corrected data for up to three years after those data originally were due. If we fail to provide information timely or are found to have knowingly submitted false information to CMS, we may be subject to civil monetary penalties and other sanctions, including termination from the MDRP.

Federal law requires that a manufacturer that participates in the MDRP also participate in the Public Health Service's 340B drug pricing program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B program is administered by the Health Resources and Services Administration ("HRSA") and requires us to agree to charge statutorily defined covered entities no more than the 340B "ceiling price" for our covered outpatient drugs when used in an outpatient setting. 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low income patients. The 340B ceiling price is calculated using a statutory formula, which is based on the AMP and rebate amount for the covered outpatient drug as calculated under the MDRP. In general, products subject to Medicaid price reporting and rebate liability are also subject to the 340B ceiling price requirement. We must report 340B ceiling prices to HRSA on a quarterly basis, and HRSA publishes them to 340B covered entities. HRSA has finalized regulations regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities for 340B eligible drugs. HRSA has also finalized an administrative dispute resolution process through which 340B covered entities may pursue claims against participating manufacturers for overcharges.

In order to be eligible to have drug products paid for with federal funds under Medicaid and Medicare Part B and purchased by certain federal agencies and grantees, a manufacturer must also participate in the U.S. Department of Veterans Affairs ("VA") Federal Supply Schedule ("FSS") pricing program. Under the VA FSS program, we must report the Non-Federal Average Manufacturer Price ("Non-FAMP") for our covered drugs to the VA and charge certain federal agencies no more than the Federal Ceiling Price, which is calculated based on Non-FAMP using a statutory formula. These four agencies are the VA, the U.S. Department of Defense, the U.S. Coast Guard, and

[Table of Contents](#)

the U.S. Public Health Service (including the Indian Health Service). We must also pay rebates on products purchased by military personnel and dependents through the TRICARE retail pharmacy program. If a manufacturer participating in the FSS program fails to provide timely information or is found to have knowingly submitted false information, the manufacturer may be subject to civil monetary penalties.

Individual states continue to consider and have enacted legislation to limit the growth of healthcare costs, including the cost of prescription drugs and combination products. A number of states have either implemented or are considering implementation of drug price transparency legislation. Requirements under such laws include advance notice of planned price increases, reporting price increase amounts and factors considered in taking such increases, wholesale acquisition cost information disclosure to prescribers, purchasers, and state agencies, and new product notice and reporting. Such legislation could limit the price or payment for certain drugs, and a number of states are authorized to impose civil monetary penalties or pursue other enforcement mechanisms against manufacturers for the untimely, inaccurate, or incomplete reporting of drug pricing information or for otherwise failing to comply with drug price transparency requirements.

Healthcare Reform, including the Inflation Reduction Act of 2022 (the "IRA")

The United States federal and state governments continue to propose and pass legislation designed to regulate the healthcare industry, including legislation that seeks to indirectly or directly regulate pharmaceutical drug pricing. Most significantly, on August 16, 2022, President Biden signed the IRA into law. This statute marks the most significant action by Congress with respect to the pharmaceutical industry since adoption of the ACA in 2010. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services ("HHS") to implement many of these provisions through guidance, as opposed to regulation, for the initial years. For that and other reasons, it is currently unclear how the IRA will be effectuated, and while the impact of the IRA on our business and the pharmaceutical industry cannot yet be fully determined, it is likely to be significant. In particular, if a product becomes subject to the IRA negotiation provision and related price cap, that may significantly alter the economic rationale for developing and commercializing a biosimilar.

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, carbon emissions tax or other mitigation measure that would materially impact our capital expenditures, operations or competitive position. The building where our headquarters is located in Redwood City, California, has been awarded LEED Gold Certification from the United States Green Building Council.

Human Capital Management

As of December 31, 2022, we had 359 full-time and part-time employees. All were located in the United States and none of our employees are represented by a labor union. We have not experienced any work stoppages and believe we have good relations with our employees and contractors. Our guiding principles are anchored on the goals of being able to recruit, incentivize, retain and integrate talented employees who can develop, implement, and drive long-term value creation strategies.

On March 3, 2023, we committed to a plan to reduce our workforce by approximately 20% to focus resources on strategic priorities including the commercialization of our diversified product portfolio and development of innovative immunology product candidates. We initiated a reduction in force impacting approximately 60 full-time and part-time employees effective March 10, 2023 for most employees.

Compensation and Benefits

We believe our base salaries are fair and competitive with the external labor markets in which our employees work and are reviewed on a regular basis. We offer incentive programs that provide cash bonus opportunities to encourage and reward participants for our achievement of financial and other key performance metrics and strengthen the connection between pay and performance. We also

[Table of Contents](#)

grant equity compensation awards that vest over time through our long-term incentive plan to employees to align such employees' incentives with our long-term strategic objectives and the interests of our stockholders.

We also offer competitive benefits to our employees, including paid vacation and holidays, family leave, disability insurance, life insurance, healthcare, dental and vision coverage, dependent care flexible spending accounts, a 401(k) plan with a company match, and an Employee Stock Purchase Plan. Additionally, we offer an Employee Assistance Program ("EAP") that includes professional support for employees to balance the stress of personal and professional demands.

Inclusion and Diversity

People are a critical component of our efforts to drive growth and deliver value for stockholders. One of the ways we have put people at the center of our business is by continuing to work toward a more inclusive and diverse workplace where each person feels respected, valued and seen and can be the best version of themselves. We believe that having a truly diverse workplace helps our company to achieve the best results, including by striving for diversity in terms of gender, ethnicity, nationality, disability status, veteran status and other factors. We launched our Diversity and Inclusion Program to our employees in 2020 and intend to continue implementation of the program in 2023. As of December 31, 2022, ethnically diverse employees represented approximately 41% of our employees and women comprised 51% of our employees. We donate to non-profit organizations such as Life Science Cares, an organization focused on eliminating the impact of poverty on our neighbors. Our Chief Executive Officer also serves on the Board of Advisors of Life Science Cares.

Health and Safety

We are committed to a safe workplace for our employees and have implemented health and safety management processes, including training and awareness, into our operations. In response to the COVID-19 pandemic, we implemented additional safety measures for the protection of our employees, including work-from-home measures for applicable employees and additional cleaning and protective measures. We require that all employees are fully-vaccinated and get all booster shots recommended by the United States Centers of Disease Control and Prevention. We react to emergencies on an ongoing basis to protect our employees, for example when there was a severe storm approaching in January 2023, our management team required that employees work from home rather than try to commute to work in our headquarters in Redwood City.

Training, Development and Engagement

We have launched a training platform that provides a variety of training topics and offers management training to advance leadership skills. Through our online learning platform, we deliver a variety of required learning modules, including those modules tied to our Code of Business Conduct, unlawful harassment and anti-corruption policies, which are completed annually by all team members. We also have Performance Management Training and Interview Training programs for our managers. We have a highly collaborative, engaging company environment.

Additional Information

We view our operations and measure our business as one reportable segment operating primarily in the United States. See "Note 1. Organization and Significant Accounting Policies" in the "Notes to Consolidated Financial Statements" contained in Part II, Item 8 of 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 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 on our website at <https://www.coherus.com> free of charge. We also periodically release and publicize press releases to the public that are also available on our website's section entitled "News" which we use as a recognized channel of distribution for our investors and other people interested in our company. The SEC maintains a website (<http://www.sec.gov>) that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC. Such filings are placed on our website as soon as reasonably

[Table of Contents](#)

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 law.

Item 1A. Risk Factors

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.

- We have a limited history of profitability, which we have not maintained and may not achieve again, and only two products that have been approved and marketed, with multiple products either approved and not yet marketed or not approved and still in development.
- The applicability of clinical data generated outside the United States, particularly from a single country such as China, is subject to FDA concurrence for its suitability in supporting product approvals in the United States. If the FDA or comparable regulatory agencies do not accept data from such trials, our development plans will be delayed and diminished, which could materially harm our business.
- The commercial success of our existing products or any future products will depend upon the degree of market acceptance and adoption by prescribing physicians, healthcare providers and the patients to whom our medicines are prescribed. Additionally, obtaining placement on national and/or local clinical guidelines/pathways, as well as coverage on third-party payor formularies, can impact our short and long-term financial performance.
- Our business, financial condition, results of operations and growth could be harmed by the effects of the COVID-19 pandemic.
- As we have in-licensed development and/or commercial rights to toripalimab and CHS-006, we rely on prior and ongoing preclinical, clinical, regulatory and manufacturing expertise of our collaborators in order to advance these product candidates through regulatory approvals in the United States and other licensed territories.
- Our products and our product candidates, even if approved, will remain subject to regulatory scrutiny.
- 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, and conduct foreign inspections of manufacturing facilities, 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.
- Our biosimilar products or our 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. Toripalimab, if approved, will face significant competition from other immuno-oncology biologics. If we fail to compete effectively, we may not achieve significant market penetration and expansion.

[Table of Contents](#)

- 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.
- The future commercial success of toripalimab, CHS-006 and any other immuno-oncology products, if approved, will depend on our ability to successfully transition our company's clinical, commercial, manufacturing, regulatory, marketing and general historical focus on biosimilars to a new strategy to build a leading immuno-oncology franchise funded with cash generated by our commercial biosimilar business.
- If an improved version of an originator product, such as Neulasta, Humira or Lucentis, is developed or if the market for the originator product significantly declines, sales or potential sales of our biosimilar product candidates may suffer.
- Healthcare reform measures, including the IRA, may increase the difficulty and cost for us to obtain marketing approval for and commercialize our products, affect the prices we may set, and have a material adverse effect on our business and results of operations.
- 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.
- The continuation of the war between Russia and Ukraine may exacerbate certain risks we face.
- Our products 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 biopharmaceutical company, including one with significant international partnerships and multiple products in development, is a highly speculative undertaking and involves a substantial degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information in this Annual Report on Form 10-K. If any of the following risks are realized, our business, financial condition, results of operations and prospects could be materially and adversely affected. The risks described below are not the only risks facing us. 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, results of operations and/or prospects.

Risks Related to Our Financial Condition and Capital Requirements

We have a limited history of profitability, which we have not maintained and may not achieve again, and only two products that have been approved and marketed, with multiple products either approved and not yet marketed or not approved and still in development.

With the exception of generating net income of \$132.2 million and \$89.8 million in 2020 and 2019, respectively, we incurred net losses in each year from our inception in September 2010 through December 31, 2022, including net losses of \$291.8 million and \$287.1 million in 2022 and 2021, respectively. It is uncertain that we will be profitable in future periods as research and development is expensive and risky. The amount of our future net losses or any future net income will depend, in part, on the amount of our future expenditures offset by the amount of future product sales, including sales of our current products or any other products that may receive regulatory approval. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk.

For example, as of December 31, 2022, we had an accumulated deficit of \$1.3 billion. 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.

We have incurred and anticipate we will continue to incur certain development and pre-commercial expenses for toripalimab, the anti-PD-1 antibody we licensed from Junshi Biosciences in 2021, and have agreed to pay up to \$90.0 million for the achievement of certain regulatory approvals and up to \$290.0 million for the attainment of certain sales thresholds. Advancing this and our other product candidates through clinical development will be expensive and could result in us continuing to experience future net losses.

For YUSIMRY, which is approved but not yet marketed, and for CIMERLI, which is approved and recently launched, and if we obtain regulatory approval to market any other 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 if additional product candidates in addition to our current products gain regulatory approval and are commercialized, we may not remain profitable.

Our expenses will increase substantially if and as we:

- further develop our sales, marketing and distribution infrastructure for our current products and develop such infrastructure for new products once they are launched;
- establish a sales, marketing and distribution infrastructure to commercialize 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 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;

[Table of Contents](#)

- 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 achieve 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 as well as any settlements or judgments from such litigation, the execution of collaboration, licensing or other agreements and the timing of any payments we make or receive thereunder.

We continue to be dependent on the ability to raise funds. 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, 2022, our cash, cash equivalents and investments were \$191.7 million. We expect that our existing cash and cash equivalents, investments and cash collected from our product 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 our products.

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 our 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 long-term debt; 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, such as sales from time to time through our ATM Offering, may 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 those contained in the loan agreement we entered into in January 2022 (as amended to date, the “Loan Agreement”) with BioPharma Credit PLC, (as the “Collateral Agent”), BPCR

[Table of Contents](#)

Limited Partnership, (as a "Lender") and Biopharma Credit Investments V (Master) LP, acting by its general partner, BioPharma Credit Investments V GP LLC (as a "Lender") that provides for a senior secured term loan facility of up to \$300.0 million, including 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. For more information on our restrictive covenants please read the Loan Agreement and the First Amendment to Loan Agreement referenced as Exhibit 10.21 and 10.24, respectively, to our Annual Report on Form 10-K for the Fiscal Year ended December 31, 2022. We could also be required to seek funds through arrangements with collaborative partners or otherwise at an earlier stage or for a lower price 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 or at all, stay profitable or generate any 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 products or 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 shareholders who own, directly or indirectly, 5% or more of our common stock, or are otherwise treated as "5% shareholders" 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, 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 our Products and our Product Candidates

The applicability of clinical data generated outside the United States, particularly from a single country such as China, is subject to FDA concurrence for its suitability in supporting approval in the United States. If the FDA or comparable regulatory agencies do not accept data from such trials, our development plans may be delayed, which could materially harm our business.

Certain clinical trials supporting our regulatory strategies were conducted outside the United States in foreign countries such as China, and we or our collaborators in the future may choose to conduct one or more clinical trials or a portion of such clinical trials for our product candidates outside the United States. For example, the clinical trials supporting our original BLA for toripalimab were conducted exclusively outside the United States. The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the United States population and United States medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, the FDA will not accept the data as support for an application for marketing approval unless the study is well-designed and well-conducted in accordance with GCP requirements and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction, including the data supporting our BLA for toripalimab. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in current or future product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction.

We have a limited operating history in an emerging regulatory environment on which to assess our business.

We are a biopharmaceutical company with a limited operating history in an emerging regulatory environment of biosimilar and immuno-oncology 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, our only approved products include UDENYCA, YUSIMRY and CIMERLI which are approved for commercialization in the United States, 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 our products, and to complete the development of, and obtain the regulatory and marketing approvals necessary to commercialize, one or more of our product pipeline candidates, which include:

- toripalimab;
- CHS-006;
- additional presentations of UDENYCA; and
- CHS-1000.

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 product presentations and CIMERLI;
- our ability to successfully launch and commercialize YUSIMRY in a very competitive adalimumab market;
- competing against numerous current and future pegfilgrastim, ranibizumab and adalimumab products with significant market share;
- healthcare providers, payers, and patients adopting our products and 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 products and 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 our products and 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 products and product candidates, if approved;
- addressing any competing technological and market developments;
- identifying, assessing and developing (or acquiring/in-licensing on favorable terms) 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 European Medical Agency (the "EMA"), other regulatory agencies, domestic or foreign, or by any unfavorable outcomes in intellectual

[Table of Contents](#)

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 or immuno-oncology 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 or immuno-oncology companies (including competition from large pharmaceutical companies entering the biosimilar market or possessing large established positions in the immuno-oncology market that may be able to gain advantages in the sale of biosimilar or immuno-oncology products based on brand recognition and/or existing relationships with customers and payers) and whether we own (or have partnered with companies owning) the commercial rights for that territory. If the market for our products and product candidates (or our share of that market) is not as significant as we expect, the price of our products is not what we project, 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 our existing products or any future products will depend upon the degree of market acceptance and adoption by prescribing physicians, healthcare providers and the patients to whom our medicines are prescribed. Additionally, obtaining placement on national and/or local clinical guidelines/pathways, as well as coverage on third-party payor formularies, can impact our short and long-term financial performance.

Even with the requisite approvals from the FDA and comparable foreign regulatory authorities, the commercial success of our products or product candidates, if approved, will depend in part on the medical community, patients and third-party payers accepting our products and 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 our newly launched product, CIMERLI, or 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 and any limitations or warnings contained in a product's approved labeling;
- the clinical indications for which approval is granted;
- for our immuno-oncology product candidates, our ability to compete in a competitive immuno-oncology market that may differ from the biosimilar market;
- inclusion, in either parity or better position, on commonly accepted clinical guidelines or pathways that influence prescribing patterns and/or affect reimbursement;
- for our biosimilar product candidates, the possibility that a competitor may achieve interchangeability and we may not;
- relative convenience, ease of administration and any real or perceived benefit from administration at home as opposed to in the clinic;
- 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, integrated delivery networks and managed care organizations;
- publicity concerning our products or competing products and treatments;
- the extent to which third-party payers (including government and national/regional commercial plans) provide adequate third-party coverage and reimbursement for our products and product candidates, if approved;
- the price at which we sell our products;

[Table of Contents](#)

- the potential impact of the IRA on the pharmaceutical industry and the market for biosimilars;
- the actions taken by current and future competitors to delay, restrict or block customer usage of the product; and
- our ability to maintain compliance with regulatory requirements.

Market acceptance of any future product candidates, if approved, will not be fully known until after they are launched and may be negatively affected by a potential poor safety experience and the track record of other biosimilar and immuno-oncology products and product candidates. Further, continued market acceptance of UDENYCA and CIMERLI, and the market acceptance of YUSIMRY, once launched, and any future product candidates that may be approved, depends on our efforts to educate the medical community and third-party payers on the benefits of our products and product candidates and will require significant resources from us and we have significantly less resources compared to large, well-funded pharmaceutical entities. Given the resource disparity, our outreach may have little success or may never be successful. If our products or any future product candidates that are approved 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 sustain profitability.

The future commercial success of toripalimab, CHS-006 and any other immuno-oncology product candidates, if approved, will depend on our ability to successfully transition our company's clinical, commercial, manufacturing, regulatory, marketing and general historical focus on biosimilars to a new strategy to build a leading immuno-oncology franchise funded with cash generated by our commercial biosimilar business. We may have little or no success making this strategic transition if there is difficulty hiring and retaining employees with expertise in both biosimilar and immuno-oncology products, managing our licensing relationship with our partner for toripalimab and CHS-006, regulatory differences between biosimilars and immuno-oncology products and other factors.

Our acquisition of toripalimab and CHS-006 represented a significant strategic shift for our company from a historical focus on biosimilars to a new strategy to build a leading immuno-oncology franchise funded with cash generated by our commercial biosimilar business. Pivoting in this manner requires hiring and retaining new employees with expertise across multiple therapeutic areas, particularly immuno-oncology, in a highly competitive global market for talent. In addition, our strategic transition requires us to rely heavily on our licensing relationship with Junshi Biosciences, our partner for toripalimab. A bilateral relationship involves significant risks, including those discussed below in the Risk Factor titled "we are dependent on Junshi Biosciences, Bioeq, and Orox) for the commercialization of our 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 managed in a highly complex regulatory environment for biosimilars in the past where approval from the FDA primarily requires a demonstration that our product shows biosimilarity with the reference product. However, with our strategic shift to operating in both the biosimilar and immuno-oncological spaces, we must still maintain regulatory expertise within the biosimilar area while also building capabilities in the immuno-oncology market. FDA regulation of immuno-oncology product candidates like toripalimab is different than for biosimilars because we must demonstrate the safety, purity and efficacy of the product candidate to the satisfaction of the FDA rather than relying on the safety and efficacy data of the reference product and demonstrate biosimilarity. This process of generating acceptable safety and efficacy data from clinical trials represents a relatively new approach for our company, so it involves more execution risk for us than for biosimilars where we have many years of experience advancing product candidates. If we fail to successfully manage the transition of our focus on biosimilars to our new strategy to build a leading immuno-oncology franchise funded with cash generated by our commercial biosimilar business it will materially and adversely affect our financial results.

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

Pricing, coverage and reimbursement of our products, or any of our product candidates, if approved, may not be adequate to support our commercial infrastructure. The prices required to successfully compete 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 commercial payers are essential to enable provider/patient access to our products and our patient support services must be sufficiently scaled to meet the needs of patients receiving our products. 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 our products 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.

[Table of Contents](#)

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 enable providers to separately bill for UDENYCA to have its own reimbursement rate 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 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 our products 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 of the United States, pharmaceutical businesses are generally subject to extensive governmental price controls and other market regulations. We believe the increasing emphasis on cost-containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of our product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

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 our products or any of our product candidates. While cost containment practices generally benefit biosimilars, severe cost containment practices may adversely affect our product sales. Furthermore, the impact of the IRA on our business and the pharmaceutical industry generally is currently unknown. We expect to experience pricing pressures in connection with the sale of our products and any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes.

Our products and our product candidates, even if approved, will remain subject to regulatory scrutiny.

Our products and our product candidates, even if approved, 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 "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 submitted under Section 351(a) of the Public Health Service Act PHSA, Section 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

[Table of Contents](#)

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, China or other foreign countries.

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, and conduct foreign inspections of manufacturing facilities, 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 drugs and biologics or modifications to approved drugs and biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the United States

[Table of Contents](#)

government has periodically shut down and certain regulatory agencies, such as the FDA, had to furlough critical FDA employees and stop critical activities.

Separately, in response to the COVID-19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. Even though the FDA has since resumed standard inspection operations of domestic facilities where feasible, the FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates as it adapts to the evolving COVID-19 pandemic, and any resurgence of the virus or emergence of new variants may lead to further inspectional delays. 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 they are put in place again in regions such as China, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, including in China where we partner with Junshi Biosciences for toripalimab, 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. For example, in the CRL we received from the FDA for toripalimab, the FDA indicated that the review period for the resubmission of the original BLA for toripalimab would be impacted by travel restrictions and closures occurring in China as a result of the COVID-19 pandemic. While the FDA provided an initial estimate of such timing impacts, the ultimate delay could be substantially greater for reasons outside of our control.

Risks Related to COVID-19

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

We are subject to risks related to public health crises such as the global pandemic associated with the COVID-19 pandemic. As a result of the COVID-19 outbreak, we have experienced and may continue to experience disruptions that could severely impact our business, competitive position, clinical trials and preclinical studies, including, but not limited to:

- decreased sales of our products;
- our ability to compete with Neulasta Onpro® during the period of time when the UDENYCA on-body injector is not approved and is not commercially available if a large number of patients demonstrate a preference to administer medication at home due to COVID-19, other viral pandemics, convenience or other factors;
- our ability to maintain or expand the commercial use of our products due to, among other factors, healthcare providers, payers and patients not utilizing or adopting our products due to resources being strained or otherwise focused on the COVID-19 pandemic and our sales team efficacy in selling our products being limited due to such strained resources or other factors such as travel restrictions;
- fewer individuals undertaking or completing cancer treatments, or participating in clinical trials, 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 our products 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 foreign, 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 FDA and comparable foreign regulatory agencies, which may impact regulatory review and approval timelines, such as for the review of our resubmitted original BLA for toripalimab;
- 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 or fear of sickness of employees or their families; and
- negative impact from government orders, quarantines and similar government orders and restrictions.

[Table of Contents](#)

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 of Neulasta's dosage forms, achieve a successful launch of new products, 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. Multiple times in 2021, 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 for certain periods, slowdowns and delays, travel restrictions and cancellation of events, among other effects, thereby negatively impacting our operations. In addition, there was a lockdown order in all of Shanghai, China in 2022, where our partner Junshi Biosciences has its headquarters. Such orders or restrictions may continue or be re-instated, as the case may be, thereby causing additional negative impact on our operations. Although a number of orders and restrictions have been relaxed in China, ongoing impacts remain due to the spread of COVID-19 throughout China. Further, because the full rollout of COVID-19 vaccines and booster doses has suffered from reluctance from eligible individuals to be fully inoculated, the COVID-19 pandemic may last longer than expected and could result in additional outbreaks that prompt additional closings. In addition, the spread of more contagious and deadly variants, such as the Delta variant and the omicron variant, could cause the COVID-19 pandemic to last longer or be more severe than expected. We have no ability to predict the future spread of severe and deadly pandemics that could disrupt our business and materially impact our financial position.

While the long-term economic impact and the duration of the COVID-19 pandemic or other viral pandemics 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 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 Competitive Activity

Our biosimilar products or our 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. Toripalimab, if approved, will face significant competition from other immuno-oncology biologics. If we fail to compete effectively, we may not achieve 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 molecules, 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, legal, governmental affairs, manufacturing, personnel, marketing resources, and the benefits of mergers and acquisitions.

Toripalimab, if approved, will enter a competitive market in the United States where a number of anti-PD-1 or PD-L1 antibody drugs have been approved by the FDA including the following marketed products from several competitors: Keytruda® (pembrolizumab) from Merck, Opdivo® (nivolumab) from BMS, Tecentriq® (atezolizumab) from Genentech, Imfinzi® (durvalumab) from AstraZeneca, Bavencio® (avelumab) from EMD Serono Inc. and Pfizer, and Libtayo® (cemiplimab-rwlc) from Regeneron and Sanofi, and Jemperli (dostarlimab-gxly) from GlaxoSmithKline. In addition to toripalimab, multiple other competitors are seeking to develop and approve novel anti-PD-1 or PD-L1 antibody drugs in the United States in the coming years, including but not limited to BeiGene, Ltd. (in collaboration with Novartis). We believe there is potentially a high unmet need for toripalimab for treatment for NPC based on the current FDA-approved treatment alternatives and the lack of any approved immunotherapies.

UDENYCA faces competition in the United States from Amgen, Viatrix, Sandoz, Pfizer, and Spectrum, and is expected to face competition from Amneal and Fresenius, each of which has announced the approval of a pegfilgrastim biosimilar.

CIMERLI faces competition in the United States from Roche/Genentech (the manufacturer of Lucentis, Vabysmo and Susvimo™). Biogen with collaborator Samsung Bioepis, Xbrane (in collaboration with STADA and Bausch & Lomb) have each disclosed the development of a Lucentis biosimilar candidate.

[Table of Contents](#)

YUSIMRY, following our planned launch, may face competition in the United States from AbbVie (the holder of rights to Humira), Amgen (Amjevita™ (adalimumab-atto)), Sandoz (Hyrimoz™ (adalimumab-adaz)), Samsung Bioepis (Hadlima™ (adalimumab-bwwd)), Pfizer (Abrilada™ (adalimumab-afzb)), Boehringer Ingelheim (Cyltezo™ (adalimumab-adbm)) as well as Viartis / Biocon (Hulio® (adalimumab-fkjp)), Alvotect Holdings S.A. and Fresenius, each a company that has disclosed development plans for a Humira biosimilar candidate. As a result of continued expected competition from Humira and a large number of potential adalimumab (Humira) biosimilar competitors, we may not be able to achieve substantial topline sales for YUSIMRY in the United States when we launch it as planned in July 2023.

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 United States federal district courts and seeking injunctive relief to reverse approval of biosimilar applications;
- restricting access to reference brand products for equivalence and biosimilarity testing that interferes with timely biosimilar development plans;
- attempting to influence potential market share by conducting medical education with physicians, 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 United States Pharmacopeia, an industry recognized compilation of drug and biologic standards;
- obtaining new patents covering existing products or processes, which could extend patent exclusivity for a number of years or otherwise delay the launch of biosimilars; and
- influencing legislatures so that they attach special patent extension amendments to unrelated federal legislation.

Our products and our product candidates, if approved, could face price competition from other products or 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 through PBMs, payers and their third-party administrators, IDNs and hospitals who exert downward pricing pressure on our product 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. There could be similar price competition in the immuno-oncology market that could adversely affect our results in the future. 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, less costly, easier to administer or more effective than ours, which may adversely affect our financial condition and our ability to successfully commercialize our product candidates.

[Table of Contents](#)

Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and more 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. Our competitors may have products that are easier to administer than our products, which could adversely affect our results, such as due to the observed trend that a large number of patients demonstrate a preference to administer medication at home due to COVID-19 or other factors. Biosimilar or immuno-oncology 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 adalimumab (Humira), are approved and successfully commercialized before YUSIMRY, our business would suffer. If other competitors to toripalimab and CHS-006 are approved and successfully commercialized before toripalimab and CHS-006, our business would suffer.

Approvals have already been obtained and we expect additional companies to continue to seek approval to manufacture and market biosimilar versions of Humira. Similarly, there are a number of companies that currently commercialize PD-1/PD-L1 blocking antibodies or antibodies targeting TIGIT or are developing such compounds for commercialization in the United States. If other biosimilars of these branded biologics are approved and successfully commercialized before YUSIMRY and if other competitors to toripalimab and CHS-006 are successfully commercialized before toripalimab and CHS-006, 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.

If an improved version of an originator product, such as Neulasta, Humira or Lucentis, is developed or if the market for the originator product significantly declines, sales or potential sales of our biosimilar products and 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 products and 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. External developments such as the COVID-19 pandemic can also result in changing preferences for convenient forms of administration of products that may impact our business. 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.

Any product candidates for which we intend to seek approval as original biologic products may face competition sooner than anticipated.

Our development of novel biologic product candidates, such as toripalimab, subjects us to additional risks relating to biosimilar competition. In particular, under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product.

We believe that any of our future product candidates approved under an original BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to Congressional action or otherwise, or that the FDA will

not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, could be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products will depend on a number of marketplace and regulatory factors that are still developing.

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, product development 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, product development 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 product development and commercialization efforts. Our success also depends on our continued ability to attract, retain and motivate highly qualified management and technical personnel. We may not be able to attract or retain qualified management and scientific and product development personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses, particularly those located in the San Francisco Bay Area. We also use equity compensation as a part of a comprehensive compensation package for our personnel and to the extent our stock price declines significantly or is highly volatile due to a variety of factors outside of our control, our equity compensation packages may not provide the retention and motivation incentive that we believe they should. Certain of our outstanding options have exercise prices that are above our current stock price. See the tables describing our outstanding stock options in Footnote 11. Stock-Based Compensation and Employee Benefits to our financial statements included in this report. 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 may need to expand our organization, particularly due to the transition of our strategy from a biosimilars business to a company using cash flows from our commercial biosimilars portfolio to fund our immuno-oncology pipeline, and we may experience difficulties in managing this transition and associated growth, which could disrupt our operations.

As of December 31, 2022, we had 359 full-time and part-time employees. As our development and commercialization plans and strategies develop and evolve from time to time, we may need to hire additional people in the future. Further, as we develop and build our immuno-oncology platform, such work could further divert internal 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, including building our immuno-oncology platform. 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 Parties

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 clinical research organizations (“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, GCP, and 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 or remote regulatory assessments (“RRAs”) 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. There can be no assurance that upon inspection or conclusion of an RRA 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.

[Table of Contents](#)

Reliance on third-party manufacturers entails additional risks, including reliance on the third party for regulatory compliance and quality assurance, the possible breach of the manufacturing agreement by the third party and the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us. In addition, third-party manufacturers may not be able to comply with cGMP or similar regulatory requirements outside the United States. Our failure or the failure of our third-party manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates or any other product candidates or products that we may develop. Any failure or refusal to supply the components for our product candidates that we may develop could delay, prevent or impair our clinical development or commercialization efforts. If our contract manufacturers were to breach or terminate their manufacturing arrangements with us, the development or commercialization of the affected products or product candidates could be delayed, which could have an adverse effect on our business. Any change in our manufacturers could be costly because the commercial terms of any new arrangement could be less favorable and because the expenses relating to the transfer of necessary technology and processes could be significant.

If any of our product candidates are approved, in order to produce the quantities necessary to meet anticipated market demand, any contract manufacturer that we engage may need to increase manufacturing capacity. If we are unable to 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 Junshi Biosciences, Bioeq, and Orox for the commercialization of our 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 exclusive licenses from Junshi Biosciences to develop and commercialize toripalimab and CHS-006 in the United States and Canada. We have an exclusive license from Bioeq to commercialize CIMERLI in the United States. Our licensors are responsible for supplying us with drug substance and final drug products.

Our exclusive licensee, Orox, is responsible for commercialization of certain of our products and product candidates, including UDENYCA and YUSIMRY in certain Caribbean and Latin American countries (excluding Brazil, and in the case of UDENYCA, also excluding Argentina).

Our licenses with Junshi Biosciences, Bioeq, Orox, or other future license or collaboration agreements, may not result in positive outcomes. 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, including because of import restrictions, or they may be ineffective in doing so;
- our existing and potential collaboration partners may fail regulatory inspections or RRAs 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 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 and the risks of inaccurately forecasting sales of our products. Any adverse developments affecting the manufacturing operations of our 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;
- 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; and
- disruption of supply chains for critical and specialized raw materials, delays in regulatory inspections of manufacturing and testing facilities, and reduced manufacturing capacities created by global events such as the COVID-19 pandemic and the ongoing conflict in Ukraine.

We have experienced 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 products that are manufactured in reliance on a forecast that proves to be inaccurate because we do not sell as many units as forecasted. For example, during the third quarter of 2022, we recorded a \$26.0 million write-down of inventory that was at risk of expiration. Although we believe that the assumptions that we use in estimating inventory write-downs are reasonable, additional write-downs of inventory may be required in the future if actual market conditions are less favorable than our projections, which could materially and adversely impact our financial results. In addition to such write-offs, we may also have to incur charges and expenses related to firm purchase commitments or 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 our products 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 September 2022 we entered into the Bioeq Manufacturing Agreement for our supply of CIMERLI. 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. Additional delays or cost increases could occur due to the direct or indirect effects of the COVID-19 pandemic and the ongoing conflict in Ukraine. 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 Section 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. We have faced a delay in the inspection of our partner's manufacturing facilities in China, which has resulted in a delay of the approval of our original BLA for toripalimab. 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, audit or initiate an RRA of the manufacturing facilities of our collaboration partners and third-party contractors. If any such inspection, audit or RRA 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, audit or RRA, 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 biosimilar 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.

[Table of Contents](#)

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 biosimilar 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

Our products 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 our products 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.

[Table of Contents](#)

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

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

Third parties may assert that we are employing their proprietary technology without authorization. We are aware of third-party patents or patent applications with claims, for example, to compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. While we have conducted freedom to operate analyses with respect to our

[Table of Contents](#)

products 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 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 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 United States 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 United States 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 United States 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 United States 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 United States 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 our 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 YUSIMRY. The global settlements resolve all pending disputes

[Table of Contents](#)

between the parties related to YUSIMRY. Under the United States 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 proceeding 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 and Switzerland seeking to extend certain patent protection, which, if approved, may interfere with or delay the launch of one or more of our 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

[Table of Contents](#)

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. Senior members of our commercial team and medical affairs team who will be responsible for any launch of additional presentations of UDENYCA formerly held positions at Amgen. Our board of directors and scientific advisory board include members who were former employees of Genentech, Amgen and Abbott Laboratories. Although we have procedures in place to 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 filed an action against us, KBI Biopharma, 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 we 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), with Genentech (pertaining to Genentech's intellectual property related to CIMERLI) and with AbbVie (pertaining to AbbVie's intellectual property related to YUSIMRY) 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.

[Table of Contents](#)

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 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 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 United States Supreme Court, as discussed further below, ruled in 2017 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 Section 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

[Table of Contents](#)

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-day 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 Section 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 Section 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 have three approved products: UDENYCA, CIMERLI and YUSIMRY.

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, YUSIMRY received FDA approval but we still will not launch it until July 2023 due to our settlement agreement with AbbVie, and the toripalimab original BLA remains under review by the FDA. Other than certain PK bridging studies, we have not initiated phase 3 clinical trials for other product candidates 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. 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 develop new products or obtain approval for new products by the FDA and comparable foreign authorities is unpredictable, may take many years following the completion of clinical studies and depends upon numerous factors. Further, applications to the Human Genetic Resources Administration of China (HGRAC) required for any activities, including development activities and data sharing with our partners in China, may result in product development delays. 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, in 2020 during FDA's review of Bioeq's Section 351(k) BLA for CIMERLI, the FDA requested that Bioeq submit additional manufacturing data for the equipment in its new location, leading Bioeq to withdraw its Section 351(k) BLA for this candidate in order to provide the requested data and to resubmit the application thereafter. Neither we nor any collaboration partner has obtained regulatory approval for any of our product candidates, other than UDENYCA, which has received approval from the FDA and EMA, YUSIMRY, and CIMERLI which have received approval from the FDA, and toripalimab, which is approved for use in China only, and it is possible that none of our other current or future product candidates will ever obtain additional regulatory approvals.

[Table of Contents](#)

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 Section 351(k) BLA, 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 FDA may determine that the population studied in the clinical program may not be sufficiently broad or representative to assure safety and efficacy in the full population for which we seek approval, or that conclusions of clinical trials conducted in a single country or region outside the United States may not be generalizable to the patient population in the United States;
- 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.

Toripalimab may not be approved in a timely manner or at all by regulatory agencies.

On April 29, 2022, the FDA issued a CRL in response to our original BLA for toripalimab. The letter identified certain issues, including a request for a quality process change. On July 6, 2022, we announced that the FDA accepted the resubmission of the original BLA for toripalimab and announced that the FDA set a PDUFA action date for December 23, 2022. On December 24, 2022, we announced that we did not receive an action letter from the FDA by the PDUFA action date. The FDA previously communicated that an on-site inspection of Junshi Biosciences' manufacturing facility for toripalimab is required before the FDA can approve the original BLA; however, they were unable to conduct the inspection by December 23, 2022 due to the impact of COVID-19 related restrictions on travel in China. The BLA for toripalimab remains under review, and we and Junshi Biosciences are still engaged in ongoing discussions with the FDA about the pre-approval inspection plans. Even though the FDA accepted our resubmission of the BLA for toripalimab, there is no guarantee that the FDA will be able to conduct its required inspection or that the FDA will conclude that the information in that resubmission will be sufficient to support approval and we may fail to obtain regulatory approval in the United States for toripalimab. Additionally, certain factors beyond our control, such as the COVID-19 pandemic, may impact the timeliness of the regulatory reviews of our submissions or any applications for approval.

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

[Table of Contents](#)

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 or our collaboration partners, or both, as the case may be, 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 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 IRB approval at each clinical study site;
- imposition of a clinical hold by regulatory agencies, after review of an IND 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;

[Table of Contents](#)

- 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.

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.

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.

[Table of Contents](#)

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

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

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

We are marketing UDENYCA and CIMERLI in the United States, and subject to product approvals and relevant patent and settlement agreement expirations, we intend to market our other biosimilar products in the United States and outside the United States 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) (for which we discontinued development), 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 United States.

In order to market our products in the E.U., the United States and other jurisdictions, we and our collaboration partners must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The EMA is responsible for the centralized

[Table of Contents](#)

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 reform measures, including the IRA, may increase the difficulty and cost for us to obtain marketing approval for and commercialize our products, affect the prices we may set, and 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 ACA, was passed, which substantially changed the way health care is financed by both governmental and private insurers and has impacted and continues to impact the United States pharmaceutical industry. The ACA, among other things, modified the AMP definition under the MDRP for drugs that are inhaled, infused, instilled, implanted or injected and not generally distributed through the retail channel; expanded rebate payments under the MDRP to include utilization by individuals enrolled in Medicaid managed care organizations; added a provision to increase the Medicaid rebate for line extension drugs; established annual fees and taxes on manufacturers of certain branded prescription drugs; expanded the entities eligible for discounts under the Public Health Service 340B drug pricing program; and established the Medicare Part D coverage gap discount program, in which manufacturers must agree to offer point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the United States Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes include the American Rescue Plan Act of 2021, which eliminates the statutory cap on the Medicaid drug rebate, currently set at 100% of a drug's AMP, beginning January 1, 2024.

[Table of Contents](#)

Most significantly, on August 16, 2022, President Biden signed the IRA into law. This statute marks the most significant action by Congress with respect to the pharmaceutical industry since adoption of the ACA in 2010. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. For that and other reasons, it is currently unclear how the IRA will be effectuated, and while the impact of the IRA on our business and the pharmaceutical industry cannot yet be fully determined, it is likely to be significant. In particular, if a product becomes subject to the IRA negotiation provision and related price cap, that may significantly alter the economic rationale for developing and commercializing a biosimilar.

The cost of prescription pharmaceuticals in the United States is likely to remain the subject of considerable discussion. There have been several Congressional inquiries and proposed and enacted legislation designed to, among other things, reform government program reimbursement methodologies. The likelihood of implementation of these and other reform initiatives is uncertain. In the coming years, additional legislative and regulatory changes could be made to governmental health programs that could significantly impact pharmaceutical companies and the success of our product candidates. We expect that healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates.

Individual states in the United States have also proposed and enacted legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, marketing cost disclosure and other transparency measures, and, in some cases, measures 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.

We expect that healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates.

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 United States 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. 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,

[Table of Contents](#)

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;
- 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 (defined to include doctors, dentists, optometrists, podiatrists, chiropractors, and certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants and certified nurse midwives)), and teaching hospitals and ownership and investment interests held by physicians and their immediate family members; 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 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.

We participate in governmental programs that impose drug price reporting, payment, and other compliance obligations on pharmaceutical manufacturers. Medicaid is a joint federal and state program for low income and disabled beneficiaries. Medicare is a federal program that is administered by the federal government covering individuals age 65 and over as well as those with certain disabilities. Medicare Part B reimburses physicians who administer our products. Under the MDRP, as a condition of having federal funds

[Table of Contents](#)

available for our covered outpatient drugs under Medicaid and under Medicare Part B, we must enter into, and have entered into, an agreement with the Secretary of Health and Human Services to pay a rebate to state Medicaid programs for each unit of our covered outpatient drugs dispensed to a Medicaid beneficiary and paid for by the state Medicaid program. Medicaid rebates are based on pricing data that we are required to report on a monthly and quarterly basis to CMS, the federal agency that administers the MDRP and Medicare programs. For the MDRP, these data include the AMP for each drug and, in the case of innovator products, the Best Price, which represents the lowest price available from us to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity in the United States in any pricing structure, calculated to include all applicable sales and associated rebates, discounts and other price concessions. In connection with Medicare Part B, we must provide CMS with ASP information on a quarterly basis. CMS uses this information to compute Medicare Part B payment rates, which consist of ASP plus a specified percentage. If we become aware that our MDRP submissions for a prior period were incorrect or have changed as a result of recalculation of the pricing data, we must resubmit the corrected data for up to three years after those data originally were due. Pursuant to the IRA, the AMP and ASP figures we report will also be used to compute rebates under Medicare Part D and Medicare Part B triggered by price increases that outpace inflation. If we fail to provide information timely or are found to have knowingly submitted false information to CMS, we may be subject to civil monetary penalties and other sanctions, including termination from the MDRP.

Federal law requires that any company that participates in the MDRP also participate in the Public Health Service's 340B drug pricing program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B program is administered by the HRSA and requires us to agree to charge statutorily defined covered entities no more than the 340B "ceiling price" for our covered drugs when used in an outpatient setting. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low income patients. The 340B ceiling price is calculated using a statutory formula, which is based on the AMP and rebate amount for the covered outpatient drug as calculated under the MDRP. In general, products subject to Medicaid price reporting and rebate liability are also subject to the 340B ceiling price requirement. We must report 340B ceiling prices to HRSA on a quarterly basis, and HRSA publishes them to 340B covered entities. HRSA has finalized regulations regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities for 340B eligible drugs. HRSA has also finalized an administrative dispute resolution process through which 340B covered entities may pursue claims against participating manufacturers for overcharges.

In order to be eligible to have drug products paid for with federal funds under Medicaid and Medicare Part B and purchased by certain federal agencies and grantees, a pharmaceutical manufacturer must also participate in VA FSS pricing program. Under the VA FSS program, we must report the Non-FAMP for our covered drugs to the VA and charge certain federal agencies no more than the Federal Ceiling Price, which is calculated based on Non FAMP using a statutory formula. These four agencies are the VA, the U.S. Department of Defense, the U.S. Coast Guard, and the U.S. Public Health Service (including the Indian Health Service). We must also pay rebates on products purchased by military personnel and dependents through the TRICARE retail pharmacy program. If a manufacturer participating in the FSS program fails to provide timely information or is found to have knowingly submitted false information, the manufacturer may be subject to civil monetary penalties.

Individual states continue to consider and have enacted legislation to limit the growth of healthcare costs, including the cost of prescription drugs and combination products. A number of states have either implemented or are considering implementation of drug price transparency legislation that may prevent or limit our ability to take price increases at certain rates or frequencies. Requirements under such laws include advance notice of planned price increases, reporting price increase amounts and factors considered in taking such increases, wholesale acquisition cost information disclosure to prescribers, purchasers, and state agencies, and new product notice and reporting. Such legislation could limit the price or payment for certain drugs, and a number of states are authorized to impose civil monetary penalties or pursue other enforcement mechanisms against manufacturers for the untimely, inaccurate, or incomplete reporting of drug pricing information or for otherwise failing to comply with drug price transparency requirements. If we are found to have violated state law requirements, we may become subject to penalties or other enforcement mechanisms, which could have a material adverse effect on our business.

Pricing and rebate calculations vary across products and programs, are complex, and are often subject to interpretation by us, governmental or regulatory agencies, and the courts, which can change and evolve over time. Such pricing calculations and reporting, along with any necessary restatements and recalculations, could increase costs for complying with the laws and regulations governing the MDRP and other governmental programs, and under the MDRP could result in an overage or underage in Medicaid rebate liability for past quarters. Price recalculations under the MDRP also may affect the ceiling price at which we are required to offer products under the 340B program. Civil monetary penalties can be applied if we are found to have knowingly submitted any false price or product information to the government, if we are found to have made a misrepresentation in the reporting of ASP, if we fail to submit the required price data on a timely basis, or if we are found to have charged 340B covered entities more than the statutorily mandated ceiling price. CMS could also

[Table of Contents](#)

terminate our Medicaid drug rebate agreement, in which case federal payments may not be available under Medicaid or Medicare Part B for our covered outpatient drugs. We cannot assure you that our submissions will not be found by CMS or other governmental agencies to be incomplete or incorrect.

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 \$5.58 to \$38.10 per share during the period from November 6, 2014 through December 31, 2022 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:

- the Covid-19 pandemic and other viral pandemics;
- adverse results or delays in preclinical or clinical studies;
- any inability to obtain additional funding;
- any delay in filing an IND, NDA, BLA, Section 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, BLA, Section 351(k) BLA or other regulatory submission;
- the perception of limited market sizes or pricing for our products and 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;
- difficulties in the implementation of the shift in our clinical, commercial, manufacturing, regulatory, marketing and general historical focus on biosimilars to a new strategy to build a leading immuno-oncology franchise funded with cash generated by our commercial biosimilar business;
- 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 but not limited to complaints initiated by stockholders, customers and collaboration partners, 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;

[Table of Contents](#)

- 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, including rising interest rates and inflation;
- 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, 2022, our executive officers, directors, five percent stockholders and their affiliates beneficially owned approximately 63.8% 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.

Our indebtedness could adversely affect our financial condition, our ability to raise additional capital to fund our operations, our ability to operate our business, our ability to react to changes in the economy or our industry and our ability to pay our debts and could divert our cash flow from operations for debt payments.

Our leverage and debt service obligations could adversely impact our business, including by:

- impairing our ability to generate cash sufficient to pay interest or principal, including periodic principal payments;
- increasing our vulnerability to general adverse economic and industry conditions;
- requiring the dedication of a portion of our cash flow from operations to service our debt, thereby reducing the amount of our cash flow available for other purposes, including funds for clinical development or to pursue future business opportunities;
- requiring us to sell debt or equity securities or to sell some of our core assets, possibly on unfavorable terms, to meet payment obligations;
- limiting our flexibility in planning for, or reacting to, changes in our business and the industries in which we compete; and
- placing us at a possible competitive disadvantage with less leveraged competitors and competitors that may have better access to capital resources.

Any of the foregoing factors could have negative consequences on our financial condition and results of operations.

This indebtedness could be due sooner upon the triggering of certain covenants in our debt agreements and or upon the occurrence of an event of default. If and when our indebtedness becomes due, if we do not have sufficient cash or access to capital to pay such indebtedness, we will default on our obligations which will adversely harm our business. We also recently entered into a Loan Agreement that contains affirmative and negative covenants that restrict our operations, including, among other restrictions, the requirement to maintain minimum trailing twelve-month net sales in an amount that begins at \$200.0 million in the first quarter of 2022 and increases to \$210.0 million for the quarter ended March 31, 2024 and increases to be as much as \$300.0 million for the quarter ended December 31, 2024. Further, the Loan Agreement includes certain other affirmative covenants and negative covenants, including, covenants and restrictions that among other things, restrict our ability to incur liens, incur additional indebtedness, make investments, engage in certain mergers and acquisitions or asset sales, and declare dividends or redeem or repurchase capital stock.

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 the market price of our common stock could decline. In addition we may authorize our sales agent to sell our common stock from time to time as part of the ATM Offering. As of December 31, 2022, there were 78.9 million shares of common stock outstanding.

In addition, as of December 31, 2022, approximately 29.3 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. Certain of our outstanding options have exercise prices that are above our current stock price. See the tables describing our outstanding stock options in Footnote 11. Stock-Based Compensation and Employee Benefits to our financial statements included in this report. 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 or ongoing financing transactions like the ATM Offering or the shares of common stock that may be issued after we enter into definitive agreements contemplated by the Term Sheet with Klinge Biopharma for the exclusive commercialization rights to FYB203, a biosimilar candidate to Eylea® (aflibercept), 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. 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. 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 (“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 ESPP. The number of shares available for issuance under the 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 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, 2022, we reserved for future issuance under the 2016 Plan a total of 0.9 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 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, 2026. 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 any 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 any 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

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

[Table of Contents](#)

We currently have limited international operations of our own and have and may have in the future a number of international collaborations, including our significant collaboration with Junshi Biosciences in China. Doing business internationally involves a number of risks, including but not limited to:

- failure of the FDA to conduct required inspections in foreign countries such as China or accept clinical trial data obtained by our product candidates in clinical trials in China, which could result in an inability to obtain acceptance or increased costs to pursue clinical trials in the United States;
- 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, including those that affect our work with a collaboration partner in China;
- 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 United States, E.U. and Russian regulatory bodies in connection with Russia's invasion of Ukraine in February 2022; 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 United States Foreign Corrupt Practices Act, its books and records provisions or its anti-bribery provisions.

Investors' expectations of our performance relating to environmental, social and governance factors may impose additional costs and expose us to new risks.

There is an increasing focus from certain investors, employees, regulators and other stakeholders concerning corporate responsibility, specifically related to environmental, social and governance (or "ESG") factors. Some investors and investor advocacy groups may use these factors to guide investment strategies and, in some cases, investors may choose not to invest in our company if they believe our policies relating to corporate responsibility are inadequate. Third-party providers of corporate responsibility ratings and reports on companies have increased to meet growing investor demand for measurement of corporate responsibility performance, and a variety of organizations currently measure the performance of companies on such ESG topics, and the results of these assessments are widely publicized. Investors, particularly institutional investors, use these ratings to benchmark companies against their peers and if we are perceived as lagging with respect to ESG initiatives, certain investors may engage with us to improve ESG disclosures or performance and may also make voting decisions, or take other actions, to hold us and our board of directors accountable. In addition, the criteria by which our corporate responsibility practices are assessed may change, which could result in greater expectations of us and cause us to undertake costly initiatives to satisfy such new criteria. If we elect not to or are unable to satisfy such new criteria, investors may conclude that our

[Table of Contents](#)

policies with respect to corporate responsibility are inadequate. We may face reputational damage in the event that our corporate responsibility procedures or standards do not meet the standards set by various constituencies. We also face significant costs from complying with new ESG regulations, for example, the SEC's proposed climate disclosure rule would result in significant costs of compliance if it is approved as proposed in the future.

We may face reputational damage in the event our corporate responsibility initiatives or objectives do not meet the standards set by our investors, stockholders, lawmakers, listing exchange or other constituencies, or if we are unable to achieve an acceptable ESG or sustainability rating from third-party rating services. A low ESG or sustainability rating by a third-party rating service could also result in the exclusion of our common stock from consideration by certain investors who may elect to invest with our competition instead. Ongoing focus on corporate responsibility matters by investors and other parties as described above may impose additional costs or expose us to new risks. Any failure or perceived failure by us in this regard could have a material adverse effect on our reputation and on our business, share price, financial condition, or results of operations, including the sustainability of our business over time.

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.

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, publicly 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., United States 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 United States 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 United States 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 United States transitioned to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications claiming the same invention are filed by different parties. A third party that files a patent application in the USPTO before we do, could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. The change to "first-to-file" from "first-to-invent" is one of the changes to the patent laws of the United States resulting from the Leahy-Smith America Invents Act (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

[Table of Contents](#)

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 biosimilar 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 United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Further, licensing partners may choose not to file patent applications in certain jurisdictions in which we may obtain commercial rights, thereby precluding the possibility of later obtaining patent protection in these countries. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States or importing products made using our inventions into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export infringing products to territories 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.

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 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, floods 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.

The continuation of the war in Ukraine may exacerbate certain risks we face.

Russia's invasion of Ukraine in February 2022 and the global response, including the imposition of sanctions by the United States and other countries, could create or exacerbate risks facing our business. We have evaluated our operations and partner contracts, and we currently do not expect the outbreak to directly have a significant effect on our financial condition or results of operations. However, if the war in Ukraine persists, escalates or expands, risks that we have identified in this Annual Report on Form 10-K may be materially increased. For example, if our supply arrangements or clinical operations are disrupted due to expanded sanctions or involvement of countries where we have operations or relationships, our business could be materially disrupted. Further, the use of cyberattacks could expand as part of the ongoing conflict, which could adversely affect our ability to maintain or enhance our cyber security measures. These and other risks are described more fully in this "Risk Factors" section.

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, 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 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. For example, the SEC's proposed climate disclosure rule

[Table of Contents](#)

would result in significant costs of compliance if final rules that are similar to the proposed rules are approved in the future. 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 information technology systems, or those used by our third-party CROs or other contractors or consultants, may fail or suffer security breaches and geopolitical tensions or conflicts, such as the ongoing war in Ukraine, may create a heightened risk of cyberattacks.

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. In addition, geopolitical tensions or conflicts, such as Russia’s invasion of Ukraine, may create a heightened risk of cyberattacks. We have also outsourced elements of our information technology infrastructure, and as a result a number of third-party vendors may or could have access to our confidential information. If we or any of our third-party collaborators or service providers 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.

We and certain of our service providers are from time to time subject to cyberattacks and security incidents. While we do not believe that we have experienced any significant system failure, accident or security breach to date, 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.

Attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. Further, 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. Because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence.

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. Federal, state and international laws and regulations can expose us to enforcement actions and investigations by regulatory authorities, and potentially result in regulatory penalties, fines and significant legal liability, if our information technology security efforts fail. We may also be exposed to a risk of loss or litigation and potential liability, which could materially and adversely affect our business, results of operations or financial condition. 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 face the significant risks associated with our recent company-wide implementation of an ERP system that may adversely affect our business and results of operations or the effectiveness of our internal controls over financial reporting.

We recently implemented a company-wide ERP system to upgrade certain existing business, operational, and financial processes. Our ERP implementation is a complex, expensive and time-consuming project and our ERP system initially went live in August 2022. Any deficiencies in the design and implementation of the new ERP system could result in potentially higher costs than we had incurred previously and could adversely affect our ability to develop product candidates, launch products, file reports with the SEC in a timely manner, operate our business or otherwise affect our controls environment. Any of these consequences could have a material and adverse effect on our results of operations and financial condition.

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.

The global data protection landscape is rapidly evolving, and we are or may become subject to numerous state, federal and foreign laws, requirements and regulations governing the collection, use, disclosure, retention, and security of personal information, such as information that we may collect in connection with clinical trials in the U.S. and abroad. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on our business. This evolution may create uncertainty in our business, affect our ability to operate in certain jurisdictions or to collect, store, transfer use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. Compliance with these privacy and data security requirements is rigorous and time-intensive and may increase our cost of doing business. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulations, our internal policies and procedures or our contracts governing our processing of personal information could result in negative publicity, 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.

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 has increased the likelihood of, and risks associated with, data breach litigation. Further, the California Privacy Rights Act (“CPRA”) generally went into effect on January 1, 2023, and significantly amends the CCPA. It imposes 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 also creates a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. Additional compliance investment and potential business process changes may also be required. Similar laws have passed in Virginia, Colorado, Connecticut and Utah, and have been proposed in other states and at the federal level, reflecting a trend toward more stringent privacy legislation in the United States. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging. In the event that we are subject to or affected by HIPAA, the CCPA, the CPRA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

[Table of Contents](#)

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. Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States; in July 2020, the Court of Justice of the EU (“CJEU”) limited how organizations could lawfully transfer personal data from the EU/EEA to the United States by invalidating the Privacy Shield for purposes of international transfers and imposing further restrictions on the use of standard contractual clauses (“SCCs”). In March 2022, the U.S. and EU announced a new regulatory regime intended to replace the invalidated regulations; however, this new EU-U.S. Data Privacy Framework has not been implemented beyond an executive order signed by President Biden on October 7, 2022 on Enhancing Safeguards for United States Signals Intelligence Activities. European court and regulatory decisions subsequent to the CJEU decision of July 16, 2020 have taken a restrictive approach to international data transfers. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the SCCs cannot be used, and/or start taking enforcement action, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results. Penalties and fines for failure to comply with GDPR are significant, including fines of up to €20 million or 4% of total worldwide annual turnover, whichever is higher.

The EU has also adopted the EU Clinical Trials Regulation, which came into effect on January 31, 2022. This regulation imposes new obligations on the use of data generated from clinical trials and enables European patients to have the opportunity to access information about clinical trials.

Further, since the beginning of 2021, we have also been subject to the UK data protection regime, which imposes separate but similar obligations to those under the GDPR and comparable penalties, including fines of up to £17.5 million or 4% of a noncompliant company's global annual revenue for the preceding financial year, whichever is greater. Other foreign jurisdictions are increasingly implementing or developing their own privacy regimes with complex and onerous compliance obligations and robust regulatory enforcement powers. As we continue to expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business.

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.

We may be negatively impacted by continued inflation.

We may be adversely impacted by continued increases in inflation. Current and future inflation may be driven by the following factors: supply chain disruptions, increased costs of transportation, increased input costs such as the cost of fuel, shortages, and governmental stimulus or fiscal policies. Continuing increases in inflation could impact the overall demand for our products, our costs for labor and materials and the size of any margins we are able to realize on our revenues. This would have a material and adverse impact on our business, financial position, results of operations and cash flows. Inflation may also result in higher interest rates, which in turn would result in higher interest expense related to our variable rate indebtedness.

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.

[Table of Contents](#)

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*

The information called for by this Item is incorporated herein by reference to Item 8. "Financial Statements and Supplementary Data," Note 8. "Commitments and Contingencies."

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. As of February 28, 2023, there were approximately 26 stockholders of record of our common stock.

Dividends

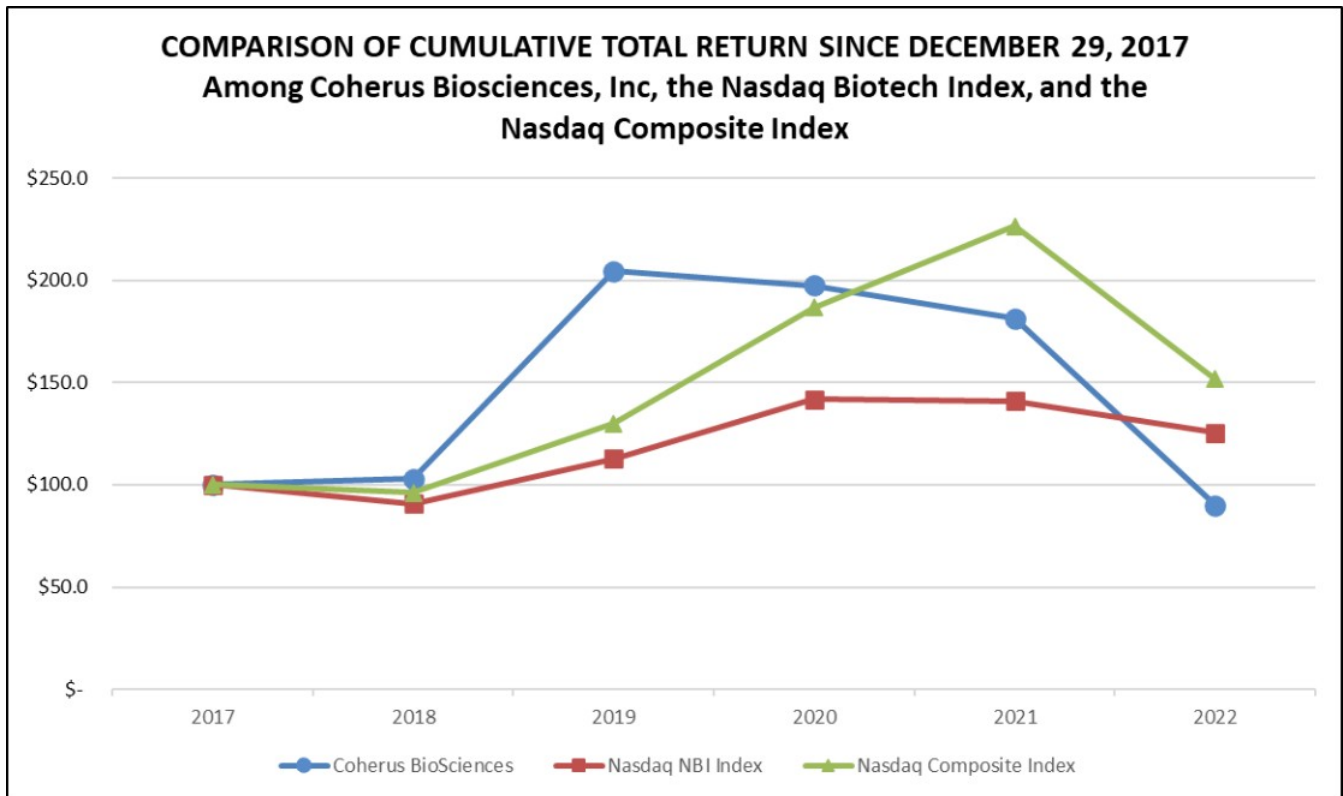
We have never declared or paid any cash dividends on our capital stock and do not anticipate paying cash dividends in the foreseeable future.

Stock Performance Graph

The following graph shows the total stockholder's return on an investment of \$100 in cash at market close on December 29, 2017 (the last trading day before the beginning of our fifth preceding fiscal year) through December 31, 2022 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

[Table of Contents](#)

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, 2022 through December 31, 2022, there were no sales or issuances of unregistered securities that were not otherwise reported on a Quarterly Report on Form 10-Q or Current Report on Form 8-K.

Issuer Purchases of Equity Securities

We did not repurchase any of our equity securities during the fourth quarter ended December 31, 2022. A total of 15,364 shares were surrendered to Coherus in the fourth quarter of 2022, to satisfy minimum tax withholding obligations in connection with the vesting or exercise of stock-based awards.

Item 6. [Reserved]

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

[Table of Contents](#)

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.

This MD&A section generally discusses 2022 and 2021 items and year-to-year comparisons between 2022 and 2021. Discussions of 2020 items and year-to-year comparisons between 2021 and 2020 that are not included in this Form 10-K can be found in "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Part II, Item 7 of our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, filed with the SEC on February 23, 2022.

Overview

We are a commercial-stage biopharmaceutical company focused on the research, development and commercialization of innovative cancer treatments and the commercialization of our portfolio of FDA-approved biosimilars. Our strategy is to build a leading immuno-oncology franchise funded with cash generated through net sales of our diversified portfolio of FDA-approved therapeutics.

Our commercial portfolio includes three FDA-approved biosimilar products. Our first product, UDENYCA, a biosimilar to Neulasta, a long-acting G-CSF, was launched commercially in the United States in January 2019. Our second product, CIMERLI, was approved by the FDA in August 2022 as a biosimilar product interchangeable with Lucentis for the treatment of neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema, diabetic retinopathy, and myopic choroidal neovascularization. The FDA also granted CIMERLI 12 months of first interchangeable exclusivity. We launched CIMERLI commercially in the United States on October 3, 2022. In December 2021, the FDA-approved YUSIMRY, which we plan to launch in the United States on or after July 1, 2023, pursuant to the terms of an agreement with Humira's manufacturer, AbbVie.

In addition to our three FDA-approved biosimilar products, we also have an original BLA under review by the FDA for toripalimab. Toripalimab is being developed for its ability to block PD-1 interactions with its ligands, PD-L1 and PD-L2 by binding to the FG loop on the PD-1, and for enhanced PD-1 receptor internalization (endocytosis function). We believe blocking PD-1 interactions with PD-L1 and PD-L2 have the potential to promote the immune system's ability to attack and kill tumor cells. The original BLA for toripalimab was for the use of toripalimab in combination with gemcitabine and cisplatin for first-line treatment of adults with metastatic or recurrent locally advanced NPC, and for use as a monotherapy in the second- or later-line treatment of patients with recurrent unresectable or metastatic NPC that have progressed on or after a platinum-containing chemotherapy. On April 29, 2022, we received a CRL from the FDA for the original BLA for toripalimab requesting certain manufacturing process changes that we and Junshi Biosciences believe are readily addressable. On July 6, 2022, we announced that the FDA accepted the resubmission of the original BLA for toripalimab and announced that the FDA set a PDUFA action date for December 23, 2022. On December 24, 2022, we announced that we did not receive an action letter from the FDA by the PDUFA action date. The FDA previously communicated that an on-site inspection of Junshi Biosciences' manufacturing facility for toripalimab is required before the FDA can approve the original BLA; however, they were unable to conduct the inspection by December 23, 2022 due to the impact of COVID-19 related restrictions on travel in China. The BLA for toripalimab remains under review, and we and Junshi Biosciences are engaged in ongoing discussions with the FDA about the pre-approval inspection plans. Since the decision in February 2022 by the FDA to not approve the BLA for sintilimab, the FDA's current stance is to reject most product candidates that do not have data that is reflective of U.S. medical practice and/or the U.S. patient population and in particular with clinical trials conducted in a single country such as China. However, we believe that our original BLA for toripalimab for NPC is a distinct case because there are no approved immunotherapies for NPC in the United States and the FDA has stated that NPC warrants regulatory flexibility with respect to the sufficiency of single country clinical data. We plan to launch toripalimab in the United States in the third quarter of 2023, if approved by July 1, 2023. In January 2023, we and Junshi Biosciences acted to reduce the scope of the ongoing development plan for toripalimab in the United States that is used as part of the calculation for reimbursable research and development expense under the Collaboration Agreement.

In May 2022, we discontinued development of CHS-305, an Avastin biosimilar candidate.

We have built an experienced and robust oncology market access, key account management and medical affairs capability in the United States, which have supported the successful commercialization of UDENYCA and CIMERLI. We expect to leverage these capabilities as we build and launch our immuno-oncology franchise, continue to grow our ophthalmology product portfolio and launch the commercialization of other biosimilar products.

We primarily operate in the United States and partner with companies that operate in other countries. We have no material direct exposure to Russia and Ukraine; however, we are monitoring any broader economic impact from Russia's invasion of Ukraine and the ongoing war between the two nations, including heightened risk of cyberattacks, increased prices of fuel and other commodities, and potential impacts to our partners' supply chains.

Business Update

On January 9, 2023, we announced that we entered into the Term Sheet with Klinge Biopharma for the exclusive commercialization rights to FYB203, a biosimilar candidate to Eylea® (aflibercept), in the United States. The parties to the Term Sheet expect to execute the Definitive Agreements contemplated by the Term Sheet and complete the transaction in the first half of 2023. Under the Term Sheet, we will make a total upfront payment of approximately €30 million, comprised of cash and our common stock, thirty days after the execution of the Definitive Agreements. We also agreed to make other regulatory and launch milestone payments and to make royalty payments based on approximately equal sharing of profits from the sale of FYB203 in consideration for the commercialization rights to FYB203 in the United States.

The material terms of the transaction with Klinge Biopharma will be set forth in the Definitive Agreements, which we will include in a subsequent filing when such Definitive Agreements are executed.

On November 8, 2022, we filed a registration statement on Form S-3, which was declared effective on November 17, 2022 (the "Registration Statement"). Under the Registration Statement, we may offer and sell up to \$150.0 million in the aggregate of our common stock, preferred stock, debt securities, warrants and units from time to time in one or more offerings. Also on November 8, 2022, we entered into a sales agreement ("Sales Agreement") with Cowen and Company, LLC ("Cowen") pursuant to which we may issue and sell from time to time up to \$150.0 million of our common stock through or to Cowen as our sales agent or principal in an at-the-market offering ("ATM Offering"). Any shares of our common stock offered and sold in the ATM Offering are to be issued pursuant to the Registration Statement and the 424(b) prospectus supplement relating to the ATM Offering dated November 17, 2022. As of December 31, 2022, we sold 916,884 shares of common stock at a weighted-average price per share of \$7.30 for gross proceeds of \$6.7 million pursuant to the ATM Offering and received net proceeds of \$6.5 million, net of \$0.2 million of commissions and fees. In January 2023, we settled an additional 295,200 shares at a weighted-average price per share of \$7.41 for gross proceeds of \$2.2 million pursuant to the ATM Offering and received net proceeds of \$2.1 million, net of \$0.1 million of commissions and fees.

In January 2022, we entered into the Loan Agreement with the Collateral Agent and the Lenders that provides for a senior secured term loan facility of up to \$300.0 million to be funded in four committed tranches: (i) a Tranche A Loan in an aggregate principal amount of \$100.0 million (the "Tranche A Loan") that was funded on January 5, 2022 (the "Tranche A Closing Date"); (ii) a Tranche B Loan in an aggregate principal amount of \$100.0 million (the "Tranche B Loan") that was funded on March 31, 2022; (iii) a Tranche C Loan in an aggregate principal amount of \$50.0 million (the "Tranche C Loan") that was not funded; and (iv) a Tranche D Loan in an aggregate principal amount of \$50.0 million (the "Tranche D Loan" and, together with the Tranche A Loan, the Tranche B Loan, and the Tranche C Loan, the "2027 Term Loans") that was funded on September 14, 2022. We have the right to request an uncommitted additional facility amount of up to \$100.0 million that is subject to new terms and conditions.

The 2027 Term Loans mature on either (i) the fifth anniversary of the Tranche A Closing Date; or (ii) October 15, 2025, if the outstanding aggregate principal amount of our 2026 Convertible Notes is greater than \$50.0 million on October 1, 2025. The outstanding tranches of the 2027 Term Loans accrue interest from inception through March 31, 2023 at 8.25% plus three-month LIBOR per annum with a LIBOR floor of 1.0%; and, starting April 1, 2023, accrue interest at 8.25% plus the sum (the "Adjusted Term SOFR") of three-month SOFR and 0.26161% per annum, with a floor on Adjusted Term SOFR of 1.0%. The interest rate for the fourth quarter of 2022 was 12.00%. Interest is payable quarterly in arrears on March 31, June 30, September 30 and December 31 of each year. Repayment of outstanding principal of the 2027 Term Loans will be made in five equal quarterly payments of principal commencing March 31, 2026.

Products and Product Candidates

Our portfolio includes the following products and product candidates:

Oncology

- UDENYCA is a biosimilar to Neulasta, a long-acting G-CSF. We launched UDENYCA commercially in the United States in January 2019. In 2022, 2021 and 2020, we recorded UDENYCA net product sales of \$203.8 million, \$326.5 million and \$475.8 million, respectively. In addition to the currently marketed PFS presentation and UDENYCA AI, which had its prior approval supplement approved on March 3, 2023, we are also developing additional presentations of UDENYCA, such as a proprietary OBI and an AI. In October 2021, we announced positive results from a randomized, open-label, crossover study assessing the PK and pharmacodynamic bioequivalence of UDENYCA administered via OBI compared to our currently marketed UDENYCA PFS. We are planning a 2023 launch of UDENYCA OBI, if approved by the FDA. We submitted a prior approval supplement to

the FDA for UDENYCA AI in 2022. The FDA approved the prior approval supplement for UDENYCA AI on March 3, 2023. Commercial availability of UDENYCA AI is planned for the second quarter of 2023.

- Toripalimab is being developed for its ability to block PD-1 interactions with its ligands, PD-L1 and PD-L2 by binding to the FG loop on the PD-1, and for enhanced PD-1 receptor internalization (endocytosis function). We believe blocking PD-1 interactions with PD-L1 and PD-L2 can help to promote the immune system's ability to attack and kill tumor cells. More than thirty company-sponsored toripalimab clinical studies covering more than fifteen indications have been conducted by our partner Junshi Biosciences, including in China, the United States, Southeast Asia, and European countries.

Together with Junshi Biosciences, in the third quarter of 2021 we completed the submission of the original BLA for toripalimab to the FDA seeking approval for the use of toripalimab in combination with gemcitabine and cisplatin for first-line treatment of adults with metastatic or recurrent locally advanced NPC, and for use as a monotherapy in the second- or later-line treatment of patients with recurrent unresectable or metastatic NPC that have progressed on or after a platinum-containing chemotherapy. The FDA issued a CRL for the original BLA for toripalimab requesting certain manufacturing process changes. On July 6, 2022, we announced that the FDA accepted the resubmission of the original BLA for toripalimab and announced that the FDA set a PDUFA action date for December 23, 2022. On December 24, 2022, we announced that we did not receive an action letter from the FDA by the PDUFA action date. The FDA previously communicated that an on-site inspection of Junshi Biosciences' manufacturing facility for toripalimab is required before the FDA can approve the original BLA; however, they were unable to conduct the inspection by December 23, 2022 due to the impact of COVID-19 related restrictions on travel in China. The BLA for toripalimab remains under review, and we and Junshi Biosciences are engaged in ongoing discussions with the FDA about the pre-approval inspection plans. We plan to launch toripalimab in the United States in the third quarter of 2023, if approved by July 1, 2023. We believe there is potentially a high unmet need in NPC based on the current FDA-approved treatment alternatives and the lack of any approved immunotherapies.

The FDA has granted Breakthrough Therapy designation to toripalimab for the treatment of patients with recurrent or metastatic NPC with disease progression on or after platinum-containing chemotherapy and for toripalimab in combination with chemotherapy (gemcitabine and cisplatin) for the first-line treatment of recurrent or metastatic NPC.

- CHS-006 is an investigational recombinant humanized IgG4k monoclonal antibody designed to act specifically against human TIGIT that we are developing in collaboration with Junshi Biosciences. A number of third-party preclinical and clinical studies have demonstrated that activation of the TIGIT pathway could be a crucial underlying mechanism for tumor immune evasion and resistance to PD-1 blockade therapy in some tumor types. Combination of TIGIT and PD-1/PD-L1 antibodies showed a synergistic potential to enhance antitumor response, to overcome anti-PD-1 resistance and possibly broaden the cancer patient population that can benefit from immunotherapy.

A dose escalation, dose expansion clinical trial (clinicaltrials.gov identifier# NCT05061628) evaluating the safety, tolerability and pharmacokinetic properties of CHS-006 as monotherapy and in combination with PD-1 inhibitor toripalimab in patients with advanced solid tumors is ongoing in China. The FDA has allowed clinical trials for CHS-006 to proceed in the United States under an IND, and we plan to advance toripalimab in combination with CHS-006 in a clinical trial in North America in the second quarter of 2023.

- We are pursuing an early-stage development candidate designed to improve anti-PD-1 clinical benefit by transforming an unfavorable TME to a more favorable TME. We expect to submit an IND to the FDA in 2023 for CHS-1000, an antibody targeting ILT4.

Immunology

- YUSIMRY, a biosimilar of Humira (adalimumab), a monoclonal antibody that can bind to TNF. YUSIMRY provides certain therapeutic benefits for treatment of patients with certain inflammatory diseases characterized by increased production of TNF in the body, including rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, psoriasis and ulcerative colitis. In December 2021, the FDA approved YUSIMRY, which we plan to launch in the United States on or after July 1, 2023, pursuant to the terms of an agreement with Humira's manufacturer, AbbVie Inc. Based on our current review, we believe the adalimumab market will be very competitive when we are able to launch on July 1, 2023.

Ophthalmology

- CIMERLI is a Lucentis biosimilar. In November 2019, we entered into a license agreement with Bioeq for the commercialization of CIMERLI in certain dosage forms in both a vial and PFS presentation. Under the Bioeq Agreement, Bioeq granted to us an exclusive royalty-bearing license to commercialize CIMERLI in the field of ophthalmology (and any other approved labelled indication) in the United States.

On August 2, 2022, the FDA approved CIMERLI as a biosimilar product interchangeable with Lucentis for the treatment of neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema, diabetic retinopathy, and myopic choroidal neovascularization. The FDA also granted CIMERLI 12 months of first interchangeable exclusivity. On October 3, 2022, we launched CIMERLI commercially in the United States in both 0.3 mg and 0.5 mg dosage forms.

Discontinued Product Candidates

In January 2020, we entered into a license agreement with Innovent for the development and commercialization of a biosimilar version of bevacizumab (Avastin) in any dosage form and presentations in the United States and Canada. On May 3, 2022, we provided notice of termination of the Innovent Agreement to Innovent to discontinue development of CHS-305, a bevacizumab (Avastin) biosimilar candidate, because regulatory approval of the licensed product could not be reasonably obtained within the agreed time period.

In October 2022, we discontinued development of our preclinical immuno-oncology program, CHS-3318, an antibody targeting CCR8.

License Agreement with Junshi Biosciences

On February 1, 2021, we entered into 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, we paid \$150.0 million upfront for exclusive rights to toripalimab in the United States and Canada, an option in these territories to Junshi Biosciences' anti-TIGIT antibody CHS-006, an option in these territories to a 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 regulatory and sales milestones.

In March 2022, we paid \$35.0 million for the exercise of our option to license CHS-006. We and Junshi Biosciences are jointly developing CHS-006 with each party responsible for the associated development costs as set forth in the Collaboration Agreement. If we exercise our remaining option for the IL-2 cytokine, we will be obligated to pay an additional option exercise fee of \$35.0 million. Additionally, for each exercised option, we will be obligated to pay Junshi Biosciences an 18% royalty on net sales, up to \$85.0 million for the achievement of certain regulatory approvals, and 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, including CHS-006, and will pay for a portion of these co-development activities up to a maximum of \$25.0 million per licensed compound per year. Additionally, we are responsible for certain associated regulatory and technology transfer costs for toripalimab and other licensed compounds and will reimburse Junshi Biosciences for such costs.

We accounted for the licensing transaction as an asset acquisition under the relevant accounting rules. The \$35.0 million payment for the option to license CHS-006 was reflected in our first quarter of 2022 financial statements. We recorded research and development expense of \$145.0 million during the first quarter of 2021, related to an upfront payment for exclusive rights to toripalimab in the United States and Canada. We had entered into a Right of First Negotiation agreement with Junshi Biosciences and paid a fee of \$5.0 million which was expensed as research and development expense in the fourth quarter of 2020. The Right of First Negotiation fee was fully credited against the total upfront license fee obligation under the Collaboration Agreement. As of December 31, 2022, we did not have any outstanding milestone or royalty payment obligations to Junshi Biosciences. The additional milestone payments, option fee for the IL-2 cytokine and royalties are contingent upon future events and, therefore, will be recorded if and when it becomes probable that a milestone will be achieved, or when an option fee or royalties are incurred.

In connection with the Collaboration Agreement, we entered into a Stock Purchase Agreement with Junshi Biosciences agreeing, subject to customary conditions, to acquire certain equity interests in us. Pursuant to the Stock Purchase Agreement, on April 16, 2021,

[Table of Contents](#)

we issued 2,491,988 unregistered shares of our common stock to Junshi Biosciences, at a price per share of \$20.06, for an aggregate amount of approximately \$50.0 million in cash. Under the terms of the Stock Purchase Agreement, Junshi Biosciences is not permitted to sell, transfer, make any short sale of, or grant any option for the sale of the common stock for the two year period following its effective date.

COVID-19 Update

As a result of the COVID-19 pandemic, we have experienced and may continue to experience disruptions that could severely impact our business, clinical trials and preclinical studies. See "Risk Factors – Risks Related to COVID-19." 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 or regulatory milestones for our product candidates, each of which would harm our business, financial condition, results of operations and growth. Although cases and deaths from the COVID-19 pandemic have generally declined in the United States in the past year, outbreaks of COVID-19 in China recently resulted in a protracted lockdown covering all of Shanghai where our partner Junshi Biosciences has its headquarters. The lingering impacts of recent outbreaks of COVID-19 in China may impact the timeline to manufacture toripalimab and the FDA has communicated to us the COVID-19 pandemic will impact the FDA's ability to conduct foreign inspections of our partner's manufacturing facilities in China. Until further outbreaks of COVID-19 are controlled, we expect it may continue to adversely impact our sales growth. In addition, the spread of more contagious and/or deadly variants could cause future outbreaks of COVID-19 and could result in the reinstatement of restrictive orders that could disrupt our business.

While the long-term economic impact and future outbreaks of COVID-19 may be difficult to predict, the pandemic has resulted in, and future outbreaks may continue to cause, 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, market correction or depression resulting from the world's ongoing recovery from the COVID-19 pandemic 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 United States sales of UDENYCA on January 3, 2019. In December 2021, the FDA-approved YUSIMRY, which we plan to launch in the United States on or after July 1, 2023, pursuant to the terms of an agreement with Humira's manufacturer, AbbVie. On August 2, 2022, the FDA approved CIMERLI, which we launched on October 3, 2022. Total net revenues were \$211.0 million and \$326.6 million in 2022 and 2021, respectively.

Cost of Goods Sold

Cost of goods sold consists primarily of third-party manufacturing, distribution, and certain overhead costs. During the third quarter of 2022, we recorded an inventory write-down of \$26.0 million for inventory at risk of expiration, and in the year ended December 31, 2021 we recorded a net \$5.1 million inventory write-off for inventory that did not meet acceptance criteria. Through March 31, 2021, a portion of the costs of producing UDENYCA sold was expensed as research and development before the FDA approval of UDENYCA and therefore is not reflected in cost of goods sold. All the inventory expensed prior to approval of UDENYCA was fully utilized by March 31, 2021; thus, the costs of producing UDENYCA are fully reflected in cost of goods sold beginning April 1, 2021. On May 2, 2019, we 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 July 1, 2019 and continues for five years from then. Additionally, 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, and pursuant to the Genentech Agreement we incur a royalty that is a low single-digit percentage of net sales of CIMERLI that must be paid through the end of 2023.

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:

[Table of Contents](#)

- expense incurred under agreements with collaborators, consultants, third-party 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 CMOs, and related costs associated with release and stability testing;
- costs associated with manufacturing process development activities, analytical activities and pre-launch inventory manufactured prior to regulatory approval being obtained or deemed to be probable; and
- upfront and certain 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 licensing and collaboration costs, clinical development and manufacturing process development of our product candidates.

The process of conducting the necessary clinical research to obtain regulatory approval is costly and time consuming. Furthermore, in the past, we have entered into collaborations with third parties to participate in the development and commercialization of our product candidates, and we may enter into additional collaborations in the future. In situations in which third parties have substantial influence over the development activities for product candidates, the estimated completion dates are not fully under our control. For example, our partners in licensed territories may exert considerable influence on the regulatory filing process globally. Therefore, we cannot forecast with any degree of certainty the duration and completion costs of these or other current or future clinical trials of our product candidates. We may never succeed in achieving regulatory approval for any of our pipeline product candidates. In addition, we may enter into other collaboration arrangements for our other product candidates, which could affect our development plans or capital requirements.

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

(in thousands)	Development Status as of December 31, 2022	Year Ended December 31,	
		2022	2021
External costs incurred by product candidate:			
UDENYCA	Approved ⁽¹⁾	\$ 17,358	\$ 39,026
YUSIMRY	Approved ⁽²⁾	26,309	48,326
Toripalimab	Pivotal Clinical Trials ⁽³⁾	36,871	43,368
CHS-006	Clinical Trials ⁽⁴⁾	4,650	—
CHS-1000	Early-Stage Development ⁽⁵⁾	2,671	—
Discontinued projects	Discontinued ⁽⁶⁾	1,007	20,262
Junshi Biosciences upfront and option exercise payments		35,000	136,000
Other research and development expenses ⁽⁷⁾		1,838	5,295
Internal costs		73,654	70,828
Total research and development expenses		\$ 199,358	\$ 363,105

(1) Expenses related primarily to development efforts to obtain Prior Approval Supplements (“PAS”) for additional presentations of UDENYCA.

(2) YUSIMRY, formerly CHS-1420, was approved by the FDA in December 2021. Expenses in 2021 primarily related to FDA pre-approval inspections and scaling up process performance qualification production runs. Expenses in 2022 primarily related to on-going manufacturing efforts for new formulations and clinical studies.

(3) The FDA has granted Priority Review for the toripalimab BLA, as well as Breakthrough Therapy Designation for toripalimab for the treatment of NPC, and the original BLA for toripalimab is currently under review. In 2022 and 2021, we reimbursed Junshi Biosciences \$25.0 million per year for

[Table of Contents](#)

toripalimab clinical trials that were included in the development plan for toripalimab as described in the Collaboration Agreement and with changes approved by the joint development committee.

- (4) In March 2022, we exercised our option to license CHS-006, a TIGIT-targeted antibody, in the United States and Canada from Junshi Biosciences, expanding our 2021 immuno-oncology collaboration agreement. Expenses in 2022 included our reimbursement for certain costs related to an ongoing CHS-006 clinical trial being conducted by Junshi Biosciences.
- (5) We expect to submit an IND to the FDA in 2023 for CHS-1000, an antibody targeting ILT4.
- (6) The \$1.0 million of expense in 2022 relates to CHS-3318 and CHS-305 which were both discontinued during the year. The expense in 2021 includes \$11.2 million related to CHS-2020 which was discontinued during 2021 and \$9.1 million related to CHS-305.
- (7) Amount consists of expenses for other pipeline candidates and CIMERLI, which was approved by the FDA in August 2022.

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, CIMERLI, YUSIMRY and our product candidate, toripalimab. Personnel costs consist of salaries, benefits and stock-based compensation.

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 outstanding debt agreements.

Loss on Debt Extinguishment

Loss on debt extinguishment consists of losses incurred related to the early repayment of debt obligations.

Other Income (Expense), Net

Other income (expense), net consists primarily of interest earned on our cash, cash equivalents and investments in marketable securities, foreign exchange gains (losses) resulting from currency fluctuations, and gains (losses) from disposal of long-lived assets.

Results of Operations

Comparison of Years Ended December 31, 2022 and 2021

Revenue

(in thousands)	Year Ended December 31,		
	2022	2021	Change
Net revenue	\$ 211,042	\$ 326,551	\$ (115,509)

The decrease in net revenue was primarily due to a decrease in the number of UDENYCA units sold and a reduction in the average net selling price per unit resulting from competition and lower patient enrollment. Our net revenue and market penetration may continue to be adversely impacted by pricing trends and competitive dynamics in the overall pegfilgrastim market. In addition, the COVID-19 pandemic has negatively impacted the pre-filled syringe pegfilgrastim market due to preferences to administer medication at home. These negative factors were partially offset by our CIMERLI launch in October 2022 which contributed \$6.9 million of net revenue in 2022.

We expect our net revenue to increase during 2023, as a result of CIMERLI's launch in October 2022 and the planned launches in 2023 of toripalimab and YUSIMRY and additional presentations of UDENYCA.

[Table of Contents](#)*Cost of Goods Sold*

(in thousands)	Year Ended December 31,		
	2022	2021	Change
Cost of goods sold	\$ 70,083	\$ 57,591	\$ 12,492
Gross margin	67 %	82 %	

The increase in cost of goods sold primarily resulted from the \$26.0 million write-down in the third quarter of 2022 of inventory at risk of expiration compared to the \$5.1 million net write-off of inventory in 2021 for inventory that did not meet acceptance criteria, partially offset by decreases in the number of UDENYCA units sold, lower royalty costs by \$3.0 million as well as the sale of \$3.3 million of previously expensed UDENYCA batches that were required to be expensed as research and development prior to the FDA approval of UDENYCA and, therefore, was not reflected in the cost of goods sold in 2021.

We expect our gross margin to decrease during 2023 primarily driven by royalties paid for CIMERLI sales, sales of YUSIMRY in a very competitive market and continued declines in net realized prices of UDENYCA. This decrease is expected to be partially offset by the \$26.0 million write-down of UDENYCA inventory at risk of expiration in 2022.

Research and Development Expense

(in thousands)	Year Ended December 31,		
	2022	2021	Change
Research and development	\$ 199,358	\$ 363,105	\$ (163,747)

The decrease in research and development expense was primarily due to:

- higher license fees in 2021, including \$145.0 million in expense pursuant to the Collaboration Agreement with Junshi Biosciences in February 2021, which was partially offset by a \$9.0 million credit related to the fair value of the discount for lack of marketability on the common shares purchased under the Stock Purchase Agreement, as compared to 2022 which included an upfront payment of \$35.0 million to exercise our option to license CHS-006, a TIGIT-targeted antibody, in the United States and Canada;
- a decrease of \$22.0 million related to the development of YUSIMRY mainly due to higher costs in 2021 associated with FDA pre-approval inspections and scaling up process performance qualification production runs;
- a decrease of \$21.7 million related to the development of additional presentations of UDENYCA;
- a decrease of \$11.2 million in CHS-2020 costs related to the discontinuation of its development in the first quarter of 2021;
- a decrease of \$8.5 million in costs for the development of bevacizumab (Avastin) biosimilar, a former product candidate which we discontinued development in May 2022; and
- a decrease of \$1.8 million in co-development costs for toripalimab and CHS-006.

The decrease was partially offset by:

- an increase of \$2.7 million for early stage development of an antibody targeting ILT4; and
- an increase of \$1.8 million in personnel and consulting costs to advance our research and development programs.

We expect our research and development expense in 2023 to be lower than in 2022, excluding potential milestone payments related to our product candidates, because of the reduced scope of the development plan for toripalimab in the United States based on changes approved by us and Junshi Biosciences.

[Table of Contents](#)*Selling, General and Administrative Expense*

(in thousands)	Year Ended December 31,		
	2022	2021	Change
Selling, general and administrative	\$ 198,481	\$ 169,713	\$ 28,768

The increase in selling, general and administrative expense was primarily due to the following:

- a net increase of \$22.1 million for personnel, consulting, professional services, marketing, advertising and other expenses resulting from an increase in sales force personnel and related commercial functions to support our current and future product sales;
- an increase of \$4.1 million in facilities, supplies and materials and other infrastructure related expenses to support our commercial infrastructure for our current and future products; and
- an increase of \$3.2 million in travel expenses as a result of curtailed travel in 2021 due to COVID-19.

We expect our selling, general and administrative expense in 2023 to be lower than in 2022 primarily as a result of decreased commercial costs.

Interest Expense

(in thousands)	Year Ended December 31,		
	2022	2021	Change
Interest expense	\$ 32,474	\$ 22,959	\$ 9,515

The increase in interest expense in 2022 was primarily due to a higher average outstanding debt balance and interest rate increases in the United States in 2022, which has led to a higher weighted-average interest rate in 2022 as compared to 2021. In addition, the increase in interest expense was due to \$3.9 million of interest expense related to the 2027 Term Loan discount and debt issuance costs that were allocated to unfunded tranches and subsequently amortized over the respective commitment periods for tranches, including \$2.3 million allocated to Tranche B that was fully amortized in the first quarter of 2022.

Our 2027 Term Loans have a variable interest rate component that resets the first day of every quarter, and the total interest rate ranged from 9.25% in the first quarter of 2022 to 12.00% in the fourth quarter of 2022. The interest rate on the 2027 Term Loans increased to 13.03% for the first quarter of 2023. As a result of the higher interest rate and higher average outstanding debt balance, we expect higher interest expense in 2023.

Loss on Debt Extinguishment

(in thousands)	Year Ended December 31,		
	2022	2021	Change
Loss on debt extinguishment	\$ 6,222	\$ —	\$ 6,222

The \$6.2 million loss on debt extinguishment recorded in 2022 resulted from voluntarily prepaying all amounts outstanding under the loan agreement between us and affiliates of Healthcare Royalty Partners dated as of January 7, 2019 (the "2025 Term Loan") in January 2022.

Other Income (Expense), Net

(in thousands)	Year Ended December 31,		
	2022	2021	Change
Other income (expense), net	\$ 3,822	\$ (283)	\$ 4,105

In 2022 other income (expense), net increased primarily as a result of interest income on our cash, cash equivalents and marketable securities. The interest rate in 2022 was higher than in 2021 due to several interest rate increases in the United States in 2022. The net expense in 2021 was due to the realized loss upon liquidating our investments in marketable securities.

Liquidity and Capital Resources

Certain relevant measures of our liquidity and capital resources are summarized as follows:

<u>(in thousands)</u>	<u>December 31,</u> <u>2022</u>	<u>December 31,</u> <u>2021</u>
Financial assets		
Total Cash, cash equivalents and marketable securities	<u>\$ 191,681</u>	<u>\$ 417,195</u>
Debt obligations:		
2027 Term Loans	\$ 245,483 ⁽¹⁾	\$ —
2025 Term Loan	—	75,513 ⁽¹⁾
2022 Convertible Notes	—	108,479 ⁽¹⁾
2026 Convertible Notes	<u>225,575</u>	<u>224,288</u>
Total debt obligations	<u>\$ 471,058</u>	<u>\$ 408,280</u>

(1) The 2027 Term Loans were entered into in January 2022 in connection with the payoff and refinancing of existing debt facilities. See below for further discussion and “Note 7. Debt Obligations” in the “Notes to Consolidated Financial Statements” contained in Part II, Item 8 of this Annual Report on Form 10-K.

Although we were profitable in 2020 and 2019, due to our research and development expenditures and decline in revenue beginning in 2021, we have generated significant operating losses in all other years since our inception, including in 2022 and 2021. We have funded our operations primarily through sales of our common stock, issuance and incurrence of convertible and term debt and sales of UDENYCA.

We entered into the Sales Agreement related to the ATM Offering pursuant to which we may issue and sell from time to time up to \$150.0 million of our common stock. As of December 31, 2022, we sold 916,884 shares of common stock at a weighted-average price per share of \$7.30 for gross proceeds of \$6.7 million pursuant to the ATM Offering and received net proceeds of \$6.5 million, net of \$0.2 million of commissions and fees. In January 2023, we settled an additional 295,200 shares at a weighted-average price per share of \$7.41 for gross proceeds of \$2.2 million pursuant to the ATM Offering and received net proceeds of \$2.1 million, net of \$0.1 million of commissions and fees. The ability to elect to sell shares of our common stock in the ATM Offering from time to time adds to our financial flexibility.

As of December 31, 2022, we had an accumulated deficit of \$1.3 billion and cash, cash equivalents, and marketable securities of \$191.7 million. We believe that our available cash, cash equivalents, marketable securities, cash collected from product sales and ATM Offering proceeds will be sufficient to fund our planned expenditures and meet our obligations for at least the twelve 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. We may need to raise additional funds in the future; however, there can be no assurance that such efforts will be successful or that, if they are successful, the terms and conditions of such financing will be favorable. Our future funding requirements will depend on many factors, including the following:

- cash proceeds from product sales;
- the costs of manufacturing, distributing and marketing our products;
- 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;

[Table of Contents](#)

- 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;
- the extent to which we acquire or invest in businesses, products or technologies;
- the impact of general economic conditions on our business, including but not limited to increased interest rates and high inflation; and
- the costs of the impact from the COVID-19 pandemic and future outbreaks.

For further discussion of risks related to our financial condition and capital requirements, please see “Risk Factors—Risks Related to Our Financial Condition and Capital Requirements.”

Financing arrangements

2027 Term Loans

In January 2022, we entered into the 2027 Term Loans which provide for a senior secured term loan facility of up to \$300.0 million to be funded in four committed tranches: (i) a Tranche A Loan in an aggregate principal amount of \$100.0 million that was funded on January 5, 2022; (ii) a Tranche B Loan in an aggregate principal amount of \$100.0 million that was funded on March 31, 2022, in connection with the full repayment of our 2022 Convertible Notes due in March 2022; (iii) a Tranche C Loan in an aggregate principal amount of \$50.0 million that was not funded; and (iv) a Tranche D Loan in an aggregate principal amount of \$50.0 million that was funded on September 14, 2022. We have the right to request an uncommitted additional facility amount of up to \$100.0 million that is subject to new terms and conditions.

The 2027 Term Loans mature on either (i) January 5, 2027; or (ii) October 15, 2025, if the outstanding aggregate principal amount of our 2026 Convertible Notes is greater than \$50.0 million on October 1, 2025. The 2027 Term Loans accrue interest from inception through March 31, 2023 at 8.25% plus three-month LIBOR per annum with a LIBOR floor of 1.0%; and, starting April 1, 2023, accrue interest at 8.25% plus the Adjusted Term SOFR, with a floor on Adjusted Term SOFR of 1.0%. Interest is payable quarterly in arrears. Repayment of outstanding principal of the 2027 Term Loans will be made in five equal quarterly payments of principal commencing March 31, 2026.

In January 2022, we paid to the Lenders of the 2027 Term Loans \$6.0 million for a funding fee equal to 2.00% of the Lenders' total committed amount to fund all four tranches.

Pursuant to the Loan agreement, and subject to certain restrictions, proceeds of the 2027 Term Loans were and will be used to fund our general corporate and working capital requirements except for the following: in January 2022, proceeds of the Tranche A Loan were used to voluntarily repay in full all amounts outstanding under the 2025 Term Loan, as well as all associated costs and expenses; and proceeds of the Tranche B Loan were drawn in connection with the full repayment of our 2022 Convertible Notes due in March 2022.

2025 Term Loan

As of December 31, 2021, the carrying amount of our \$75.0 million aggregate principal 2025 Term Loan was \$75.5 million. In January 2022, we used proceeds from a separate borrowing, Tranche A Loan of the 2027 Term Loans, to voluntarily prepay all amounts outstanding under the 2025 Term Loan, pursuant to the \$81.9 million payoff amount which included all costs and fees.

2022 Convertible Notes

As of December 31, 2021, the carrying amount of our \$100.0 million aggregate principal amount convertible senior notes due March 31, 2022 was \$108.5 million, inclusive of a 9% premium due at maturity or redemption, if not earlier converted. During the first quarter of 2022, we fully repaid these notes, and in connection with the repayment, drew \$100.0 million from the Tranche B Loan of the

[Table of Contents](#)

2027 Term Loans. Excluding accrued interest, the payoff amount of the 2022 Convertible Notes was \$109.0 million.

2026 Convertible Notes

As of December 31, 2022, the carrying amount of our \$230.0 million aggregate principal amount convertible senior subordinated notes due 2026 was \$225.6 million. 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, and will mature on April 15, 2026, unless earlier repurchased or converted at the option of holders. Since inception, the conversion price has been 51.9224 shares of common stock per \$1,000 principal amount of the 2026 Convertible Notes, which represents a 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 \$14.82 per share of our common stock on the Nasdaq Global Market on April 14, 2020, the date the 2026 Convertible Notes were issued. The conversion rate and conversion price will be subject to customary adjustments upon the occurrence of certain events. The 2026 Convertible Notes are not redeemable at our election before maturity. If the 2026 Convertible Notes were converted on December 31, 2022, the holders of the 2026 Convertible Notes would have received common shares with an aggregate value of \$94.6 million based on our closing stock price of \$7.92 as of December 30, 2022.

In connection with the pricing of the 2026 Convertible Notes, we entered into privately negotiated capped call transactions with certain of the initial purchasers of the 2026 Convertible Notes and other financial institutions. Since inception, the cap price has been \$25.93 per share, which represents a premium of approximately 75.0% over the last reported sale price of our common stock of \$14.82 per share on April 14, 2020, and is subject to certain adjustments under the terms of the capped call transactions.

Contingent Milestones

We have obligations to make future payments to third parties that become due and payable upon the achievement of certain development, regulatory and commercial milestones (such as clinical trial achievements, the filing of a BLA, approval by the FDA or product launch). These milestone payments and other similar fees are contingent upon future events and therefore are only recorded when it becomes probable that a milestone will be achieved or other applicable criteria will be met. Because the achievement of these milestones had not reached the threshold for recognition as of December 31, 2022, such contingencies were not recorded in our financial statements.

The following table presents a summary of our active partnerships and collaborations that have contingent regulatory and sales milestones as of December 31, 2022:

Counterparty	Description	Potential Aggregate Milestone Amount ⁽¹⁾
Junshi Biosciences	Toripalimab	\$380.0 million ⁽²⁾
	CHS-006 anti-TIGIT antibody	\$255.0 million ⁽³⁾
Bioeq	CIMERLI	€5.0 million ⁽⁴⁾

- (1) Excludes the potential aggregate upfront and milestone amounts for the Term Sheet with Klinge Biopharma for the exclusive commercialization rights to FYB203. The parties to the Term Sheet expect to execute the Definitive Agreements contemplated by the Term Sheet and complete the transaction in the first half of 2023.
- (2) The FDA issued a CRL for the original BLA we had submitted for toripalimab requesting a quality process change that we and Junshi Biosciences believe is readily addressable. On July 6, 2022, we announced that the FDA accepted the resubmission of the original BLA for toripalimab and that the FDA set a PDUFA action date for December 23, 2022. On December 24, 2022, we announced that we did not receive an action letter from the FDA by the PDUFA action date. The BLA for toripalimab remains under review, and we and Junshi Biosciences are engaged in ongoing discussions with the FDA about the pre-approval inspection plans. If such regulatory approval is achieved, we will be required to pay Junshi Biosciences a milestone payment of \$25.0 million.
- (3) Upon initiation of the first qualifying clinical trial that contains the optioned TIGIT molecule, we will be required to pay Junshi Biosciences a milestone payment of \$20.0 million.
- (4) Relates to a milestone contingent upon the launch readiness of a PFS product, if achieved during 2023.

Other Commitments

Non-cancelable purchase commitments

We enter into contracts in the normal course of business with CROs for preclinical research studies and clinical trials, research

[Table of Contents](#)

supplies and other services and products for operating purposes. We have also entered into agreements with several CMOs for the manufacture and clinical drug supply of our commercial and product candidates. Our non-cancelable purchase commitments as of December 31, 2022 were \$68.8 million, as outlined in “Note 8. Commitments and Contingencies” in the “Notes to Consolidated Financial Statements” contained in Part II, Item 8 of this Annual Report on Form 10-K.

Leases

We lease office and laboratory facilities through arrangements treated as operating leases, and we lease vehicles through finance leases. Our total non-cancelable contractual obligations arising from these agreements as of December 31, 2022 was \$10.3 million, with \$4.9 million of these obligations due within twelve months.

Summary Statement of Cash Flows

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

(in thousands)	Year Ended December 31,	
	2022	2021
Net cash used in operating activities	\$ (241,124)	\$ (37,432)
Net cash used in investing activities	(166,850)	(138,410)
Net cash provided by financing activities	54,326	51,879
Net decrease in cash, cash equivalents and restricted cash	<u>\$ (353,648)</u>	<u>\$ (123,963)</u>

Net cash used in operating activities

Cash used in operating activities of \$241.1 million in 2022 was primarily due to the net loss of \$291.8 million adjusted for the classification of the cash option payment to Junshi Biosciences of \$35.0 million to investing activities, non-cash items including stock-based compensation expense of \$50.7 million, net inventory write-offs of \$26.0 million and other non-cash adjustments of \$18.2 million, partially offset by the changes in our operating assets and liabilities of \$79.3 million.

Cash used in operating activities of \$37.4 million in 2021 was primarily due to the net loss of \$287.1 million adjusted for the classification of the upfront license fee payment to Junshi Biosciences of \$136.0 million pursuant to the Collaboration Agreement, non-cash items including stock-based compensation expense of \$51.4 million, net inventory write-offs of \$5.1 million and other non-cash adjustments of \$14.8 million, as well as the changes in our operating assets and liabilities of \$42.4 million.

Net cash used in investing activities

Cash used in investing activities of \$166.9 million in 2022 was primarily due to purchases of investments in marketable securities of \$127.4 million, the option fee payment of \$35.0 million to license CHS-006 from Junshi Biosciences, a \$2.4 million milestone payment to Bioeq related to the launch of CIMERLI, and purchases of property and equipment of \$2.0 million.

Cash used in investing activities of \$138.4 million in 2021 was primarily due to purchases of investments in marketable securities of \$182.5 million, upfront license fee of \$145.0 million to Junshi Biosciences pursuant to the Collaboration Agreement, partially offset by a \$9.0 million adjustment related to the fair value of the DLOM on our common stock purchased by Junshi Biosciences, and purchases of property and equipment of \$1.3 million. These uses of cash were partially offset by the proceeds from sales and maturities of investments in marketable securities of \$181.4 million.

Net cash provided by financing activities

Cash provided by financing activities of \$54.3 million in 2022 was primarily due to proceeds of \$240.7 million under the 2027 Term Loans, net of debt discount and issuance costs, proceeds of \$6.4 million from the ATM Offering, net of issuance costs, and \$2.3 million proceeds from purchase under the ESPP. These were partially offset by fully repaying \$109.0 million on the 2022 Convertible Notes and \$81.8 million on the 2025 Term Loan (excluding interest which is presented as an operating activity), and \$3.7 million in tax payments related to net share settlement of RSUs.

Cash provided by financing activities of \$51.9 million in 2021 was primarily due to \$50.0 million of gross proceeds from issuance of our common stock to Junshi Biosciences partially offset by \$9.0 million related to the fair value of the DLOM on the common stock

[Table of Contents](#)

purchased by Junshi Biosciences, \$10.4 million proceeds from the exercise of stock options and \$3.0 million proceeds from purchases under the ESPP, partially offset by \$1.8 million in tax payments related to net share settlement of RSUs.

Critical Accounting Estimates

The preparation of our consolidated financial statements in accordance with United States generally accepted accounting principles (“U.S. GAAP”) 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. “Note 1. Organization and Significant Accounting Policies” in the “Notes to Consolidated Financial Statements” in Part II, Item 8 of this Form 10-K describes the significant accounting policies and methods used in the preparation of our consolidated financial statements. 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.

Product Sales Discounts and Allowances

We recognize revenue when a customer obtains control of the product, which generally occurs upon delivery to and acceptance by the customer. The amount recognized in net revenue reflects the consideration which we expect to receive in exchange for product sold, which includes adjustments to gross sales amounts for estimated chargebacks, rebates, discounts for prompt payment, co-payment assistance, product returns and other allowances. 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.

The most significant and judgmental gross to net revenue adjustments are for chargebacks and rebates we provide to customers, hospitals, clinics, and payers under commercial and government programs. Amounts payable are provided for under various programs and vary by payer and individual payer plans. In developing our estimates of chargebacks and rebates, we use our historical claims experience and also consider payer mix, statutory discount rates and expected utilization, contractual terms, market events and trends, customer and commercially available payer data, as well as data collected from the healthcare providers, channel inventory data obtained from our customers and other relevant information.

In 2022, 2021 and 2020, total sales deductions to gross product sales were 73%, 67% and 59%, respectively. Adjustments to provisions for rebates and chargebacks related to sales made in prior periods were less than 3% of the actual payments and customer credits issued in each of the years 2022 and 2021. A change of 10% in our total provisions for product sales discounts and allowances as of December 31, 2022, would have resulted in a change of our pre-tax earnings in 2022 by approximately \$10.1 million. A summary of the activities and ending reserve balances for each significant category of discounts and allowances, can be found in “Note 2. Revenue” in the “Notes to Consolidated Financial Statements” in Part II, Item 8 of this Form 10-K.

Inventory

Our inventory is stated at the lower of cost or estimated net realizable value with cost determined under the first-in first-out method. The determination of excess or obsolete inventory requires judgment including consideration of many factors, such as estimates of future product demand, current and future market conditions, product expiration information and potential product obsolescence, among others.

Although we believe that the assumptions we use in estimating potential inventory write-downs are reasonable, if actual market conditions are less favorable than projected by us, write-downs of inventory, charges related to firm purchase commitments, or both may be required which would be recorded as cost of goods sold in our consolidated statement of operations. Adverse developments affecting our assumptions of the level and timing of demand for our products include those that are outside of our control such as the actions taken by competitors and customers, the direct or indirect effects of the COVID-19 pandemic, and other factors.

In 2022, 2021 and 2020, cost of goods sold included inventory write-offs, net of \$26.0 million, \$5.1 million and \$2.2 million, respectively. As of December 31, 2022, a 10% reduction in the carrying value of inventory we expect to sell in 2023 would be approximately \$3.9 million.

Recent Accounting Pronouncements

For a description of the impact of recent accounting pronouncements, see “Note 1. Organization and Significant Accounting Policies” in the “Notes to Consolidated Financial Statements” contained in Part II, Item 8 of this Annual Report on Form 10-K.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

As of December 31, 2022, we had cash and cash equivalents and marketable securities of \$191.7 million, consisting of cash, investments in money market funds and investments in marketable securities. A portion of our cash equivalents and investments in marketable securities 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 on these investments is not significant and a 1% movement in market interest rates would not have a material impact to our financial results. We do not enter into investments for trading or speculative purposes.

Our financial instruments that are exposed to concentration of credit risk consist primarily of cash, cash equivalents, investments and accounts receivables. We attempt to minimize the risks related to cash, cash equivalents and investments by investing in a broad and diverse range of financial instruments. The investment portfolio is maintained in accordance with our investment policy, which defines allowable investments, specifies credit quality standards and limits the credit exposure of any single issuer. There were no material losses from credit risks on such accounts during any of the periods presented. We are not exposed to any significant concentrations of credit risk from these financial instruments.

We are also subject to credit risk from trade receivables related to product sales, and we monitor the credit worthiness of customers that are granted credit in the normal course of business. In general, there is no requirement for collateral from customers. We have not experienced significant losses with respect to the collection of trade receivables.

We are exposed to interest rate risk with respect to variable rate debt. As of December 31, 2022, we had \$250.0 million principal outstanding on our 2027 Term Loans that accrue interest from inception through March 31, 2023 at 8.25% plus three-month LIBOR per annum with a LIBOR floor of 1.0%; and, starting April 1, 2023, accrue interest at 8.25% plus the Adjusted Term SOFR, with a floor on Adjusted Term SOFR of 1.0%. We currently do not hedge our variable interest rate debt. The interest rate for our variable rate debt during the quarter ended December 31, 2022 was 12.00%, and the interest rate during the first quarter of 2023 will be 13.03% based on the 3-month LIBOR on January 1, 2023. A hypothetical 100 basis point increase in the interest rate on our variable rate debt could result in up to a \$2.5 million increase in the annual interest expense as of December 31, 2022.

In April 2020, we issued \$230.0 million aggregate principal amount of 2026 Convertible Notes with a fixed interest rate of 1.5%. Since the notes have a fixed annual interest rate, we have no financial or economic interest exposure associated with changes in interest rates. However, the fair value of fixed rate debt fluctuates when interest rates change. Additionally, the fair value of the 2026 Convertible Notes can be impacted when the market price of our common stock fluctuates. We carry the 2026 Convertible Notes on our balance sheet at face value less the unamortized discount and issuance costs, and we present the fair value for required disclosure purposes only.

Substantially all of our sales are denominated in U.S. dollars. We have exposure to the exchange rate between the U.S. Dollar and the Euro because we make purchases of CIMERLI inventory from and pay royalties to our partner Bioeq that are denominated in Euros and we are therefore subject to fluctuations due to changes in foreign currency exchange rates. Accordingly, fluctuations in the exchange rate between the U.S. Dollar and the Euro may impact our consolidated statements of operations.

Item 8. Consolidated Financial Statements and Supplementary Data

COHERUS BIOSCIENCES, INC.

ANNUAL REPORT ON FORM 10-K

INDEX TO AUDITED CONSOLIDATED FINANCIAL STATEMENTS

	<u>Page</u>
Report of Independent Registered Public Accounting Firm (PCAOB ID 42)	88
Audited Consolidated Financial Statements	
Consolidated Balance Sheets	91
Consolidated Statements of Operations	92
Consolidated Statements of Comprehensive (Loss) Income	93
Consolidated Statements of Stockholders' Equity (Deficit)	94
Consolidated Statements of Cash Flows	95
Notes to Consolidated Financial Statements	96

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, 2022 and 2021, the related consolidated statements of operations, comprehensive (loss) income, stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2022, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022, 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, 2022, 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 March 6, 2023 expressed an unqualified opinion thereon.

Basis for Opinion

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

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

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved especially challenging, subjective or complex judgments. The communication of critical audit matters 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 matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Estimate of Reserves for Chargebacks and Rebates

Description of the Matter

As described in Note 1 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 \$42.7 million at December 31, 2022. Estimated rebates are presented within accrued rebates, fees and reserves and other liabilities, non-current on the consolidated balance sheet and totaled \$38.7 million at December 31, 2022.

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, 2022, 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.

Excess and Obsolete Inventory Reserve

Description of the Matter

As of December 31, 2022, the Company had \$115.1 million of inventory which included \$10.3 million of raw materials, \$86.7 million of work in progress and \$18.1 million of finished goods. As disclosed in Note 1 to the Company's consolidated financial statements, inventories are stated at the lower of cost or estimated net realizable value. The Company assesses its inventory levels along with its purchase commitments each reporting period and writes down inventory that is either expected to be at risk of expiration prior to sale or has a cost basis in excess of its expected net realizable value.

Auditing management's estimates for excess inventory involved subjective auditor judgment because the estimates rely on a number of factors that are affected by market and economic conditions outside the Company's control. In particular, the excess inventory calculations are sensitive to significant assumptions, including the expected demand for the Company's product, the effect on demand of competitive products and the Company's purchase commitments.

[Table of Contents](#)

*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 excess and obsolete inventory reserve process including management's review of the significant assumptions described above and controls over the completeness and accuracy of the information used to develop the estimate.

Our substantive audit procedures included, among others, evaluating methodologies used and data utilized in the analysis for inventory expected to be at risk for expiration or excess. We evaluated purchase commitments or alternative uses, compared forecasted demand to historical trends, compared actual inventory levels to forecasted demand requirements, and evaluated the sensitivity of sales forecast assumptions on the amount of inventory reserves recorded.

/s/ Ernst & Young LLP

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

San Mateo, California
March 6, 2023

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

	December 31,	
	2022	2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 63,547	\$ 417,195
Investments in marketable securities	128,134	—
Trade receivables, net	109,964	123,022
Inventory	38,791	37,642
Prepaid manufacturing	17,880	13,666
Other prepaids and current assets	22,918	10,798
Total current assets	381,234	602,323
Property and equipment, net	8,754	7,813
Inventory, non-current	76,260	55,610
Goodwill and intangible assets	5,931	3,563
Other assets, non-current	8,668	10,025
Total assets	\$ 480,847	\$ 679,334
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	\$ 11,526	\$ 16,159
Accrued rebates, fees and reserves	54,461	79,027
Accrued compensation	22,610	22,014
Accrued and other current liabilities	50,097	48,127
Total current liabilities	138,694	165,327
Term loans	245,483	75,513
Convertible notes	225,575	332,767
Lease liabilities, non-current	5,046	7,251
Other liabilities, non-current	3,467	750
Total liabilities	618,265	581,608
Commitments and contingencies (Note 8)		
Stockholders' equity (deficit):		
Common stock (\$0.0001 par value; shares authorized: 300,000,000; shares issued and outstanding: 78,851,516 and 76,930,096 at December 31, 2022 and 2021, respectively)	8	7
Additional paid-in capital	1,204,431	1,147,843
Accumulated other comprehensive loss	(249)	(270)
Accumulated deficit	(1,341,608)	(1,049,854)
Total stockholders' equity (deficit)	(137,418)	97,726
Total liabilities and stockholders' equity (deficit)	\$ 480,847	\$ 679,334

See accompanying notes.

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

	Year Ended December 31,		
	2022	2021	2020
Net revenue	\$ 211,042	\$ 326,551	\$ 475,824
Costs and expenses:			
Cost of goods sold	70,083	57,591	37,667
Research and development	199,358	363,105	142,759
Selling, general and administrative	198,481	169,713	139,079
Total costs and expenses	467,922	590,409	319,505
(Loss) income from operations	(256,880)	(263,858)	156,319
Interest expense	(32,474)	(22,959)	(21,166)
Loss on debt extinguishment	(6,222)	—	—
Other income (expense), net	3,822	(283)	554
(Loss) income before income taxes	(291,754)	(287,100)	135,707
Income tax provision	—	—	3,463
Net (loss) income	<u>\$ (291,754)</u>	<u>\$ (287,100)</u>	<u>\$ 132,244</u>
Net (loss) income per share:			
Basic	<u>\$ (3.76)</u>	<u>\$ (3.81)</u>	<u>\$ 1.85</u>
Diluted	<u>\$ (3.76)</u>	<u>\$ (3.81)</u>	<u>\$ 1.62</u>
Weighted-average number of shares used in computing basic and diluted net (loss) income per share:			
Basic	<u>77,630,020</u>	<u>75,449,632</u>	<u>71,411,705</u>
Diluted	<u>77,630,020</u>	<u>75,449,632</u>	<u>83,491,898</u>

See accompanying notes.

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

	Year Ended December 31,		
	2022	2021	2020
Net (loss) income	\$ (291,754)	(287,100)	\$ 132,244
Other comprehensive (loss) income:			
Unrealized gain on available-for-sale securities, net of tax	22	—	—
Foreign currency translation adjustments, net of tax	(1)	—	288
Comprehensive (loss) income	<u>\$ (291,733)</u>	<u>\$ (287,100)</u>	<u>\$ 132,532</u>

See accompanying notes.

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 Stockholders' Equity (Deficit)
	Shares	Amount				
Balances at December 31, 2019	70,366,661	7	1,000,763	(558)	(894,998)	105,214
Net income	—	—	—	—	132,244	132,244
Issuance of common stock upon exercise of stock options	1,704,764	—	17,061	—	—	17,061
Issuance of common stock upon vesting of restricted stock units ("RSUs")	89,668	—	—	—	—	—
Issuance of common stock under the ESPP	267,772	—	3,801	—	—	3,801
Issuance of common stock upon 2019 bonus payout in RSUs	134,099	—	2,378	—	—	2,378
Taxes paid related to net share settlement of bonus payout in RSUs	(49,616)	—	(880)	—	—	(880)
Purchase of capped call options related to convertible notes due 2026	—	—	(18,170)	—	—	(18,170)
Stock-based compensation expense	—	—	39,038	—	—	39,038
Cumulative translation adjustment	—	—	—	288	—	288
Balances at December 31, 2020	72,513,348	7	1,043,991	(270)	(762,754)	280,974
Net loss	—	—	—	—	(287,100)	(287,100)
Issuance of common stock upon exercise of stock options	1,316,361	—	10,410	—	—	10,410
Issuance of common stock upon vesting of RSUs	465,930	—	—	—	—	—
Issuance of common stock under the ESPP	238,934	—	3,002	—	—	3,002
Issuance of common stock to Junshi Biosciences, net of issuance costs	2,491,988	—	40,903	—	—	40,903
Taxes paid related to net share settlement of RSUs	(96,465)	—	(1,753)	—	—	(1,753)
Stock-based compensation expense	—	—	51,290	—	—	51,290
Balances at December 31, 2021	76,930,096	7	1,147,843	(270)	(1,049,854)	97,726
Net loss	—	—	—	—	(291,754)	(291,754)
Issuance of common stock upon exercise of stock options	141,897	—	691	—	—	691
Issuance of common stock upon vesting of RSUs	806,854	—	—	—	—	—
Issuance of common stock under the ESPP	347,883	—	2,320	—	—	2,320
Issuance of common stock under ATM Offering, net of issuance costs	916,884	1	6,133	—	—	6,134
Taxes paid related to net share settlement of RSUs	(292,098)	—	(3,744)	—	—	(3,744)
Stock-based compensation expense	—	—	51,188	—	—	51,188
Other comprehensive gain, net of tax	—	—	—	21	—	21
Balances at December 31, 2022	<u>78,851,516</u>	<u>\$ 8</u>	<u>\$ 1,204,431</u>	<u>\$ (249)</u>	<u>\$ (1,341,608)</u>	<u>\$ (137,418)</u>

See accompanying notes.

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

	Years Ended December 31,		
	2022	2021	2020
Operating activities			
Net (loss) income	\$ (291,754)	\$ (287,100)	\$ 132,244
Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities:			
Depreciation and amortization	3,699	3,454	2,888
Stock-based compensation expense	50,737	51,364	38,160
Write-off of prepaid manufacturing services related to the termination of CHS-2020	—	3,210	—
Inventory write-offs, net	26,000	5,133	2,171
Non-cash interest expense from amortization of debt discount & issuance costs	6,431	4,257	3,481
Upfront and option payments to Junshi Biosciences	35,000	136,000	—
Other upfront and milestone based license fee payments	—	—	7,500
Loss on debt extinguishment	6,222	—	—
Other non-cash adjustments, net	1,798	3,890	2,352
Changes in operating assets and liabilities:			
Trade receivables, net	13,052	34,062	(15,218)
Inventory	(47,348)	(6,253)	(38,359)
Prepaid manufacturing	(4,214)	3,828	(10,851)
Other prepaid, current and non-current assets	(13,424)	(5,351)	(2,020)
Accounts payable	(4,548)	874	(9,820)
Accrued rebates, fees and reserves	(24,566)	(2,502)	30,409
Accrued compensation	596	(230)	6,212
Accrued and other current and non-current liabilities	1,195	17,932	4,996
Net cash (used in) provided by operating activities	<u>(241,124)</u>	<u>(37,432)</u>	<u>154,145</u>
Investing activities			
Purchases of property and equipment	(2,039)	(1,289)	(7,231)
Proceeds from disposal of property and equipment	—	—	175
Purchases of investments in marketable securities	(127,382)	(182,485)	(273,845)
Proceeds from maturities of investments in marketable securities	—	99,692	274,000
Proceeds from sale of investments in marketable securities	—	81,672	—
Upfront and option payments to Junshi Biosciences	(35,000)	(136,000)	—
Other upfront and milestone based license fee payments	(2,429)	—	(7,500)
Net cash used in investing activities	<u>(166,850)</u>	<u>(138,410)</u>	<u>(14,401)</u>
Financing activities			
Proceeds from issuance of 2026 Convertible Notes, net of issuance costs	—	—	222,156
Proceeds from 2027 Term Loans, net of debt discount & issuance costs	240,679	—	—
Proceeds from issuance of common stock to Junshi Biosciences, net of issuance costs	—	40,903	—
Proceeds from issuance of common stock under ATM Offering, net of issuance costs	6,358	—	—
Proceeds from issuance of common stock upon exercise of stock options	691	10,399	17,428
Proceeds from purchase under the employee stock purchase plan	2,320	3,002	3,801
Purchase of capped call options related to 2026 Convertible Notes	—	—	(18,170)
Taxes paid related to net share settlement of RSUs	(3,744)	(1,753)	(880)
Repayment of 2022 Convertible Notes and premiums	(109,000)	—	—
Repayment of 2025 Term Loan, premiums and exit fees	(81,750)	—	—
Other financing activities	(1,228)	(672)	(389)
Net cash provided by financing activities	<u>54,326</u>	<u>51,879</u>	<u>223,946</u>
Net (decrease) increase in cash, cash equivalents and restricted cash	(353,648)	(123,963)	363,690
Cash, cash equivalents and restricted cash at beginning of period	417,635	541,598	177,908
Cash, cash equivalents and restricted cash at end of period	<u>\$ 63,987</u>	<u>\$ 417,635</u>	<u>\$ 541,598</u>
Supplemental disclosure of cash flow information			
Cash paid for interest	\$ 34,878	\$ 18,684	\$ 16,959
Cash paid for income taxes	\$ 40	\$ 1,221	\$ 3,953
Supplemental disclosures of non-cash investing and financing activities			
Purchase of property and equipment in accounts payable and accrued liabilities	\$ 32	\$ 119	\$ 109
Non-cash employee bonuses settled in common stock	\$ —	\$ —	\$ 1,498

See accompanying notes.

Coherus BioSciences, Inc.
Notes to Consolidated Financial Statements

1. Organization and Significant Accounting Policies

Description of the Business

Coherus BioSciences, Inc. (the “Company” or “Coherus”) is a commercial-stage biopharmaceutical company focused on the research, development and commercialization of innovative cancer treatments and commercialization of its portfolio of FDA-approved biosimilars. The Company’s strategy is to build a leading immuno-oncology franchise funded with cash generated through net sales of its diversified portfolio of FDA-approved therapeutics. The Company’s headquarters and laboratories are located in Redwood City, California and in Camarillo, California, respectively. The Company sells Udenyca (pegfilgrastim-cbqv), a biosimilar to Neulasta, a long-acting granulocyte-colony stimulating factor, in the United States. The FDA approved YUSIMRY (adalimumab-aqvh), a biosimilar to Humira, in December 2021, which the Company plans to launch in the United States on or after July 1, 2023, pursuant to the terms of an agreement with Humira’s manufacturer, AbbVie. On August 2, 2022, the FDA approved CIMERLI (ranibizumab-eqrn), a biosimilar to Lucentis, and commercial launch commenced on October 3, 2022 in the United States.

The Company’s product pipeline comprises the following three product candidates: toripalimab, an anti-PD-1 antibody being developed in collaboration with Junshi Biosciences; CHS-006, an antibody targeting TIGIT being developed in collaboration with Junshi Biosciences; and one wholly-owned preclinical immuno-oncology program, CHS-1000, an antibody targeting ILT4. In May 2022, the Company discontinued development of its bevacizumab (Avastin) biosimilar product candidate in-licensed from Innovent. In October 2022, the Company discontinued development of its preclinical immuno-oncology program, CHS-3318, an antibody targeting CCR8. On January 9, 2023, the Company announced that it entered into the Term Sheet with Klinge Biopharma for the exclusive commercialization rights to FYB203, a biosimilar candidate to Eylea® (aflibercept), in the United States. The parties to the Term Sheet expect to execute the Definitive Agreements contemplated by the Term Sheet and complete the transaction in the first half of 2023.

Basis of Consolidation

The accompanying consolidated financial statements have been prepared in accordance with U.S. GAAP and include the accounts of Coherus and its wholly-owned subsidiaries. The Company does not have any significant interests in variable interest entities. All material intercompany transactions and balances have been eliminated upon consolidation.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make judgements, estimates and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses, and related disclosures. Management bases its estimates on historical experience and on various other 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. Estimates are assessed each period and updated to reflect current information, such as the economic considerations related to the impact that COVID-19 outbreaks could have on the Company’s significant accounting estimates. Accounting estimates and judgements are inherently uncertain and the actual results could differ from these estimates.

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 human pharmaceutical products. The Company’s chief executive officer, as the chief operating decision maker (“CODM”), manages and allocates resources to the operations of the Company on an entity-wide basis. Managing and allocating resources on an entity-wide basis enables the CODM to assess the overall level of resources available and how to best deploy these resources across functions. Primarily, all revenue is generated and all long-lived assets are maintained in the United States.

Cash, Cash Equivalents and Restricted Cash

Cash, cash equivalents and restricted cash comprise cash and highly liquid investments with original maturities of 90 days or less.

[Table of Contents](#)

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)	January 1,		
	2022	2021	2020
At beginning of period:			
Cash and cash equivalents	\$ 417,195	\$ 541,158	\$ 177,668
Restricted cash	440	440	240
Total cash, cash equivalents and restricted cash	<u>\$ 417,635</u>	<u>\$ 541,598</u>	<u>\$ 177,908</u>
	December 31,		
	2022	2021	2020
At end of period:			
Cash and cash equivalents	\$ 63,547	\$ 417,195	\$ 541,158
Restricted cash	440	440	440
Total cash, cash equivalents and restricted cash	<u>\$ 63,987</u>	<u>\$ 417,635</u>	<u>\$ 541,598</u>

Restricted cash consists of deposits for letters of credit that the Company has provided to secure its obligations under certain leases and is included in other assets, non-current in the consolidated balance sheets.

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

Investments in marketable securities primarily consist of U.S. Treasury securities, commercial paper, corporate debt obligations and short-term money market instruments. 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 limits its exposure to any single issuer, except for securities issued by the U.S. government. All investments in marketable debt 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. The Company regularly reviews its investments for declines in fair value below the amortized cost basis to determine whether the impairment, if any, is due to credit-related or other factors. This review includes the credit worthiness of the security issuers, the severity of the unrealized losses, whether the Company has the intent to sell the securities and whether it is more likely than not that the Company will be required to sell the securities before the recovery of the amortized cost basis. Unrealized gains and losses on available-for-sale debt securities are reported as a component of accumulated comprehensive income (loss), with the exception of unrealized losses believed to be related to credit losses, if any, which are recognized in 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 available-for-sale debt 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. There were no impairments related to credit losses during any of the periods presented. Realized gains and losses, if any, on available-for-sale securities are included in other income (expense), net, in the consolidated statements of operations based on the specific identification method. During 2022, 2021 and 2020, interest income from marketable securities was \$1.9 million, \$1.4 million and \$0.6 million, respectively, and is included in other income (expense), net, in the consolidated statements of operations.

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 and was not material during the periods presented. The Company believes that its allowance for expected credit losses was adequate and immaterial as of December 31, 2022 and 2021.

Concentrations of Risk

The Company's financial instruments that are exposed to concentration of credit risk consist primarily of cash, cash equivalents, investments in marketable securities and trade receivables. The Company attempts to minimize the risks related to cash, cash equivalents and marketable securities by investing in 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 monitors the credit worthiness of customers that are granted credit in the normal course of business. In general, there is no requirement for collateral from customers.

Substantially all of the Company's revenues are in the United States to three wholesalers. UDENYCA and CIMERLI were the only products sold by the Company during 2022. UDENYCA was the only product sold and accounted for all of the Company's revenues in 2021 and 2020.

The Company enters into a strategic commercial supply agreement for each of its products. The Company currently has not engaged back-up suppliers or vendors. If any of the Company's current vendors are 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.

Foreign Currency

Assets and liabilities denominated in foreign currency are remeasured at period-end exchange rates for monetary assets and liabilities. Non-monetary assets and liabilities denominated in foreign currencies are remeasured at historical rates. Translation gains and losses are included in accumulated other comprehensive loss in stockholders' equity (deficit). Revenue and expense accounts are translated to U.S. dollars at average exchange rates in effect during the period with resulting transaction gains and losses recognized in other income (expense), net in the consolidated statements of operations. The Company has not had material foreign currency impacts for all years presented.

Inventory

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 excess or obsolete inventory requires judgment including consideration of many factors, such as estimates of future product demand, current and future market conditions, product expiration information, and potential product obsolescence, among others. During the third quarter of 2022, the Company recorded a \$26.0 million write-down of inventory in cost of goods sold in the consolidated statements of operations due to the competitive environment and lower demand for UDENYCA resulting in certain inventory becoming at risk of expiration. For 2022, this increased the net loss by \$26.0 million and basic and diluted net loss per share by \$0.33.

Although the Company believes the assumptions used in estimating potential inventory write-downs are reasonable, if actual market conditions are less favorable than projected by management, write-downs of inventory, charges related to firm purchase commitments, or both may be required which would be recorded as cost of goods sold in the consolidated statement of operations. Adverse developments affecting the Company's assumptions of the level and timing of demand for its products include those that are outside of the Company's control such as the actions taken by competitors and customers, the direct or indirect effects of the COVID-19 pandemic, and other factors.

Prior to the regulatory approval of product candidates, the Company incurred expenses for the manufacture of drug product that could potentially be available to support the commercial launch of the products. Inventory costs are capitalized when future commercialization is considered probable and the future economic benefit is expected to be realized, based on management's judgment. A number of factors are considered, including the current status in the regulatory approval process, potential impediments to the approval process such as safety or efficacy, viability of commercialization and marketplace trends. Inventory in the consolidated balance sheets as of December 31, 2022 was related to UDENYCA, YUSIMRY and CIMERLI. The Company began to capitalize inventory costs associated with UDENYCA and CIMERLI after receiving final regulatory approval in November 2018 and August 2022, respectively, and capitalization of YUSIMRY inventory costs began in the second quarter of 2022 when sales were deemed probable.

Property and Equipment

Property and equipment is stated at cost less accumulated depreciation and amortization. Maintenance and repairs are charged to expense as incurred. Interest costs incurred during the construction of major capital projects are capitalized until the underlying asset is ready for its intended use, at which point the capitalized interest costs are amortized as depreciation or amortization expense over the life of the underlying asset. When the Company disposes of property and equipment, it removes the associated cost and accumulated depreciation from the related accounts in the consolidated balance sheets and include any resulting gain or loss in the consolidated statements of operations. Eligible costs of internal use software and implementation costs of certain hosting arrangements are capitalized and amortized over the estimated useful life of the software or associated hosting arrangement, as applicable. Depreciation and amortization are recognized using the straight-line method over the following estimated useful lives:

Computer equipment and software	3 - 7 years
Furniture and fixtures	5 years
Machinery and equipment	5 years
Leasehold improvements	Shorter of lease term or useful life

Goodwill and Intangible Assets

Goodwill represents the excess of the consideration transferred over the fair value of net assets acquired in a business combination. Goodwill is not amortized but is evaluated for impairment on an annual basis, during the fourth quarter, or more frequently if an event occurs or circumstances change that would more-likely-than-not reduce the fair value of the Company's single reporting unit below its carrying amount. The Company's goodwill balance was \$0.9 million as of December 31, 2022 and 2021, and no goodwill impairment charges were recognized in 2022, 2021 or 2020.

Acquired in-process research and development ("IPR&D") that the Company acquires in conjunction with the acquisition of a business represents the fair value assigned to incomplete research projects which, at the time of acquisition, have not reached technological feasibility. The amounts are capitalized and are accounted for as indefinite-lived intangible assets, subject to impairment testing until completion or abandonment of the projects. Upon successful completion of each IPR&D project, the Company will make a determination as to the then-useful life of the intangible asset, generally determined by the period in which the substantial majority of the cash flows are expected to be generated, and begin amortization. The Company evaluates IPR&D for impairment on an annual basis, during the fourth quarter, or more frequently if impairment indicators exist. The Company's IPR&D balance was \$2.6 million as of December 31, 2022 and 2021, and no IPR&D impairment charges were recognized in 2022, 2021 or 2020.

As of December 31, 2022, the Company had a \$2.4 million definite-lived intangible asset, net related to a 2022 capitalized milestone payment under a license agreement. This is amortized on a straight-line basis over its estimated economic life of ten years and is reviewed periodically for impairment. Amortization expense is recorded as a component of cost of goods sold in the consolidated statements of operations and was immaterial in 2022.

Impairment of Long-Lived Assets

Long-lived assets, including property and equipment and finite-lived intangible assets, are reviewed for impairment whenever facts or circumstances either internally or externally may indicate that the carrying value of an asset may not be recoverable. If there is an indication of impairment, the Company tests for recoverability by comparing the estimated undiscounted future cash flows expected to result from the use of the asset to the carrying amount of the asset or asset group. If the asset or asset group is determined to be impaired, any excess of the carrying value of the asset or asset group over its estimated fair value is recognized as an impairment loss. There were no material impairments recorded during the years ended December 31, 2022, 2021 and 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 Revenues

The Company sells to wholesalers and distributors, (collectively, "Customers"). The Customers then resell 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 United States government-mandated or privately negotiated rebates, chargebacks and discounts. The Company also enters into rebate arrangements with payers, which consist primarily of commercial insurance companies and government entities, to cover the reimbursement of products 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 at the point when a Customer obtains control of the product and the Company satisfies its performance obligation, which generally occurs at the time product is shipped to the Customer. Payment terms differ by jurisdiction and customer, but payment terms typically range from 30 to approximately 90 days from date of shipment and may be extended during the launch period of a new product.

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. 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 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. 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

[Table of Contents](#)

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.

Royalty Revenue

Royalty revenue from licensees, which is based on sales to third-parties of licensed products, is recorded when the third-party sale occurs and the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). Royalty revenue was insignificant for all periods presented and is included in net revenue.

Cost of Goods Sold

Cost of goods sold consists primarily of third-party manufacturing, distribution, and certain overhead costs. Through March 31, 2021, a portion of the costs of producing UDENYCA sold was expensed as research and development before the FDA approval of UDENYCA and therefore is not reflected in cost of goods sold. All the inventory expensed prior to approval of UDENYCA was fully utilized by March 31, 2021; thus, the costs of producing UDENYCA are fully reflected in cost of goods sold beginning April 1, 2021.

On May 2, 2019, the Company and 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. Additionally, the Company shares 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.

In 2022, 2021 and 2020, cost of goods sold included inventory write-offs, net of \$26.0 million, \$5.1 million and \$2.2 million, respectively.

Research and Development Expense

Research and development expense represents costs incurred to conduct research, such as the discovery and development of product candidates. The Company recognizes all research and development costs as they are incurred. The Company currently tracks research and development costs incurred on a product candidate basis only for external research and development expenses. The Company's external research and development expense consists primarily of:

- expense incurred under agreements with collaborators, consultants, third-party CROs, and investigative sites where a substantial portion of the Company's preclinical studies and all of its clinical trials are conducted;
- 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;
- costs associated with manufacturing process development activities, analytical activities and pre-launch inventory manufactured prior to regulatory approval being obtained or deemed to be probable; and
- upfront and milestone payments related to licensing and collaboration agreements.

Internal costs are associated with activities performed by the Company's 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.

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

[Table of Contents](#)

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 asset acquisition 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 expense comprises primarily 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 \$10.5 million, \$8.7 million and \$3.8 million in 2022, 2021 and 2020, respectively.

Stock-Based Compensation

The Company's compensation programs include stock-based awards, and the related grants under these programs are accounted for at fair value. The fair values are recognized as compensation expense on a straight-line basis over the vesting period with the related costs recorded in cost of goods sold, research and development, and selling, general and administrative expense, as appropriate. The Company accounts for forfeitures as they occur.

Income Taxes

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

The 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. The Company does not expect its unrecognized tax benefits from prior years to change significantly in 2023.

Operating and Finance Leases

The Company determines at an arrangement's inception whether it is a lease. The Company does not recognize right-of-use assets and lease liabilities related to short-term leases. The Company also does not separate lease and non-lease components for its facility and vehicle leases. Operating leases are included in accrued and other current liabilities, other assets, non-current, 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 lease term.

The terms of vehicles leased under the Company's fleet agreement ("Vehicle Lease Agreement") are 36 months. The vehicles leased under this arrangement were classified as finance leases. Finance leases are included in property and equipment, net, accrued and other current liabilities, and lease liabilities, non-current in the consolidated balance sheets. Assets under finance leases are depreciated to operating expenses on a straight-line basis over the lease term.

The operating and finance lease right-of-use 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 (Loss) Income per Share

Basic net (loss) income per share is calculated by dividing the net (loss) income by the weighted-average number of shares of common stock outstanding for the period, without consideration for potential dilutive common shares. Diluted net income per share is

[Table of Contents](#)

computed by dividing the net income by the weighted-average number of common shares outstanding for the period plus any potential dilutive 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. Diluted net loss per share is computed by dividing net loss by the weighted-average number of common shares outstanding for the period, without consideration for any potential dilutive common share equivalents as their effect would be antidilutive (see Note 13. Net (Loss) Income Per Share).

Comprehensive (Loss) Income

Comprehensive (loss) income is composed of two components: net (loss) income and other comprehensive (loss) income. Other comprehensive (loss) income refers to gains and losses that are recorded as an element of stockholders' equity (deficit), but are excluded from net (loss) income. The Company's other comprehensive (loss) income includes unrealized gain (loss) on available-for-sale securities and foreign currency translation adjustments in 2022, 2021 and 2020.

Reclassifications

Certain prior year amounts in the consolidated balance sheets and consolidated statements of cash flows have been reclassified to conform with the current year presentation in 2022. As a result, there was no change to total assets in the consolidated balance sheets or net cash (used in) provided by operating activities in the consolidated statements of cash flows for the prior years.

Recent Accounting Pronouncements

The Company has reviewed 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.

2. Revenue

The Company initiated sales in the United States of CIMERLI on October 3, 2022. The Company's net revenue was as follows:

(in thousands)	Year Ended December 31,		
	2022	2021	2020
Products			
UDENYCA	\$ 203,814	\$ 326,509	\$ 475,824
CIMERLI	6,946	—	—
Total net product revenue	210,760	326,509	475,824
Other	282	42	—
Total net revenue	<u>\$ 211,042</u>	<u>\$ 326,551</u>	<u>\$ 475,824</u>

Revenue by significant Customer was as follows:

	Year Ended December 31,		
	2022	2021	2020
McKesson Corporation	38 %	39 %	38 %
AmeriSource-Bergen Corporation	44 %	39 %	37 %
Cardinal Health, Inc.	17 %	20 %	23 %

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, 2022			
	Chargebacks and Discounts for Prompt Payment	Rebates	Other Fees, Co-pay Assistance and Returns	Total
Balances at December 31, 2021	\$ 29,665	\$ 54,004	\$ 26,054	\$ 109,723
Provision related to sales made in:				
Current period	436,865	68,399	73,435	578,699
Prior period	(2,090)	(1,050)	32	(3,108)
Payments and customer credits issued	(421,763)	(82,640)	(80,408)	(584,811)
Balances at December 31, 2022	<u>\$ 42,677</u>	<u>\$ 38,713</u>	<u>\$ 19,113</u>	<u>\$ 100,503</u>
	Year Ended December 31, 2021			
	Chargebacks and Discounts for Prompt Payment	Rebates	Other Fees, Co-pay Assistance and Returns	Total
(in thousands)				
Balances at December 31, 2020	\$ 40,580	\$ 54,058	\$ 28,760	\$ 123,398
Provision related to sales made in:				
Current period	470,791	113,705	94,703	679,199
Prior period	(2,876)	(4,976)	(3,555)	(11,407)
Payments and customer credits issued	(478,830)	(108,783)	(93,854)	(681,467)
Balances at December 31, 2021	<u>\$ 29,665</u>	<u>\$ 54,004</u>	<u>\$ 26,054</u>	<u>\$ 109,723</u>
	Year Ended December 31, 2020			
	Chargebacks and Discounts for Prompt Payment	Rebates	Other Fees, Co-pay Assistance and Returns	Total
(in thousands)				
Balances 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)
Balances at December 31, 2020	<u>\$ 40,580</u>	<u>\$ 54,058</u>	<u>\$ 28,760</u>	<u>\$ 123,398</u>

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

3. Fair Value Measurements

The fair value of financial instruments are classified into one of the following categories based upon the lowest level of input that is significant to the fair value measurement:

- 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.

[Table of Contents](#)

There were no transfers between Level 1, Level 2 and Level 3 during the periods presented. The fair values of cash equivalents approximate their carrying values due to the short-term nature of such financial instruments.

Financial assets measured at fair value on a recurring basis are summarized as follows:

(in thousands)	Fair Value Measurements December 31, 2022			
	Level 1	Level 2	Level 3	Total
Financial Assets:				
Money market funds	\$ 55,060	\$ —	\$ —	\$ 55,060
Marketable debt securities:				
U.S. government agency securities	19,964	—	—	19,964
U.S. treasury securities	68,418	—	—	68,418
Commercial paper and corporate notes	—	48,203	—	48,203
Total	\$ 143,442	\$ 48,203	\$ —	\$ 191,645

The financial assets at December 31, 2021 consisted of money market funds and were classified as Level 1.

The cost, unrealized gains or losses, and fair value by investment type are summarized as follows:

(in thousands)	December 31, 2022			
	Cost	Unrealized Gain	Unrealized (Loss)	Fair Value
Money market funds	\$ 55,060	\$ —	\$ —	\$ 55,060
U.S. government agency securities	19,929	35	—	19,964
U.S. treasury securities	68,431	8	(21)	68,418
Commercial paper and corporate notes	48,203	—	—	48,203
Total	\$ 191,623	\$ 43	\$ (21)	\$ 191,645

The Company held 13 positions that were in unrealized loss positions as of December 31, 2022, and aggregated gross unrealized losses on available-for-sale debt securities were not material. No impairment was recognized in 2022. Excluding restricted cash and as of December 31, 2022, the remaining contractual maturities of available-for-sale securities were less than one year, and the average maturity of investments upon acquisition was approximately 7 months. The accrued interest receivable on available-for-sale marketable securities was immaterial at December 31, 2022, and is included in other prepaids and current assets.

There were no investments in marketable securities as of December 31, 2021; thus, no unrealized gain (loss) was recognized as of December 31, 2021.

4. Inventory

Inventory consisted of the following:

(in thousands)	December 31,	
	2022	2021
Raw materials	\$ 10,262	\$ 4,870
Work in process	86,712	65,117
Finished goods	18,077	23,265
Total	\$ 115,051	\$ 93,252

[Table of Contents](#)

The Company began capitalizing YUSIMRY inventory in the second quarter of 2022 and had \$23.7 million of such inventory recognized in the consolidated balance sheets at December 31, 2022. Inventory expected to be sold more than twelve months from the balance sheet date is classified as inventory, non-current in the consolidated balance sheets. As of December 31, 2022 and 2021, the non-current portion of inventory consisted of raw materials, work in process and a portion of finished goods. The following table presents the inventory balance sheet classifications:

(in thousands)	December 31,	
	2022	2021
Inventory	\$ 38,791	\$ 37,642
Inventory, non-current	76,260	55,610
Total	<u>\$ 115,051</u>	<u>\$ 93,252</u>

Prepaid manufacturing of \$17.9 million as of December 31, 2022 includes prepayments of \$13.0 million to CMOs for manufacturing services of the Company's products, which the Company expects to be converted into inventory during 2023; and prepayments of \$4.9 million to various CMOs for research and development pipeline programs. Prepaid manufacturing of \$13.7 million as of December 31, 2021 includes prepayments of \$8.3 million to a CMO for manufacturing services for UDENYCA; and prepayments of \$5.4 million to various CMOs for other research and development pipeline programs.

In February 2021, the Company announced the discontinuation of the development of CHS-2020, a biosimilar of Eylea as part of a realignment of research and development resources toward other development programs. As a result, the Company recognized \$11.2 million within research and development expense in the consolidated statement of operations in 2021, which included an impairment charge of \$3.2 million for the write-off of prepaid manufacturing services no longer deemed to have future benefits. No material expense relating to the discontinuation of CHS-2020 was recognized after March 31, 2021.

5. Balance Sheet Components

Property and Equipment, Net

Property and equipment, net consisted of the following:

(in thousands)	December 31,	
	2022	2021
Machinery and equipment	\$ 12,944	\$ 11,876
Computer equipment and software	3,183	3,033
Furniture and fixtures	1,258	1,129
Leasehold improvements	6,198	5,942
Finance lease right of use assets	4,632	2,294
Construction in progress	696	388
Total property and equipment	<u>28,911</u>	<u>24,662</u>
Accumulated depreciation and amortization	<u>(20,157)</u>	<u>(16,849)</u>
Property and equipment, net	<u>\$ 8,754</u>	<u>\$ 7,813</u>

Depreciation and amortization expense related to property and equipment, net was \$3.6 million, \$3.5 million, and \$2.9 million in 2022, 2021 and 2020, respectively. There were no material impairments of property and equipment in 2022, 2021 and 2020.

As of December 31, 2022 and 2021, the net book value of software implementation costs related to hosting arrangements was \$3.5 million and \$1.3 million, respectively, and the amortization expense was immaterial for all periods presented.

Accrued and Other Current Liabilities

Accrued and other current liabilities consisted of the following:

(in thousands)	December 31,	
	2022	2021
Accrued commercial and research and development manufacturing	\$ 21,774	\$ 30,541
Accrued co-development costs payable to Junshi Biosciences	8,356	1,926
Lease liabilities, current	4,318	3,492
Accrued other	15,649	12,168
Total Accrued and other current liabilities	<u>\$ 50,097</u>	<u>\$ 48,127</u>

6. Collaborations and Other Arrangements

Junshi Biosciences

On February 1, 2021, the Company entered into 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 paid \$150.0 million upfront for exclusive rights to toripalimab in the United States and Canada, an option in these territories to Junshi Biosciences' anti-TIGIT antibody CHS-006, an option in these territories to a 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 toripalimab 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 regulatory and sales milestones.

In March 2022, the Company paid \$35.0 million for the exercise of its option to license CHS-006. Junshi Biosciences and the Company are jointly developing CHS-006 with each party responsible for the associated development costs as set forth in the Collaboration Agreement. If the Company exercises its remaining option for the IL-2 cytokine, it will be obligated to pay an additional option exercise fee of \$35.0 million. Additionally, for each exercised option, the Company will be obligated to pay Junshi Biosciences an 18% royalty on net sales, up to \$85.0 million for the achievement of certain regulatory approvals, and up to \$170.0 million for the 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, including CHS-006, and will pay for a portion of these co-development activities up to a maximum of \$25.0 million per licensed compound per year. Additionally, the Company is responsible for certain associated regulatory and technology transfer costs for toripalimab and other licensed compounds and will reimburse Junshi Biosciences for such costs.

The licensing transaction and the exercise of the option were accounted for as asset acquisitions under the relevant accounting rules. Research and development expenses recognized for obligations to Junshi Biosciences were \$68.5 million in 2022, inclusive of the \$35.0 million option fee, \$175.4 million in 2021, and \$5.0 million in 2020 representing the right of first negotiation fee which was fully credited against the total upfront license fee obligation under the Collaboration Agreement. The first quarter of 2021 included \$145.0 million for the upfront payment for the exclusive rights to toripalimab and the second quarter of 2021 included a credit of \$9.0 million for the DLOM, discussed below. Accrued and other current liabilities in the consolidated balance sheets as of December 31, 2022 and 2021 included \$8.4 million and \$1.9 million, respectively, related to the co-development, regulatory and technology transfer costs related to these programs.

A \$25.0 million milestone payment will be due upon the regulatory approval of toripalimab. Junshi Biosciences and the Company have not received an action letter from the FDA regarding the BLA for toripalimab in combination with chemotherapy as treatment for recurrent or metastatic nasopharyngeal carcinoma by the Prescription Drug User Fee Action date of December 23, 2022. The FDA previously communicated that on-site inspections, including Junshi Biosciences' manufacturing facility for toripalimab, are required before the FDA can approve the original BLA; however, they were unable to conduct the inspection by December 23, 2022 due to the impact of COVID-19 related restrictions on travel in China. The BLA for toripalimab remains under review, and Junshi Biosciences and the Company are engaged in ongoing discussions with the FDA about the pre-approval inspection plans. The Company plans to launch toripalimab in the United States in the third quarter of 2023, if approved by July 1, 2023. As of December 31, 2022, the Company did not have any outstanding milestone or royalty payment obligations to Junshi Biosciences. The additional milestone payments, option fee for the IL-2 cytokine and

[Table of Contents](#)

royalties are contingent upon future events and, therefore, will be recorded if and when it becomes probable that a milestone will be achieved, or when an option fee or royalties are incurred.

In connection with the Collaboration Agreement, the Company entered into 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, on April 16, 2021, the Company issued 2,491,988 unregistered shares of its common stock to Junshi Biosciences, at a price per share of \$20.06, for an aggregate amount of approximately \$50.0 million in cash. Under the terms of the Stock Purchase Agreement, Junshi Biosciences is not permitted to sell, transfer, make any short sale of, or grant any option for the sale of the common stock for the two-year period following its effective date. The Collaboration Agreement and the Stock Purchase Agreement were negotiated concurrently and were therefore evaluated as a single agreement. The Company used the "Finnerty" and "Asian put" valuation models and determined the fair value for the discount for lack of marketability was \$9.0 million at the date the shares were issued. The fair value of the DLOM was attributable to the Collaboration Agreement and was included as an offset against the research and development expense in the consolidated statement of operations for the year ended December 31, 2021.

Innovent Biologics (Suzhou) Co., Ltd.

On January 13, 2020, the Company entered into a license agreement with Innovent for the development and commercialization of the bevacizumab Licensed Product in the United States and Canada.

Under the Innovent Agreement, the Company paid Innovent \$5.0 million upfront and committed to pay 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. 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 the upfront payment and a milestone payment for the bevacizumab Licensed Product. During the year ended December 31, 2021, the Company recognized research and development expense of \$1.1 million related to bevacizumab Licensed Product development activities directly with Innovent, and during 2022 this research and development expense was immaterial. As of December 31, 2022, the Company did not have any outstanding milestone or royalty payment obligations to Innovent.

On May 3, 2022, the Company provided notice of termination of the Innovent Agreement to Innovent because regulatory approval of the licensed product could not be reasonably obtained within the agreed time period. In connection therewith, the Company has discontinued development of the bevacizumab Licensed Product.

Bioeq

On November 4, 2019, the Company entered into the Bioeq 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. Under this agreement, Bioeq granted to the Company 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 the Company 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. The 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.

Bioeq will manufacture and supply the Bioeq Licensed Products to the Company in accordance with terms and conditions specified in the Bioeq Agreement and the Bioeq Manufacturing Agreement and will remain in force until the first to occur of the following: (1) the termination of the Bioeq Agreement; (2) the exercise of a right to termination by the Company or Bioeq for a material breach of the other party that is not cured in accordance with the Bioeq Manufacturing Agreement; and (3) the exercise of a right to termination by Bioeq if invoices are not paid in full in accordance with the Bioeq Manufacturing Agreement.

Under the 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 the Company must use commercially reasonable efforts to commercialize the Bioeq 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 Bioeq Licensed Products for a limited time as specified in the agreement.

[Table of Contents](#)

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 in 2019. The terms of the Bioeq Agreement include an aggregate of up to €12.5 million in additional milestone payments in connection with the achievement of certain development and regulatory milestones with respect to the Bioeq Licensed Products in the United States including a €2.5 million milestone related to the FDA approval of the CIMERLI Section 351(k) BLA that was paid in 2022. This was recorded as an intangible asset and is being amortized over ten years. The Company shares 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. Royalties due to Bioeq were \$2.9 million as of December 31, 2022. The remaining milestone payments are contingent upon future events and, therefore, will be recorded when it becomes probable that a milestone will be achieved.

7. Debt Obligations

A summary of the Company's debt obligations, including level within the fair value hierarchy (see Note 3), is as follows:

At December 31, 2022						
(in thousands)	Principal Amount	Unamortized Debt Discount and Debt Issuance Costs	Net Carrying Value	Estimated Fair Value	Level	
Financial Liabilities:						
2027 Term Loans	\$ 250,000	\$ (4,517)	\$ 245,483	\$ 245,483	Level 2*	
2026 Convertible Notes	\$ 230,000	\$ (4,425)	\$ 225,575	\$ 157,205	Level 2**	

At December 31, 2021						
(in thousands)	Principal Amount	Unamortized Exit Fee, Debt Discount and Debt Issuance Costs	Net Carrying Value	Estimated Fair Value	Level	
Financial Liabilities:						
2026 Convertible Notes	\$ 230,000	\$ (5,712)	\$ 224,288	\$ 271,860	Level 2**	
2022 Convertible Notes	\$ 109,000	\$ (521)	\$ 108,479	\$ 108,361	Level 3***	
2025 Term Loan	\$ 75,000	\$ 513	\$ 75,513	\$ 75,513	Level 2*	

* The principal amounts outstanding are subject to variable interest rates, which are based on three-month LIBOR plus fixed percentages through March 31, 2023. Therefore, the Company believes the carrying amount of these obligations approximates fair value.

** The fair value is influenced by interest rates, the Company's stock price and stock price volatility and is determined by prices observed in market trading. Since the market for trading of the 2026 Convertible Notes is not considered to be an active market, the estimated fair value is based on Level 2 inputs.

*** The fair value was based on an income approach using 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, and therefore were Level 3 inputs. The lattice model produced 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 was used to discount straight debt cash flows.

2027 Term Loans

The Company entered into the Loan Agreement with BioPharma Credit, PLC, BPCR Limited Partnership, and Biopharma Credit Investments V (Master) LP, acting by its general partner, BioPharma Credit Investments V GP LLC that provides for a senior secured term loan facility of up to \$300.0 million to be funded in four committed tranches: (i) the Tranche A Loan in an aggregate principal amount of \$100.0 million that was funded on January 5, 2022; (ii) the Tranche B Loan in an aggregate principal amount of \$100.0 million that was funded on March 31, 2022; (iii) the Tranche C Loan in an aggregate principal amount of \$50.0 million that was not funded; and (iv) the Tranche D Loan in an aggregate principal amount of \$50.0 million that was funded on September 14, 2022. The Company has the right to request an uncommitted additional facility amount of up to \$100.0 million that is subject to new terms and conditions.

The 2027 Term Loans mature on either (i) the fifth anniversary of the Tranche A Closing Date; or (ii) October 15, 2025, if the outstanding aggregate principal amount of the Company's 2026 Convertible Notes is greater than \$50.0 million on October 1, 2025. The 2027 Term Loans accrue interest from inception through March 31, 2023 at 8.25% plus three-month LIBOR per annum with a LIBOR floor of 1.0%; and, starting April 1, 2023, accrue interest at 8.25% plus the Adjusted Term SOFR which is the sum of three-month SOFR and 0.26161% per annum, with a floor on Adjusted Term SOFR of 1.0%. The interest rate for the fourth quarter of 2022 was 12.00%. Interest

[Table of Contents](#)

is payable quarterly in arrears on March 31, June 30, September 30 and December 31 of each year. Repayment of outstanding principal of the 2027 Term Loans will be made in five equal quarterly payments of principal commencing March 31, 2026.

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.

The obligations under the Loan Agreement are secured pursuant to customary security documentation, including a guaranty and security agreement among the Credit Parties and the Collateral Agent which provides for a lien on substantially all of the Company's tangible and intangible assets and property, including intellectual property.

Pursuant to the Loan Agreement, and subject to certain restrictions, proceeds of the 2027 Term Loans were and will be used to fund the Company's general corporate and working capital requirements except for the following: in January 2022, proceeds of the Tranche A Loan were used to repay in full all amounts outstanding under the 2025 Term Loan, as well as all associated costs and expenses pursuant to which a payoff amount of \$81.9 million was outstanding; in March 2022, proceeds of the Tranche B Loan were drawn in connection with the full repayment of all amounts outstanding under the 2022 Convertible Notes, as well as all associated costs and expenses pursuant to which a payoff amount of \$111.1 million was outstanding.

The Loan Agreement contains certain customary representations and warranties. In addition, the Loan Agreement includes covenants, such as the requirement to maintain minimum trailing twelve-month net sales in an amount that begins at \$200.0 million for the quarter ending March 31, 2022, increases to \$210.0 million for the quarter ended March 31, 2024, increases to \$230.0 million for the quarter ending June 30, 2024, increases to \$270.0 million for the quarter ending September 30, 2024, and increases to \$300.0 million for the quarter ended December 31, 2024 and thereafter. Further, the Loan Agreement includes certain other affirmative covenants and negative covenants, including, covenants and restrictions that among other things, restrict the Company's ability to incur liens, incur additional indebtedness, make investments, engage in certain mergers and acquisitions or asset sales, and declare dividends or redeem or repurchase capital stock. The Loan Agreement also contains customary events of default, including among other things, the Company's failure to make any principal or interest payments when due, the occurrence of certain bankruptcy or insolvency events or its breach of the covenants under the Loan Agreement. Upon the occurrence of an event of default, the Lenders may, among other things, accelerate the Company's obligations under the Loan Agreement. A change of control of the Company triggers a mandatory prepayment of the 2027 Term Loans within ten business days.

As of December 31, 2022, the Company was in full compliance with these covenants and there were no events of default under the 2027 Term Loans.

In connection with the closing of Tranche A, the Company incurred \$7.8 million in debt discounts and issuance costs of which \$6.8 million related to all the tranches of the 2027 Term Loans and was thus allocated pro rata between the tranches. The unamortized debt discount and issuance costs allocated to funded tranches are presented as deductions to the 2027 Term Loan balance and are amortized into interest expense using the effective interest method. The \$2.3 million allocated to Tranche B was fully amortized over the commitment period prior to funding and recognized as interest expense in the first quarter of 2022. Until unfunded tranches are drawn, the associated debt discounts and issuance costs are deferred as assets and amortized into interest expense using the straight-line method over the commitment period of the respective tranches. At the closing dates of Tranche B on March 31, 2022 and Tranche D on September 14, 2022, the Company incurred an additional \$1.0 million and \$0.5 million, respectively, in debt issuance costs. As of December 31, 2022, the total remaining unamortized debt discount and debt offering costs related to Tranches A, B and D of \$4.5 million will be amortized using the effective interest rate over the remaining term of 4.0 years.

The following table represents the components of interest expense related to the 2027 Term Loans:

(in thousands)	Year Ended December 31, 2022
Stated coupon interest	\$ 20,243
Amortization of debt discount and debt issuance costs	4,550
Total interest expense	<u>\$ 24,793</u>

[Table of Contents](#)

Future payments on the 2027 Term Loans as of December 31, 2022 are as follows:

Year ending December 31, (in thousands)	
2023 - interest only	\$ 30,412
2024 - interest only	30,496
2025 - interest only	30,412
2026 - principal and interest	221,231
2027 - principal and interest	50,083
Total minimum payments	362,634
Less amount representing interest	(112,634)
2027 Term Loans, gross	250,000
Less unamortized debt discount and debt issuance costs, net	(4,517)
Net carrying amount of 2027 Term Loans	<u>\$ 245,483</u>

1.5% Convertible Senior Subordinated Notes due 2026

In April 2020, the Company issued and sold \$230.0 million aggregate principal amount of its 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, since 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 \$14.82 per share of the Company's common stock on the Nasdaq Global Market on April 14, 2020, the date the 2026 Convertible Notes were issued. 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 have customary provisions 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, 2022, the Company was in full compliance with these covenants, and there were no events of default under the 2026 Convertible Notes.

The Company evaluated the features embedded in the 2026 Convertible Notes under the relevant accounting rules and concluded that the embedded features do not meet the requirements for bifurcation, and therefore do not need to be separately accounted for as an equity component. The proceeds received from the issuance of the convertible debt were recorded as a liability in the consolidated balance sheets.

Capped Call Transactions

In connection with the pricing of the 2026 Convertible Notes, the Company also paid \$18.2 million to enter into privately

[Table of Contents](#)

negotiated capped call transactions with one or a combination of the initial purchasers, their respective affiliates and other financial institutions. 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 \$25.93 per share, which represents a premium of approximately 75.0% over the last reported sale price of the Company's common stock of \$14.82 per share on April 14, 2020, and is subject to certain adjustments under the terms of the capped call transactions.

The capped call transactions are accounted for as separate transactions from the 2026 Convertible Notes and classified as equity instruments. Therefore, the total \$18.2 million capped call premium paid was recorded as a reduction to additional paid-in capital in the consolidated balance sheets. 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 in the consolidated balance sheet. The debt issuance costs are being amortized and recognized as additional interest expense over the six-year contractual term of the notes using the effective interest rate method.

If the 2026 Convertible Notes were converted on December 31, 2022, the holders of the 2026 Convertible Notes would have received common shares with an aggregate value of \$94.6 million based on the Company's closing stock price of \$7.92 as of December 30, 2022.

The following table presents the components of interest expense related to 2026 Convertible Notes:

(in thousands)	Year Ended December 31,		
	2022	2021	2020
Stated coupon interest	\$ 3,450	\$ 3,450	\$ 2,434
Amortization of debt discount and debt issuance costs	1,286	1,259	873
Total interest expense	<u>\$ 4,736</u>	<u>\$ 4,709</u>	<u>\$ 3,307</u>

The remaining unamortized debt discount and debt offering costs related to the Company's 2026 Convertible Notes of \$4.4 million as of December 31, 2022, will be amortized using the effective interest rate over the remaining term of the 2026 Convertible Notes of 3.3 years. The annual effective interest rate is 2.1% for the 2026 Convertible Notes.

Future payments on the 2026 Convertible Notes as of December 31, 2022 are as follows:

Year ending December 31, (in thousands)	
2023 - interest only	\$ 3,450
2024 - interest only	3,450
2025 - interest only	3,450
2026	231,725
Total minimum payments	<u>242,075</u>
Less amount representing interest	<u>(12,075)</u>
2026 Convertible Notes, principal amount	230,000
Less unamortized debt discount and debt issuance costs	<u>(4,425)</u>
Net carrying amount of 2026 Convertible Notes	<u>\$ 225,575</u>

8.2% Convertible Notes due 2022

On February 29, 2016, the Company issued and sold \$100.0 million aggregate principal amount, which excluded a 9.0% premium due at maturity or redemption, of its 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 constituted general, senior unsubordinated obligations of the Company and were guaranteed by certain subsidiaries of the Company. The 2022 Convertible Notes bore 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, since March 31, 2016,

[Table of Contents](#)

and matured on March 31, 2022. The 2022 Convertible Notes also had a premium of 9.0% of the principal amount which was payable when the 2022 Convertible Notes matured or were 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.

At any time before the close of business on the business day immediately preceding March 31, 2022, the 2022 Convertible Note noteholders could have converted their 2022 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 was 44.7387 shares of common stock per \$1,000 principal amount of the 2022 Convertible Notes, which represented an initial conversion price of approximately \$22.35 per share of common stock. The initial conversion price represented a 60% premium over the average last reported sale price of the Company's common stock over the 15 trading days preceding the date the 2022 Convertible Notes were issued. The conversion rate and conversion price were subject to customary adjustments upon the occurrence of certain events. The 2022 Convertible Notes were redeemable in whole, and not in part, at the Company's option with effect from March 31, 2020, if the last reported sale price per share of common stock exceeded 160% of the conversion price on 20 or more trading days during the 30 consecutive trading days preceding the date on which the Company sent notice of such redemption to the holders of the 2022 Convertible Notes. At maturity or redemption, if not earlier converted, the Company would pay 109% of the principal amount of the 2022 Convertible Notes maturing or being redeemed, together with accrued and unpaid interest, in cash.

In March 2022, the Company fully repaid the 2022 Convertible Notes, and as a result had no continuing obligations associated with them thereafter. The payoff amount of \$111.1 million included the repayment of the entire outstanding principal amount, the 9.0% premium of the outstanding principal amount and accrued and unpaid interest.

The following table presents the components of interest expense of the 2022 Convertible Notes:

(in thousands)	Year Ended December 31,		
	2022	2021	2020
Stated coupon interest	\$ 2,050	\$ 8,200	\$ 8,200
Amortization of debt discount and debt issuance costs	521	1,966	1,791
Total interest expense	<u>\$ 2,571</u>	<u>\$ 10,166</u>	<u>\$ 9,991</u>

2025 Term Loan

On January 7, 2019 (the "2025 Term Loan Closing Date"), the Company entered into the 2025 Term Loan with affiliates of Healthcare Royalty Partners (together, the "Lender"). The 2025 Term Loan consisted 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 were guaranteed by the Company's material domestic United States subsidiaries and were secured by a lien on substantially all of the Company's tangible and intangible property, including intellectual property.

Starting January 1, 2020, the Borrowings under the 2025 Term Loan bore interest at 6.75% per annum plus three month LIBOR. Interest was payable quarterly in arrears. Under the prospective method to account for future cash payments adopted by the Company, the effective interest rate was not constant, and any change in the expected cash flows was recognized prospectively as an adjustment to the effective yield.

If all or any of the Borrowings were prepaid or required to be prepaid under the 2025 Term Loan, then the Company was required to 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 2025 Term Loan Closing Date, (ii) with respect to any prepayment paid or required to be paid after the three year anniversary of the 2025 Term Loan Closing Date but on or prior to the four year anniversary of the 2025 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 2025 Term Loan Closing Date but on or prior to the five year anniversary of the 2025 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.

[Table of Contents](#)

In connection with the 2025 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, the Company was required to pay an additional exit fee in an amount equal to 4.0% of the total principal amount of the Borrowings.

Pursuant to the terms of the 2025 Term Loan, the Company was required to begin paying principal on the Borrowings in equal quarterly installments beginning on the third anniversary of the 2025 Term Loan Closing Date, with the outstanding balance to be repaid on January 7, 2025, the maturity date. In January 2022, pursuant to the Company entering into the 2027 Term Loans, the Company voluntarily prepaid all amounts outstanding under the 2025 Term Loan. The payoff amount of \$81.9 million included principal repayment in full, accrued interest, a 5.0% prepayment premium fee of the Borrowings principal amount, and an exit fee of 4.0% of the Borrowings principal amount. The prepayment premium fee and unamortized exit fee, debt discount and debt issuance costs, net from the 2025 Term Loan totaled \$6.2 million and was recorded in loss on debt extinguishment in the consolidated statement of operations for 2022. As of December 31, 2022, the Company had no continuing obligations associated with the 2025 Term Loan.

The following table presents the components of interest expense of the 2025 Term Loan:

(in thousands)	Year Ended December 31,		
	2022	2021	2020
Stated coupon interest	\$ 154	\$ 7,034	\$ 7,053
Amortization of debt discount and debt issuance costs	16	1,032	818
Total interest expense	<u>\$ 170</u>	<u>\$ 8,066</u>	<u>\$ 7,871</u>

8. Commitments and Contingencies

Purchase Commitments

The Company entered into agreements with certain vendors to secure raw materials and certain CMOs to manufacture its supply of products. As of December 31, 2022, the Company's non-cancelable purchase commitments under the terms of its agreements are as follows:

Year ending December 31, (in thousands)	
2023	\$ 53,652
2024	13,724
2025	1,128
2026	260
Total obligations	<u>\$ 68,764</u>

The Company enters into contracts in the normal course of business with contract research organizations for preclinical studies and clinical trials and CMOs for the manufacture of clinical trial materials. The contracts are cancellable, with varying provisions regarding termination. If a contract with a specific vendor were to be terminated, the Company would generally 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.

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 assesses 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.

Legal Proceedings and Other Claims

The Company is a party to various legal proceedings and claims that arise in the ordinary, routine course of business and that have not been fully resolved. The outcome of such legal proceedings and claims is inherently uncertain. Accruals are recognized for such legal proceedings and claims to the extent that a loss is both probable and reasonably estimable. The best estimate of a loss within a range is accrued; however, if no estimate in the range is better than any other, then the minimum amount in the range is accrued. If its determined that a material loss is reasonably possible and the loss or range of loss can be estimated, the possible loss is disclosed. Sometimes it is not possible to determine the outcome of these matters or, unless otherwise noted, the outcome (including in excess of any accrual) is not expected to be material, and the maximum potential exposure or the range of possible loss cannot be reasonably estimated. The Company did not have a material accrual for such matters as of December 31, 2021 and established an accrual of approximately \$4.7 million as of December 31, 2022 that was included in accrued rebates, fees and reserves in the consolidated balance sheets.

In late April of 2022, the Company received a demand letter from Zinc Health Services, LLC ("Zinc") asserting that Zinc was entitled to approximately \$14.0 million from the Company for claims related to certain sales of UDENYCA from October 2020 through December 2021. The Company is continuing to evaluate the claims in the letter. No legal proceeding has been filed in connection with the claims in the letter and based on currently available information the final resolution of the matter is uncertain. The Company intends to defend any legal proceeding that may be filed. The Company established an accrual as of December 31, 2022 that represented its estimated liability to resolve the matter. Loss contingencies are inherently unpredictable, the assessment is highly subjective and requires judgments about future events and unfavorable developments or resolutions can occur. The Company regularly reviews litigation matters to determine whether its accrual is adequate. The amount of ultimate loss may differ materially from the amount accrued to date.

Other than the matter in connection with the demand letter described in this Note 8, there are no pending legal proceedings, other than ordinary routine litigation incidental to the business, to which the Company or any of its subsidiaries is a party, or that any of the Company or its subsidiaries' property is subject.

9. Leases

The Company leases approximately 47,789 square feet of office space for its corporate headquarters in Redwood City, California. This lease terminates in September 2024 and contains a one-time option to extend the lease term for five years. The Company also leases approximately 25,017 square feet for its laboratory facilities in Camarillo, California which commenced in January 2020. This lease terminates in May 2027 and contains a one-time option to extend the lease term for five years. Both facility leases provide for certain limited rent abatement and annual scheduled rent increases over their respective lease terms.

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 it was not reasonably certain the Company would exercise those options.

In 2019, the Company entered into the Vehicle Lease Agreement, pursuant to which the Company currently leases approximately 100 vehicles. Delivery of the vehicles commenced during the first quarter of 2020. The term of each leased vehicle is 36 months and commences upon the delivery of the vehicle. The vehicles leased under this arrangement were classified as finance leases.

For the leases that commenced prior to January 1, 2019 (adoption date of ASC 842, *Leases*), the Company determined the present value of the lease payments using the incremental borrowing rate on that date. For all other leases, the Company used the incremental borrowing rate on the lease commencement or the lease modification date, as applicable.

Supplemental information related to the Company's leases is as follows:

(in thousands)	Assets	Balance Sheet Classification	December 31,	
			2022	2021
	Operating leases	Other assets, non-current	\$ 5,690	\$ 8,193
	Finance leases	Property and equipment, net	2,584	1,220
	Total leased assets		\$ 8,274	\$ 9,413

[Table of Contents](#)

(in thousands) Liabilities	Balance Sheet Classification	December 31,	
		2022	2021
Operating lease liabilities, current	Accrued and other current liabilities	\$ 3,127	\$ 2,751
Operating lease liabilities, non-current	Lease liabilities, non-current	3,628	6,753
Total operating lease liabilities		\$ 6,755	\$ 9,504
Finance lease liabilities, current	Accrued and other current liabilities	\$ 1,191	\$ 741
Finance lease liabilities, non-current	Lease liabilities, non-current	1,418	498
Total finance lease liabilities		\$ 2,609	\$ 1,239

Other information related to lease term and discount rate is as follows:

	December 31,	
	2022	2021
Weighted-Average Remaining Lease Term		
Operating leases	2.2 years	3.2 years
Finance leases	2.2 years	1.7 years
Weighted-Average Discount Rate		
Operating leases	8.0%	8.0%
Finance leases	8.4%	5.8%

The components of lease expense were as follows:

(in thousands)	Year Ended December 31,		
	2022	2021	2020
Finance lease cost			
Amortization of right-of-use assets	\$ 1,228	\$ 707	\$ 368
Interest on lease liabilities	166	82	57
Total finance lease cost	1,394	789	425
Operating lease cost	3,154	3,066	3,126
Total lease cost	\$ 4,548	\$ 3,855	\$ 3,551

Supplemental cash flow information related to leases was as follows:

(in thousands)	Year Ended December 31,		
	2022	2021	2020
Cash paid for amounts included in measurement of lease liabilities:			
Operating cash flows from operating leases	\$ 3,401	\$ 3,435	\$ 3,217
Operating cash flows from finance leases	\$ 155	\$ 81	\$ 53
Financing cash flows from finance leases	\$ 1,228	\$ 672	\$ 388
Right-of-use assets obtained in exchange for lease obligations:			
Operating leases	\$ —	\$ 434	\$ 1,388
Finance leases	\$ 2,694	\$ 477	\$ 1,817

[Table of Contents](#)

As of December 31, 2022, the maturities of the lease liabilities were as follows:

Year ending December 31, (in thousands)	Operating leases	Finance leases
2023	\$ 3,560	\$ 1,354
2024	3,014	1,026
2025	412	481
2026	292	—
2027 and thereafter	124	—
Total lease payments	7,402	2,861
Less imputed interest	(647)	(252)
Lease liabilities	\$ 6,755	\$ 2,609

10. At-The-Market Offering

On November 8, 2022, the Company filed a Registration Statement on Form S-3, which was declared effective on November 17, 2022. Under the Registration Statement, the Company may offer and sell up to \$150.0 million in the aggregate of its common stock, preferred stock, debt securities, warrants and units from time to time in one or more offerings. Also on November 8, 2022, the Company entered into a Sales Agreement with Cowen, pursuant to which the Company may issue and sell from time to time up to \$150.0 million of its common stock through or to Cowen as the Company's sales agent or principal in the ATM Offering. As of December 31, 2022, the Company sold 916,884 shares of common stock at a weighted-average price per share of \$7.30 for gross proceeds of \$6.7 million pursuant to the ATM Offering and received net proceeds of \$6.5 million, net of \$0.2 million of commissions and fees. In January 2023, the Company settled an additional 295,200 shares at a weighted-average price per share of \$7.41 for gross proceeds of \$2.2 million pursuant to the ATM Offering and received net proceeds of \$2.1 million, net of \$0.1 million of commissions and fees.

11. Stock-Based Compensation and Employee Benefits

Equity Incentive Plans

In October 2014, the Company's board of directors and its stockholders adopted the 2014 Equity Incentive 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 that 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. While the 2014 Plan allows for non-qualified or incentive stock options, all option grants made since June 2016 have been for non-qualified stock options. Under the 2010 Plan, no awards have been issued since 2014, and there were no shares of common stock available for future issuance as of December 31, 2022. There were 1,252,865 shares of common stock available for future issuance as of December 31, 2022 under the 2014 Plan.

In June 2016, the Company adopted the 2016 Employment Commencement Incentive 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, 2022, the Company had 861,312 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 option exercises are settled with common stock from the plans' previously authorized and available pool of shares. If any shares subject to an award granted under the 2014 Plan or the 2016 Plan expire or become forfeited or canceled without the issuance of shares, the shares subject to such awards are added back into the authorized pool on the same basis that they were removed. In addition, shares withheld to pay for minimum statutory tax obligations with respect to full-value awards are added back into the authorized pool. The annual grant to eligible employees can vary on the type of award, and the award size is determined by the employee's grade level.

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 Plan and the 2014 Plan:

	Options			Aggregate Intrinsic Value (in thousands)
	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Terms (Years)	
Outstanding at December 31, 2021	19,959,815	\$ 15.89		
Granted - at fair value	4,685,750	\$ 12.09		
Exercised	(141,897)	\$ 4.88		
Forfeited/Canceled	(2,812,347)	\$ 16.97		
Outstanding at December 31, 2022	<u>21,691,321</u>	\$ 15.00	6.0	\$ 10,714
Exercisable at December 31, 2022	<u>15,027,783</u>	\$ 15.47	4.8	\$ 9,647

Aggregate intrinsic value represents the value of the Company's closing stock price on the last trading day of the year in excess of the exercise price multiplied by the number of options outstanding or exercisable.

Information on options outstanding and exercisable as of December 31, 2022 is summarized as follows:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Number Outstanding	Weighted-Average Remaining Contractual Terms (Years)	Weighted-Average Exercise Price	Number Exercisable	Weighted-Average Exercise Price
\$ 1.42 - \$ 10.05	4,801,972	5.2	\$ 6.64	3,223,663	\$ 5.99
\$ 10.78 - \$ 14.13	4,598,418	6.4	\$ 12.72	3,381,021	\$ 12.67
\$ 14.30 - \$ 17.17	4,857,557	7.2	\$ 15.91	2,530,714	\$ 16.08
\$ 17.30 - \$ 19.07	4,406,311	6.9	\$ 17.93	3,000,465	\$ 17.94
\$ 19.19 - \$ 36.85	3,027,063	3.4	\$ 25.98	2,891,920	\$ 26.22
	<u>21,691,321</u>	6.0	\$ 15.00	<u>15,027,783</u>	\$ 15.47

The intrinsic value is defined as the difference between the current market value and the exercise price. Additional information on options is summarized as follows:

(in thousands, except weighted-average grant date fair values)	Year Ended December 31,		
	2022	2021	2020
Total intrinsic value of options exercised	\$ 914	\$ 9,726	\$ 14,572
Total grant date fair value of options vested	\$ 34,916	\$ 40,365	\$ 34,090
Weighted-average grant date fair value of options granted	\$ 7.04	\$ 9.80	\$ 10.94

As of December 31, 2022, total unrecognized stock-based compensation expense related to unvested stock options was \$51.5 million, which is expected to be recognized over a weighted-average period of 2.7 years.

Restricted Stock Units

The Company grants RSUs primarily to its employees. RSUs are share awards that entitle the holder to receive freely tradable shares of the Company's 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 one to three years from

[Table of Contents](#)

the applicable grant date, provided the employee remains continuously employed with the Company. The estimated fair value of RSUs is based on the closing price of the Company's common stock on the grant date.

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, 2021	1,843,732	\$ 17.00
RSUs granted	1,686,875	\$ 13.34
RSUs vested	(806,854)	\$ 16.85
RSUs canceled	(390,446)	\$ 15.43
Balances at December 31, 2022	<u>2,333,307</u>	<u>\$ 14.66</u>

The total grant-date fair value of RSUs that vested during 2022, 2021 and 2020 was \$13.6 million, \$8.4 million and \$4.1 million, respectively. The total grant-date fair value of RSUs granted was \$22.5 million, \$27.9 million and \$21.2 million during 2022, 2021 and 2020, respectively. The estimated weighted-average grant-date fair value per share of RSUs granted during 2022, 2021 and 2020 was \$13.34, \$16.86 and \$17.86, respectively.

As of December 31, 2022, total unrecognized stock-based compensation expense related to unvested RSUs was \$20.3 million, which is expected to be recognized over a weighted-average period of 1.5 years.

Employee Stock Purchase Plan

In October 2014, the Company's board of directors and its stockholders approved the establishment of the 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 3,172,117 shares of common stock available for future issuance as of December 31, 2022. 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 the ESPP are on May 16 and November 16. As of December 31, 2022, 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 following table summarizes the classification of stock-based compensation expense in the Company's consolidated financial statements related to options and RSUs granted to employees and nonemployees:

(in thousands)	Year Ended December 31,		
	2022	2021	2020
Cost of goods sold ⁽¹⁾	\$ 736	\$ 1,099	\$ 583
Research and development	18,999	18,688	13,837
Selling, general and administrative	31,002	31,577	23,740
Stock-based compensation expense	<u>\$ 50,737</u>	<u>\$ 51,364</u>	<u>\$ 38,160</u>
Stock-based compensation expense capitalized into inventory	<u>\$ 1,187</u>	<u>\$ 1,025</u>	<u>\$ 1,460</u>

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

[Table of Contents](#)

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, 2022, 2021 and 2020:

	Year Ended December 31,		
	2022	2021	2020
Expected term (years)			
Stock options	6.1	6.1	6.1
ESPP	0.5	0.5	0.5
Expected volatility			
Stock options	62 %	65 %	68 %
ESPP	70 %	42 %	58 %
Risk-free interest rate			
Stock options	2.37 %	0.89 %	1.09 %
ESPP	3.77 %	0.06 %	0.13 %
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. Through December 31, 2020, 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 had limited historical information to develop expectations about future exercise patterns and post-vesting employment termination behavior. Since January 1, 2021, the Company has used historical data to calculate the expected term.

Expected Volatility: The expected volatility is calculated based on the Company's daily stock closing prices for a period equal to the expected life of the award.

Risk-Free Interest Rate: The risk-free interest rate is based on the United States Treasury constant maturity rate at the time of grant using a term equal to the expected life.

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. Beginning January 1, 2021, the Company made matching contributions of 100% of the first 4% of eligible compensation, up to a maximum of \$7,500. In 2020, the Company made matching contributions of 50% of the first \$6,000 of each participant's contributions. The Company recorded compensation expense related to the match of \$2.1 million, \$1.7 million and \$0.8 million in 2022, 2021 and 2020, respectively.

12. Income Taxes

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

(in thousands)	Year Ended December 31,		
	2022	2021	2020
Domestic	\$ (291,746)	\$ (287,058)	\$ 133,615
Foreign	(8)	(42)	2,092
Total	<u>\$ (291,754)</u>	<u>\$ (287,100)</u>	<u>\$ 135,707</u>

[Table of Contents](#)

Provision for income taxes:

(in thousands)	Year Ended December 31,		
	2022	2021	2020
Current:			
Federal	\$ —	\$ —	\$ —
State	—	—	3,463
Foreign	—	—	—
Subtotal	\$ —	\$ —	\$ 3,463
Deferred:			
Federal	\$ —	\$ —	\$ —
State	—	—	—
Foreign	—	—	—
Subtotal	\$ —	\$ —	\$ —
Provision for income taxes	\$ —	\$ —	\$ 3,463

There was no income tax provision in 2022 and 2021 due to the Company's history of losses and valuation of allowances against the deferred tax assets. The income tax provision in 2020 of \$3.5 million is primarily related to state taxes in jurisdictions outside of California, for which the Company has a limited operating history.

A reconciliation of the statutory United States federal rate to the Company's effective tax rate is as follows:

Percent of pre-tax income:	Year Ended December 31,		
	2022	2021	2020
United States federal statutory income tax rate	21.0 %	21.0 %	21.0 %
State taxes, net of federal benefit	1.7	2.6	2.0
Foreign rate differences	—	—	(0.3)
Permanent items	(0.1)	0.2	0.4
Research and development credit	1.8	2.6	(4.8)
Stock-based compensation costs	(2.3)	(1.2)	1.3
Other	—	—	(0.3)
Change in valuation allowance	(22.1)	(25.2)	(16.7)
Effective income tax rate	— %	— %	2.6 %

The components of the Company's net deferred tax assets as of December 31, 2022 and 2021 consist of the following:

(in thousands)	December 31,	
	2022	2021
Net operating loss carryforwards	\$ 131,423	\$ 117,793
Research and development credits	63,164	58,039
Depreciation and amortization	51,877	40,620
Stock-based compensation	32,561	30,565
Sales related accruals	23,864	17,299
Other accruals	19,717	11,798
Capitalized research and development	17,673	—
Gross deferred tax assets	340,279	276,114
Right-of-use asset	(1,903)	(2,167)
In-process research and development	(603)	(603)
Gross deferred tax liabilities	(2,506)	(2,770)
Total net deferred tax asset	337,773	273,344
Less valuation allowance	(337,773)	(273,344)
Net deferred tax assets	\$ —	\$ —

[Table of Contents](#)

The tax benefit of net operating losses, temporary differences and credit carry forwards is recorded as an asset to the extent that management assesses that realization is "more likely than not." The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which the temporary differences representing net future deductible amounts become deductible. Due to the Company's history of losses, and lack of other positive evidence, the Company has determined that it is more likely than not that its federal net deferred tax assets and certain state net deferred tax assets will not be realized, and therefore, the Company has fully offset the federal and certain state net deferred tax assets by a valuation allowance as of December 31, 2022 and 2021.

The valuation allowance increased by \$64.4 million and \$72.4 million during the years ended December 31, 2022 and 2021, respectively, and decreased by \$22.7 million during the year ended December 31, 2020.

As of December 31, 2022, the Company had operating loss carryforwards for federal income of \$591.2 million, which will start to expire in the year 2036, and various states net operating loss carryforwards of \$113.2 million, which have various expiration dates beginning in 2031.

As of December 31, 2022, the Company had federal research and development credit carryforwards for federal income tax purposes of \$57.7 million, which will start to expire in the year 2031, and state research and development credit carryforwards of \$26.4 million, which have no expiration date.

Utilization of the net operating loss and tax credit carryforwards may be subject to an annual limitation due to historical or future ownership percentage change rules provided by the Internal Revenue Code of 1986, as amended, and similar state provisions. The annual limitation may result in the expiration of certain net operating loss and tax credit carryforwards before their utilization. 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 income tax returns in the United States federal jurisdiction, various United States state jurisdictions, and a foreign jurisdiction 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 during 2022, 2021 and 2020 is as follows:

(in thousands)	Year Ended December 31,		
	2022	2021	2020
Balance at beginning of year	\$ 15,495	\$ 13,243	\$ 11,603
Additions based on tax positions related to current year	1,385	2,038	1,749
Additions (reductions) for tax positions of prior years	(42)	214	(109)
Balance at end of year	<u>\$ 16,838</u>	<u>\$ 15,495</u>	<u>\$ 13,243</u>

As of December 31, 2022, 2021 and 2020, the Company had \$16.8 million, \$15.5 million and \$13.2 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. During 2022, 2021 and 2020, 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 twelve months from the balance sheet date as reductions for tax positions of prior years.

13. Net (Loss) Income Per Share

The following table sets forth the computation of the basic and diluted net (loss) income per share:

(in thousands, except share and per share data)	Year Ended December 31,		
	2022	2021	2020
Basic net (loss) income per share			
Numerator:			
Net (loss) income	\$ (291,754)	\$ (287,100)	\$ 132,244
Denominator:			
Weighted-average common shares outstanding	77,630,020	75,449,632	71,411,705
Basic net (loss) income per share	\$ (3.76)	\$ (3.81)	\$ 1.85
Diluted net (loss) income per share			
Numerator:			
Net (loss) income	\$ (291,754)	\$ (287,100)	\$ 132,244
Add interest expense on 2026 Convertible Notes, net of tax	—	—	3,307
Numerator for diluted net (loss) income per share	(291,754)	(287,100)	135,551
Denominator:			
Denominator for basic net (loss) income per share	77,630,020	75,449,632	71,411,705
Add effect of potential dilutive securities:			
Stock options, including shares subject to ESPP	—	—	3,455,646
Restricted stock units	—	—	167,597
Shares issuable upon conversion of convertible notes	—	—	8,456,950
Denominator for diluted net (loss) income per share	77,630,020	75,449,632	83,491,898
Diluted net (loss) income per share	\$ (3.76)	\$ (3.81)	\$ 1.62

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

	Year Ended December 31,		
	2022	2021	2020
Stock options, including shares subject to ESPP	22,214,875	19,895,097	9,521,403
Restricted stock units	2,399,465	1,811,607	7,689
Shares issuable upon conversion of 2022 Convertible Notes	1,078,632	4,473,871	4,473,871
Shares issuable upon conversion of 2026 Convertible Notes	11,942,152	11,942,152	—
Total	37,635,124	38,122,727	14,002,963

14. Related Party Transactions

Consulting services

In October 2020, the Company entered into a consulting agreement with Lanfear Advisors owned by Mr. Jonathan Lanfear who is the brother of Dennis Lanfear, the Company's President, Chief Executive Officer and Chairman of the Board of Directors. Mr. Jonathan Lanfear provided consulting services with respect to the Collaboration Agreement executed with Junshi Biosciences in February 2021 and the Letter Agreement with Junshi Biosciences related to the Collaboration Agreement dated January 9, 2022 (See Note 6. Collaborations and Other Arrangements). In addition to the hourly consulting fee paid to Lanfear Advisors under the consulting agreement, the Company granted fully vested stock options to purchase 65,000 shares of common stock with an exercise price of \$17.60 per share to Mr. Jonathan Lanfear in February 2021 upon the execution of the Collaboration Agreement with Junshi Biosciences and recognized stock-based compensation expense of \$0.8 million. The Company recorded cash consulting expense of \$0.2 million and \$0.3 million in 2021 and 2020, respectively, with respect to these consulting services. There have been no subsequent material related party expenses. Total liabilities recognized in the consolidated balance sheets with respect to these services were immaterial as of December 31, 2022 and 2021.

15. Subsequent Events

On January 9, 2023, the Company announced that it entered into the Term Sheet with Klinge Biopharma for the exclusive commercialization rights to FYB203, a biosimilar candidate to Eylea® (afibercept), in the United States. The parties to the Term Sheet expect to execute the Definitive Agreements contemplated by the Term Sheet and complete the transaction in the first half of 2023. Under the Term Sheet, the Company will make a total upfront payment of approximately €30 million, comprised of cash and the Company's common stock, thirty days after the execution of the Definitive Agreements. The Company has also agreed to make other regulatory and launch milestone payments and to make royalty payments based on approximately equal sharing of profits from the sale of FYB203 in consideration for the commercialization rights to FYB203 in the United States.

The material terms of the transaction with Klinge Biopharma will be set forth in the Definitive Agreements, which will be included in a subsequent filing by the Company when such Definitive Agreements are executed.

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, 2022. 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, 2022, 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, 2022, 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 the Company as of December 31, 2022 and 2021, and the related consolidated statements of operations, comprehensive (loss) income, stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2022, and the related notes and our report dated March 6, 2023 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.

[Table of Contents](#)

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

San Mateo, California
March 6, 2023

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, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. *Other Information*

Not applicable.

Item 9C. *Disclosure Regarding Foreign Jurisdictions that Prevent Inspections*

Not applicable.

PART III

Certain information required by Part III is omitted from this Annual Report on Form 10-K because the Company will file a Definitive Proxy Statement (the "Proxy Statement") with the Securities and Exchange Commission within 120 days after the end of our fiscal year ended December 31, 2022.

Item 10. *Directors, Executive Officers and Corporate Governance*

The information required by this Item is included in the Proxy Statement to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2022, and is incorporated herein by reference.

Item 11. *Executive Compensation*

The information required by this Item is included in the Proxy Statement to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2022, and is incorporated herein by reference.

Item 12. *Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters*

The information required by this Item is included in the Proxy Statement to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2022, and is incorporated herein by reference.

Item 13. *Certain Relationships and Related Transactions, and Director Independence*

The information required by this Item is included in the Proxy Statement to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2022, and is incorporated herein by reference.

Item 14. *Principal Accounting Fees and Services*

The information required by this Item is included in the Proxy Statement to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2022, and is incorporated herein by reference.

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	Form	Incorporated by Reference		
			Date	Number	Filed Herewith
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	
4.5	Form of certificate representing the 1.5% Convertible Senior Subordinated Notes due 2026.	8-K	4/17/2020	4.1	
4.6	Notice of Successor Trustee to Indenture dated February 7, 2022	10-Q	5/5/2022	4.5	
10.1†	Distribution Agreement, effective December 26, 2012, by and between Orox Pharmaceuticals B.V. and Coherus BioSciences, Inc.	S-1	9/25/2014	10.3	
10.2†	Commercial License Agreement, effective June 25, 2012, by and between Selexis SA and Coherus BioSciences, Inc.	S-1	9/25/2014	10.6	
10.3(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)	
10.3(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)	
10.4(a)#	BioGenerics, Inc. 2010 Equity Incentive Plan, as amended.	S-1	9/25/2014	10.10(a)	
10.4(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)	
10.5(a)#	Coherus BioSciences, Inc. 2014 Equity Incentive Award Plan.	S-1/A	10/24/2014	10.11	
10.5(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)	
10.5(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)	
10.5(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)	
10.6#	Coherus BioSciences, Inc. 2014 Employee Stock Purchase Plan.	S-1/A	10/24/2014	10.12	
10.7#	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	

[Table of Contents](#)

Exhibit Number	Exhibit Description	Form	Incorporated by Reference		
			Date	Number	Filed Herewith
10.8†	Master Services Agreement, effective January 23, 2012, by and between Medpace, Inc. and BioGenerics, Inc.	S-1	9/25/2014	10.15	
10.9	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	
10.10	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	
10.11(a)#	Coherus BioSciences, Inc. 2016 Employment Commencement Incentive Plan.	10-Q	8/9/2016	10.1(a)	
10.11(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)	
10.11(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)	
10.11(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)	
10.12	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	
10.13	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	
10.14†	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	
10.15	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	
10.16	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	
10.17††	License Agreement, dated November 4, 2019, by and between Coherus BioSciences, Inc. and Bioeq IP AG	10-K	2/27/2020	10.29	
10.18††	Form of Confirmation for Base Capped Call Transactions under the Indenture.	8-K	4/17/2020	10.1	
10.19	Exclusive License and Commercialization Agreement, dated February 1, 2021, by and between Coherus Biosciences, Inc. and Shanghai Junshi Biosciences, Co. Ltd.	10-Q	5/6/2021	10.1	
10.20	Stock Purchase Agreement, dated February 1, 2021, by and between the Coherus Biosciences, Inc. and Shanghai Junshi Biosciences, Co. Ltd.	10-Q	5/6/2021	10.2	
10.21††	Loan Agreement dated as of January 5, 2022 among Coherus BioSciences, Inc., the Guarantors, the Collateral Agent and the Lenders party thereto.	8-K	1/7/2022	10.1	
10.22††	Letter Agreement, dated January 9, 2022, between Coherus BioSciences, Inc. and Shanghai Junshi Biosciences, Co., Ltd.	10-K	2/23/2022	10.32	

[Table of Contents](#)

Exhibit Number	Exhibit Description	Form	Incorporated by Reference		
			Date	Number	Filed Herewith
10.23††	Letter Agreement, dated February 9, 2022, between Coherus BioSciences, Inc. and Shanghai Junshi Biosciences, Co., Ltd.	10-Q	5/5/2022	10.1	
10.24††	First Amendment to Loan Agreement dated as of April 7, 2022, among Coherus BioSciences, Inc., the Collateral Agent and the Lenders party thereto.	10-Q	8/4/2022	10.1	
10.25††	License Agreement, dated June 22, 2022, among Coherus BioSciences, Inc., Bioeq AG and Genentech Inc.				X
23.1	Consent of Independent Registered Public Accounting Firm.				X
24.1	Power of Attorney (included in the signature page to this Form 10-K).				X
31.1	Certification of Principal Executive Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.				X
31.2	Certification of Principal Financial Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.				X
32.1	Certification of Principal Executive Officer and Principal Financial Officer Required Under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. §1350.				X
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.				X
101.SCH	Inline XBRL Taxonomy Extension Schema Document				X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document				X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document				X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document				X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document				X
104	Cover page Interactive Data File (formatted in Inline XBRL and contained in Exhibit 101)				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: March 6, 2023

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 McDavid Stilwell, his or her 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 attorneys-in-fact, or their substitute, may do or cause to be done by virtue thereof.

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

<u>/s/ Dennis M. Lanfear</u> Dennis M. Lanfear	Chairman, President and Chief Executive Officer <i>(Principal Executive Officer)</i>	March 6, 2023
<u>/s/ McDavid Stilwell</u> McDavid Stilwell	Chief Financial Officer <i>(Principal Financial Officer)</i>	March 6, 2023
<u>/s/ Bryan McMichael</u> Bryan McMichael	Senior Vice President, Accounting and Corporate Controller <i>(Principal Accounting Officer)</i>	March 6, 2023
<u>/s/ Lee N. Newcomer</u> Lee N. Newcomer	Director	March 6, 2023
<u>/s/ Charles Newton</u> Charles Newton	Director	March 6, 2023
<u>/s/ Jill O'Donnell-Tormey</u> Jill O'Donnell-Tormey	Director	March 6, 2023
<u>/s/ Ali J. Satvat</u> Ali J. Satvat	Director	March 6, 2023
<u>/s/ Mark D. Stolper</u> Mark D. Stolper	Director	March 6, 2023
<u>/s/ Kimberly J. Tzoumakas</u> Kimberly J. Tzoumakas	Director	March 6, 2023
<u>/s/ Mats Wahlström</u> Mats Wahlström	Director	March 6, 2023

[***] Certain information in this exhibit has been omitted because it is permitted to be omitted by applicable regulatory guidance.

EXECUTION COPY

LICENSE AGREEMENT

This License Agreement (the “**License Agreement**”) is made and entered into this 22nd day of June, 2022 (the “**Effective Date**”), by and between Genentech, Inc., a corporation organized under the laws of Delaware (“**Genentech**”), Coherus BioSciences, Inc., a corporation organized under the laws of Delaware (“**Coherus**”), and Bioeq AG, a Swiss company (“**Bioeq**”). Genentech, Coherus and Bioeq are sometimes referred to herein individually as a “**Party**,” and collectively, the “**Parties**”.

RECITALS

A. WHEREAS, the FDA is reviewing an application for licensure filed by Bioeq pursuant to 42 U.S.C. § 262(k) for the proposed biosimilar ranibizumab product CHS-201 (also known as FYB201), which Coherus intends to Market (as defined below) in the Licensed Territory (as defined below);

B. WHEREAS, Genentech is the reference product sponsor for Lucentis[®] (ranibizumab);

C. WHEREAS, pursuant to 42 U.S.C. § 262(l)(3), Genentech provided Bioeq with a list identifying certain patents and indicated its willingness to license those patents to Bioeq and its collaboration partners;

D. WHEREAS, on [***], Genentech and Bioeq entered into a Tolling Agreement ([***) in order to suspend certain deadlines arising under the Biologics Price Competition and Innovation Act (“BPCIA”) to give the Parties time to discuss licensing terms;

E. WHEREAS, on [***], Bioeq informed Genentech that Bioeq transferred all rights, responsibilities, and obligations associated with BLA No. 761165 to Coherus;

F. WHEREAS, on [***], Genentech and Coherus entered into a Tolling Agreement ([***) in order to renew and extend the Tolling Period;

G. WHEREAS, the Parties have agreed to enter into this License Agreement to set forth the terms and conditions under which Genentech grants Coherus, Bioeq, and their Affiliates a non-exclusive license to the Licensed Patents (as defined below);

NOW THEREFORE, in consideration of the mutual covenants and agreements set forth herein, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

SECTION I DEFINITIONS

All capitalized terms used, but not otherwise defined in this License Agreement, shall have the meanings set forth in the Settlement Agreement. As used herein, the following capitalized terms shall have the meanings ascribed to them below.

1.1 “Accounting Standards” shall mean GAAP or IFRS, in each case, as generally and consistently applied throughout the applicable Party’s organization. Each Party shall promptly notify the other in the event that it changes the Accounting Standards pursuant to which its records are maintained.

1.2 “Affiliate” means, with respect to a given Party, any person or legal entity directly or indirectly controlling, controlled by or under common control with such Party, where control shall mean the direct or indirect ownership of more than fifty percent (50%), and in the case of Bioeq, fifty percent (50%) or more, of the outstanding voting securities of an entity or such other relationship as results in the ability to have control over the management, assets, business and affairs of an entity. Notwithstanding the foregoing, for purposes of this License Agreement, [***] shall not be considered Affiliates of Genentech, unless and until Genentech elects to include one or more of such entities as an Affiliate of Genentech, by providing written notice to Coherus of such election.

1.3 “BLA” means Biologics License Application Number 761165 for the proposed biosimilar ranibizumab product CHS-201 (also known as FYB201) filed with the U.S. Food and Drug Administration (“FDA”) pursuant to 42 U.S.C. § 262 (as may be amended, replaced, or supplemented).

1.4 “Business Day” means a day other than (a) Saturday, (b) Sunday, or (c) a bank or other public holiday in the United States.

1.5 “Calendar Quarter” means a period of three (3) consecutive months ending on the last day of March, June, September, or December, respectively; provided that: (a) the first Calendar Quarter during the Royalty Term will begin on the Launch Date and end on the last day of the Calendar Quarter within which the Launch Date falls; and (b) the last Calendar Quarter shall end on the last day of the Royalty Term.

1.6 “Control” shall mean, with respect to any patent or patent application, possession by a person or entity of the ability to grant a license or a sublicense to such patent on the terms herein without violating the terms of any agreement or other arrangement with, necessitating the consent of, or incurring any royalty or other financial obligation to, any Third Party (other than royalty or other financial obligations to employees of such person or entity or any Affiliate thereof).

1.7 “Cover” means that with respect to a claim in a patent or patent application (if such patent application with such claim were to issue), in the absence of ownership or a license, the manufacture, use, offer for sale, sale or importation of Licensed Product would infringe such claim in the applicable country where the activity occurs.

1.8 “FDA” means the U.S. Food and Drug Administration (and any successor organization or agency thereto).

1.9 “Launch Date” shall mean [***], unless adjusted pursuant to Section 2.2 of this License Agreement.

1.10 “Licensed Patents” shall mean the U.S. Patents listed on Schedule 1, including any extensions, continuations, continuations-in-part, divisionals, reissues, reexaminations or supplementary protection certificates thereof, in each case whether granted or allowed before, on or after the Effective Date.

1.11 “Licensed Product” shall mean any product containing ranibizumab as the sole active ingredient that is the subject of the BLA and the pharmaceutical formulation thereof existing as of the Effective Date, that Coherus intends to Market in the Licensed Territory.

1.12 “Licensed Territory” shall mean the United States.

1.13 “Manufacture” shall mean to make or have made a product and “Manufacturing” shall have a corresponding meaning.

1.14 “Market” shall mean to sell, have sold, offer to sell or have offered to sell a product or to use, have used, commercially launch, have commercially launched, distribute, have distributed, import, have imported, export or have exported such product for such purposes, excepting those actions which are exempt from, and are not legally considered to be acts of, patent infringement, and “Marketing” shall have a corresponding meaning.

1.15 “Net Sales” means, with respect to the Licensed Product, the net sales recorded (as determined in accordance with Accounting Standards) by Coherus for any Licensed Product sold to Third Parties. The deductions booked on an accrual basis by Coherus under the current Accounting Standards to calculate the recorded Net Sales from gross sales include, but are not limited to, the following which may be updated from time to time, to the extent actually allowed or specifically allocated to the Licensed Product: [***].

With respect to the calculation of Net Sales: (i) Net Sales only include the value charged or invoiced on the arm’s length sale to a Third Party and sales between or among Coherus and its Affiliates will be disregarded for purposes of calculating Net Sales; and (ii) if the Licensed Product is delivered to the Third Party before being invoiced (or is not invoiced), Net Sales will be calculated at the time all the revenue recognition criteria under the current Accounting Standards are met.

1.16 “Royalty Term” shall mean the period of time starting with the Launch Date and ending on [***].

1.17 “Third Party” shall mean any person or entity other than a Party or its Affiliates.

1.18 “United States” shall mean every state, commonwealth, territory, and possession of the United States of America.

1.19 “Valid Claim” shall mean a claim of an issued and unexpired patent, which claim has not been revoked or held unenforceable, unpatentable or invalid by a decision of a court or other governmental agency of competent jurisdiction from which no appeal can be taken and that has not been irrevocably abandoned, disclaimed, denied or admitted to be invalid or unenforceable through reissue, re-examination or disclaimer or otherwise.

SECTION II GRANT OF LICENSE

2.1 License. Subject to the terms and conditions of this License Agreement, Genentech hereby grants to Coherus, Bioeq, and their Affiliates a non-exclusive, royalty-bearing, non- sublicensable, non-transferrable (except as permitted below) license, under the Licensed Patents, to: (i) starting from the Launch Date, Market Licensed Product in the Licensed Territory and (ii) conduct the activities permitted in Section 2.3 as of the applicable dates set forth in Section 2.3 of this License Agreement.

2.2 Adjustment of Launch Date.

(a) Genentech accepts Coherus’s representation that its intended launch date of [***] will not result in any infringement of Genentech’s supplemental protection certificates (“SPCs”) for ranibizumab in countries outside the Licensed Territory by Bioeq or any other entity collaborating with Coherus with respect to the Manufacture of Licensed Product. If Coherus wishes to adjust the Launch Date to a date earlier than [***], Coherus shall provide Genentech with (1) at least [***] prior notice of its anticipated launch date and (2) evidence sufficient to demonstrate that the adjusted Launch Date will not result in any infringement of Genentech’s SPCs, including sworn statements from Bioeq and any other entity collaborating with Coherus identifying: (i) [***], (ii) [***] and (iii) [***] for any Licensed Product that Coherus intends to Market prior to [***]. Within [***] of receiving such notice, Genentech agrees to begin good faith negotiations on an amendment to this License Agreement that adjusts the Launch Date and [***].

(b) If Coherus wishes to adjust the Launch Date to a date later than [***], Coherus shall provide Genentech with written notice of its anticipated launch date, which shall be deemed the adjusted Launch Date upon Genentech’s acknowledgement of such notice.

2.3 Pre-Entry Activities.

(a) **Manufacturing.** To the extent that such Manufacture does not infringe Genentech's SPCs for ranibizumab in any countries outside the Licensed Territory, beginning [***] prior to the Launch Date, Coherus, Bioeq, and their Affiliates may Manufacture (or have Manufactured) Licensed Product for sale in the Licensed Territory on or after the Launch Date. For the avoidance of doubt, unfinished drug substance or source material for Licensed Products may not be imported to or stored within any country in which Genentech has an unexpired SPC. Nothing in this License Agreement shall restrict Coherus, Bioeq, and their Affiliates from Manufacturing Licensed Product for sale in the Licensed Territory in any country in which no Valid Claim Covers Manufacture of Licensed Product or from transporting unfinished drug substance or source material for Licensed Products between such countries.

(b) **Stockpiling.** Beginning [***] prior to the Launch Date, Coherus, Bioeq, and their Affiliates may stockpile finished, packaged and labeled Licensed Product, for sale in the Licensed Territory on or after the Launch Date.

(c) **Marketing.** Beginning [***] prior to the Launch Date, Coherus may make non-binding offers for sale of Licensed Product in the Licensed Territory to be available on or after the Launch Date; however, Coherus is not permitted to enter into binding contracts to sell Licensed Product in the Licensed Territory prior to the Launch Date. For the avoidance of doubt, nothing in this subsection (c) shall restrict Coherus from any actions which are exempt from, and are not legally considered to be acts of, patent infringement.

(d) **Remedies.** Should Coherus engage in any Manufacture or Marketing of any Licensed Product in the Licensed Territory, or use any Licensed Product in the Licensed Territory, except in accordance with this License Agreement, Genentech may seek entry of a temporary restraining order, preliminary injunction or permanent injunction to prevent such Manufacture, Marketing or use. Coherus agrees that any uncured breach of Section 2.3 would result in irreparable injury to Genentech for which there would be no adequate remedy at law.

2.4 No Other License. Nothing in this License Agreement shall be construed as granting Coherus any license or other rights under any other patents or intellectual property, whether by implication or estoppel. For the avoidance of doubt, nothing in this License Agreement grants Coherus any license or other rights to (A) Manufacture or Market any product other than the Licensed Products, or any active ingredient other than ranibizumab, or any combination of ranibizumab and any other active ingredient or (B) directly or indirectly use or refer to the trademarks or trademark-type rights of Genentech or any of its Affiliates.

2.5 No Other Obligations. Genentech shall have no obligation whatsoever to deliver any technology, improvements thereto, or any documents to Coherus, except such documents as may be reasonably required to fulfill Genentech's obligations or effectuate Coherus's rights under this License Agreement.

2.6 Prosecution, Maintenance and Enforcement Rights. Genentech shall have the sole right, but not the obligation, to prosecute and maintain the Licensed Patents and to enforce the Licensed Patents. All damages or other

compensation of any kind recovered in any such enforcement or from any settlement or compromise thereof will be for the sole benefit of Genentech and/or its Affiliates.

SECTION III REPRESENTATIONS; COVENANTS; DISCLAIMER

3.1 General Representations of the Parties. Each Party represents and warrants to the other Party, as of the Effective Date, that:

(a) such Party is duly organized, validly existing and in good standing under the Laws of the jurisdiction of its incorporation and has full corporate power and authority to enter into this License Agreement and to carry out the provisions hereof;

(b) such Party has taken all necessary action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder;

(c) this License Agreement was negotiated on an arms' length basis, has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, binding obligation, enforceable against it in accordance with the terms hereof;

(d) such Party fully understands all the terms and conditions of this License Agreement and the meaning of each provision hereof, such Party has obtained the advice of legal counsel prior to such Party's execution and delivery of this License Agreement, and such Party's execution and delivery of this Agreement, including releases set forth in Section 7, are made voluntarily, and with the express intention of extinguishing all released obligations;

(e) the execution, delivery and performance of this Agreement by such Party does not conflict with any agreement or any provision thereof, or any instrument or understanding, oral or written, to which it is a party or by which it is bound, nor violate any law or regulation of any court, governmental body or administrative or other agency having jurisdiction over such Party; and

(f) no government authorization, consent, approval, license, exemption or filing or registration with any court or governmental department, commission, board, bureau, agency or instrumentality, domestic or foreign, under any applicable Laws currently in effect, is or will be necessary for, or in connection with, the transaction contemplated by this Agreement or any other agreement or instrument executed in connection herewith, or for the performance by it of its obligations under this Agreement.

3.2 Additional Representations by Genentech.

(a) **Right to License.** Genentech represents and warrants that, as of the Effective Date, it has the right and authority to grant the licenses, covenants and other rights granted under the Licensed Patents pursuant to this License Agreement without violating the terms of any agreement or other arrangement with, or necessitating the consent of, or incurring any royalty or other financial obligation

to, any Third Party (other than royalty or other financial obligations to employees of Genentech or any of its Affiliates).

3.3 Additional Representations by Coherus and Bioeq.

(a) **No Infringement by Coherus and Bioeq.** Coherus and Bioeq represent and warrant that, as of the Effective Date, there has been no infringement of Genentech's SPCs for ranibizumab in any countries outside the Licensed Territory by any entity collaborating with Coherus with respect to the Manufacture of Licensed Product for sale in the Licensed Territory and that the intended sale of Licensed Product on or after the Launch Date will not result in any infringement of Genentech's SPCs by any entity collaborating with Coherus with respect to the Manufacture of Licensed Product.

3.4 Covenants by Genentech.

(a) Genentech hereby covenants not to initiate any proceeding under the BPCIA relating to the BLA against Coherus, Bioeq, and their Affiliates;

(b) Genentech hereby covenants not to initiate any proceeding against Coherus, Bioeq, and their Affiliates, asserting infringement of the Licensed Patents based upon any making, having made, use, sale, offer for sale, import or other disposal of any Licensed Product authorized by this License Agreement; and

(c) Absent reasonable good faith safety or efficacy concerns, or unless requested by FDA or any other governmental authority, Genentech covenants that it shall not initiate any litigation or file any citizen petitions to interfere with or obstruct Coherus's efforts in the Licensed Territory to (i) obtain regulatory approval in connection with the Licensed Product or (ii) launch the Licensed Product as of the date and under the terms provided by this License Agreement; provided, however, that this Section 3.4(c)(ii) shall not limit Genentech from asserting any claim with respect to the Marketing of any Licensed Product after the Launch Date, including without limitation claims of unfair competition, false advertising and tortious interference with contracts, but excluding claims for infringement of the Licensed Patents based on activities authorized by this License Agreement.

3.5 Covenants by Coherus and Bioeq.

(a) Coherus and Bioeq hereby covenant they will not, and that they will ensure that their collaboration partners do not infringe any of Genentech's SPCs for ranibizumab in connection with the Manufacture of Licensed Product for sale in the Licensed Territory;

(b) Coherus and Bioeq hereby covenant that they will not, and that they will ensure that their collaboration partners do not (i) Market Licensed Product in the Licensed Territory before the Launch Date; or (b) perform any of the Pre-Entry Activities before the applicable dates set forth in Section 2.3.

(c) Coherus will indemnify, hold harmless and defend Genentech and its directors, officers, employees, agents, consultants and representatives, from and against any and all liabilities, damages, losses, costs and expenses, including the

reasonable fees of attorneys and other professional advisors, to the extent arising out of or resulting from any Third Party suits, claims, actions, proceedings, hearings, investigations, judgments, orders, decrees, stipulations, or injunctions or demands arising from or relating to any acts or omissions in connection with the development, Manufacture, Marketing, commercialization or other exploitation of the Licensed Product by or on behalf of Coherus, any of its Affiliates, or its collaboration partners in the Licensed Territory, including any product liability, personal injury, property damage or other damage, and infringement of any patent or other intellectual property right of any Third Party.

3.6 DISCLAIMER. THE GRANT OF THE RIGHTS AND LICENSES TO THE LICENSED PATENTS HEREUNDER IS MADE “AS-IS” AND “WHERE-IS.” SUBJECT TO SECTIONS 1.10, 3.1 AND 3.2 OF THIS LICENSE AGREEMENT, GENENTECH HEREBY DISCLAIMS ALL REPRESENTATIONS OR WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT OF THIRD PARTY PATENTS OR ANY OTHER MATTER WITH RESPECT TO THE LICENSED PATENTS, WHETHER USED ALONE OR COMBINED WITH OTHER PRODUCTS OR SERVICES.

SECTION IV FINANCIAL TERMS

4.1 Royalties. In consideration for the rights and licenses granted in this License Agreement, Coherus agrees to pay Genentech a royalty of [***] of Net Sales during the Royalty Term. Royalty payments shall be made within [***] after the end of each Calendar Quarter.

4.2 Royalty Reports. During the Royalty Term, Coherus shall provide Genentech a written report within [***] after the end of each Calendar Quarter showing the Net Sales of Licensed Product sold in the Licensed Territory and the royalties payable under this License Agreement.

4.3 Audit. Coherus agrees to keep full, clear, and accurate records, maintained in accordance with Accounting Standards, for a minimum period of [***] after the relevant royalty payment is owed pursuant to this License Agreement, setting forth the sales and other disposition of Licensed Product sold or otherwise disposed of in or to the Licensed Territory, in sufficient detail to enable royalties payable to Genentech to be determined. Coherus further agrees, upon not less than [***] prior written notice, to permit such records relating to the sale of Licensed Product in the Licensed Territory to be examined for the purpose of verifying the royalties payable under this License Agreement. Any such examination will be conducted by an independent accounting firm of national standing selected by Genentech. Any such examination will be performed during regular business hours, with appropriate confidentiality provisions, and for the sole purpose of verifying the accuracy and completeness of the royalty calculations provided under this Agreement. The independent accounting firm will only share the results of its audit, not the underlying records, with Genentech. The independent accounting firm will provide a courtesy copy of its audit report and the basis for any determination to Coherus at the same time such report is provided to Genentech, and its calculation shall be final and binding on the Parties. Any such audit will be at

Genentech's cost; however, if the results of the audit reveal an underpayment of royalties by [***] or more in any Calendar Quarter, (i) Coherus will promptly remit to Genentech the amount of such underpayment and (ii) the reasonable fees and expenses for such audit will be paid by Coherus. If the results of the audit reveal an overpayment of royalties by [***] or more in any Calendar Quarter, such overpayment will be (i) applied to any Calendar Quarter with an underpayment and/or (ii) to the Royalty payment for the next Calendar Quarter.

4.4 Method of Payment. All royalty payments due from Coherus to Genentech under this License Agreement shall be paid in U.S. Dollars by wire transfer to a bank in the United States designated in writing by Genentech.

4.5 Late Payments. Any undisputed amount owed by Coherus to Genentech under this Agreement that is not paid on or before the date such payment is due will bear interest at a rate per annum equal to the lesser of: (a) the greater of (i) the prime or equivalent rate per annum quoted by *The Wall Street Journal* on the first Business Day after such payment is due [***], or (ii) [***]; and (b) the highest rate permitted by applicable Law; in either case as calculated on the number of days such payments are paid after such payments are due and compounded monthly. No payments will become due and payable and neither Party will be obligated to reimburse the other Party for any costs incurred by the other Party under or in connection with this License Agreement unless and until this License Agreement becomes effective.

SECTION V TERM

5.1 Term. The term of this License Agreement shall commence on the Effective Date and continue until the expiration of all Licensed Patents or until there are no longer Valid Claims in the Licensed Patents, including any and all extensions thereto, unless earlier terminated in accordance with Section 5.2.

5.2 Termination for Breach. If either Party (the "**Non-Breaching Party**") believes that the other Party (the "**Breaching Party**") has materially breached one or more of its material obligations, then the Non-Breaching Party may deliver notice of such material breach to the Breaching Party (a "**Default Notice**"). If the Breaching Party fails to cure such breach within thirty (30) days after receipt of the Default Notice, the Non-Breaching may terminate this License Agreement immediately upon written notice to the Breaching Party. Nothing in this Section 5.2 shall limit any Party's ability to seek damages or other relief for any breach of this License Agreement.

5.3 Termination for Patent Challenge. In the event that Coherus, Bioeq or their Affiliate(s) with respect to the Licensed Product for sale in the Licensed Territory (A) initiates or participates in any challenge to the validity of any Licensed Patent or (B) assists any other person or entity in bringing or prosecuting any challenge to the validity of any Licensed Patent (including through providing information or funding to a Third Party with respect to such patent challenge), then Genentech may give written notice that it will terminate the licenses granted to Coherus, Bioeq, and their Affiliates to such Licensed Patent(s) or terminate this

License Agreement in its entirety within thirty (30) days following such notice and, unless Coherus, Bioeq, or their Affiliate(s) withdraws all such challenge(s) or stops assisting in any such challenge(s) within the thirty (30) day period, such licenses or this License Agreement in its entirety (subject to Section 5.5) will so terminate.

5.4 Termination for Insolvency. In the event that Coherus makes an assignment for the benefit of creditors, appoints or suffers appointment of a receiver or trustee over all or substantially all of its property, files a petition under any bankruptcy or insolvency act or has any such petition filed against it that is not discharged within sixty (60) days after the filing thereof, Genentech may terminate this License Agreement in its entirety (subject to Section 5.5) by providing written notice, in which case, this License Agreement will terminate on the date on which Coherus receives such written notice.

5.5 Accrued Obligations; Survival. Expiration or termination of this License Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination. Any expiration or early termination of this License Agreement shall be without prejudice to the rights of any Party against any other Party accrued or accruing under this License Agreement prior to such expiration or termination. The provisions of Sections 1 (solely for purposes of interpreting other surviving provisions), 2.4, 2.5, 2.6, 3.6, 4 (solely for purposes of payment obligations accruing prior to expiration or termination), 5.5, 6, and 8 of this License Agreement shall survive any expiration or termination of this License Agreement. For the sake of clarity, all other sections of this License Agreement shall terminate upon expiration or termination of this License Agreement.

SECTION VI CONFIDENTIALITY

6.1 Confidentiality.

(a) Obligations. The existence and terms of this License Agreement shall constitute the Parties' Confidential Information and may not be disclosed by the Parties to any other person or entity except as set forth below. Notwithstanding the foregoing:

(i) Coherus may disclose the terms of this License Agreement to the FDA, as (and solely to the extent) required for obtaining and maintaining licensure of the BLA and launching the products that are the subject of the BLA when and as provided by this License Agreement;

(ii) The Parties may disclose the terms of this License Agreement to its respective Affiliates, and each of its or their insurers, lenders, attorneys, auditors, accountants, and prospective permitted acquirers or assignees who need to know such information, subject to such recipients being bound by confidentiality obligations substantially similar to those set forth in this Section 6.1.1;

(iii) The Parties may disclose the terms of this License Agreement to its employees, advisors, consultants, agents, representatives, licensors and

licensees who need to know such information in order for such Party to exercise its rights or perform its obligations under this License Agreement, subject to such recipients being bound by confidentiality obligations materially similar to those set forth in this Section 6.1.1;

(iv) The Parties are permitted to publicly disclose the fact that Coherus will be licensed to Market the Licensed Products in the Licensed Territory as of the Launch Date pursuant to this License Agreement but no other details regarding this License Agreement except in accordance with this Section 6.1, provided that neither Party will issue (or authorize one of its collaboration partners to issue) any press release announcing the existence of the License Agreement or the Launch Date without the prior written consent of the other Party; and

(v) The Parties may make such other disclosures as mutually agreed by the Parties in writing.

(b) Required Disclosures. If a Party will be publicly disclosing information relating to this License Agreement because it is required to do so to comply with statutory, regulatory or legal process requirements, including the reporting requirements under SEC rules and regulations, the Securities Exchange Act of 1934, as amended, or the rules of any national securities exchange on which it is listed, such Party intending to make such disclosure shall give the other Party at least [***] prior notice in writing of the text of the intended disclosure, unless such statutory, regulatory or legal process requirements would require earlier disclosure, in which event, the notice shall be provided as early as practicable. Each disclosing Party agrees to use commercially reasonable efforts to have redacted such provisions of this License Agreement as the Parties may agree from any copies filed pursuant to such statutory, regulatory or legal process requirements. If any Party determines that it will be required to file a copy of this License Agreement as provided above, promptly after the giving of notice by such Party as contemplated above, the Parties will use commercially reasonable efforts to agree on those provisions of this Agreement that the Parties will seek to have redacted. If the Parties are unable to agree on the provisions of this Agreement that the Parties will seek to have redacted, the disclosure shall be limited to the minimum required, as determined by the Party required to make such disclosure in consultation with its legal counsel.

(c) Agency Disclosure.

(i) Within [***] following the Effective Date, and pursuant to current statutory law (including the applicable provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, as amended by the Patients Right to Know Drug Prices Act), the Parties shall file or cause this License Agreement to be filed with the U.S. Federal Trade Commission Bureau of Competition (“FTC”) and the Assistant Attorney General for the Antitrust Division of the U.S. Department of Justice (“DOJ,” and together with the FTC, the “Agencies”), and in each case, shall request that this License Agreement be treated as confidential to the fullest extent permitted under the law. The Parties agree that if after submitting the License Agreement, the FTC or DOJ raise objections as to any of the provisions of this License Agreement, the Parties will attempt in good faith to modify this License Agreement to overcome any such objections, and that no Party

shall be obliged to accept any modifications that frustrate the purpose of this License Agreement or materially impair its value to such Party. The Parties agree that no Party shall be prejudiced in any of its assertions or defenses if the License Agreement is rendered null and void as a result of objections by the FTC or DOJ. Each Party reserves the right to communicate with the Agencies regarding such filings as it believes appropriate. Each Party shall keep the other Parties reasonably informed of such communications. Each Party shall bear its own costs and expenses in connection with the foregoing.

(ii) In addition to the agency disclosure provided in 6.1(c)(i), a Party may disclose this License Agreement, or any provisions hereof, in order to comply with a request by an anti-trust/competition law authority or as otherwise required by law; provided, that the Party intending to make such a disclosure shall give the other Party at least [***] prior written notice of the intended disclosure unless such statutory, regulatory or legal process requirements would require earlier disclosure, in which event, the notice shall be provided as early as practicable. In the event of such disclosure, the disclosing Party shall request that this Agreement be treated as confidential to the fullest extent permitted under applicable laws.

SECTION VII RELEASES

7.1 Releases.

(a) Released Claims.

(i) Genentech. Genentech hereby irrevocably releases, acquits and forever discharges Coherus, Bioeq, their Affiliates, and their respective successors, assigns, directors, officers employees, customers, suppliers, and distributors from any and all past and present (as of the Effective Date) disputes, potential disputes, actions, causes of action, suits, arbitrations, charges, complaints, legal responsibilities, damages, judgments, claims, injuries, liabilities, penalties, fines, losses, bonds, bills, expenses, and demands whatsoever, whether at law or in equity, whether known or unknown, suspected or unsuspected, contingent or matured, and whether accrued or unaccrued, including, without limitation, claims for compensatory, equitable or injunctive relief, general, specific or punitive damages, costs, losses, expenses and compensation, arising out of or relating to any Licensed Product (“**Genentech Released Claims**”). This release and this discharge covers all such Genentech Released Claims of every kind whatsoever, existing as of the Effective Date, matured or unmatured, direct or indirect, absolute or contingent, and whether or not contemplated or asserted by Genentech relating in any reasonable way to the aforementioned Genentech Released Claims, from the beginning of time through and including the Effective Date.

(ii) Coherus. Coherus hereby irrevocably releases, acquits and forever discharges Genentech and its respective successors, assigns, directors, officers employees, customers, suppliers, and distributors from any and all past and present (as of the Effective Date) disputes, potential disputes, actions, causes of action, suits, arbitrations, charges, complaints, legal responsibilities, damages, judgments, claims, injuries, liabilities, penalties, fines, losses, bonds, bills, expenses, and demands whatsoever, whether at law or in equity, whether known

or unknown, suspected or unsuspected, contingent or matured, and whether accrued or unaccrued, including, without limitation, claims for compensatory, equitable or injunctive relief, general, specific or punitive damages, costs, losses, expenses and compensation, arising out of or relating to any Licensed Product (“**Coherus Released Claims**”). This release and this discharge covers all such Coherus Released Claims of every kind whatsoever, existing as of the Effective Date, matured or unmatured, direct or indirect, absolute or contingent, and whether or not contemplated or asserted by Coherus relating in any reasonable way to the aforementioned Coherus Released Claims, from the beginning of time through and including the Effective Date.

(iii) Bioeq. Bioeq hereby irrevocably releases, acquits and forever discharges Genentech and its respective successors, assigns, directors, officers employees, customers, suppliers, and distributors from any and all past and present (as of the Effective Date) disputes, potential disputes, actions, causes of action, suits, arbitrations, charges, complaints, legal responsibilities, damages, judgments, claims, injuries, liabilities, penalties, fines, losses, bonds, bills, expenses, and demands whatsoever, whether at law or in equity, whether known or unknown, suspected or unsuspected, contingent or matured, and whether accrued or unaccrued, including, without limitation, claims for compensatory, equitable or injunctive relief, general, specific or punitive damages, costs, losses, expenses and compensation, arising out of or relating to any Licensed Product (“**Bioeq Released Claims**”). This release and this discharge covers all such Bioeq Released Claims of every kind whatsoever, existing as of the Effective Date, matured or unmatured, direct or indirect, absolute or contingent, and whether or not contemplated or asserted by Bioeq relating in any reasonable way to the aforementioned Bioeq Released Claims, from the beginning of time through and including the Effective Date.

EACH PARTY AGREES THAT THE FOREGOING RELEASES SHALL APPLY TO ALL UNKNOWN OR UNANTICIPATED RESULTS OF THE PENDING CLAIMS DESCRIBED ABOVE, AS WELL AS THOSE KNOWN OR ANTICIPATED.

(b) Scope of Release. Notwithstanding anything to the contrary in this Section 7, nothing in this License Agreement is intended to prevent or preclude any Party from initiating or in any way participating in future proceedings that bear upon or relate to: (a) the Parties’ respective obligations or rights under this License Agreement, including (i) post-Effective Date treatment or resolution of issues related to this License Agreement or (ii) the enforcement of this License Agreement; or (b) except with respect to activities within the scope of the license granted in Section 2.1 and permitted activities under Section 2.3, any claim that is (i) unrelated to the Licensed Product or (ii) related to activities outside the Licensed Territory.

(c) Known and Unknown Claims. EACH PARTY ACKNOWLEDGES THAT IT MAY HEREAFTER DISCOVER CLAIMS OR FACTS IN ADDITION TO OR DIFFERENT FROM THOSE WHICH IT NOW KNOWS OR BELIEVES TO EXIST WITH RESPECT TO THE APPLICABLE RELEASED CLAIMS AND THE FACTS AND CIRCUMSTANCES EXISTING AT THE TIME OF ENTRY INTO THIS AGREEMENT, WHICH, IF KNOWN OR SUSPECTED AT THE TIME OF EXECUTING THIS AGREEMENT, MAY HAVE MATERIALLY

AFFECTED THIS AGREEMENT. NEVERTHELESS, EACH PARTY HEREBY ACKNOWLEDGES THAT THE RELEASED CLAIMS INCLUDE WAIVERS OF ANY RIGHTS, CLAIMS OR CAUSES OF ACTION THAT MIGHT ARISE AS A RESULT OF SUCH DIFFERENT OR ADDITIONAL CLAIMS OR FACTS. EACH PARTY ACKNOWLEDGES THAT IT UNDERSTANDS THE SIGNIFICANCE AND POTENTIAL CONSEQUENCES OF SUCH A RELEASE OF UNKNOWN UNITED STATES AND OTHER JURISDICTION CLAIMS AND OF SUCH A SPECIFIC WAIVER OF RIGHTS. EACH PARTY INTENDS THAT THE CLAIMS RELEASED BY IT UNDER THIS SECTION 7 BE CONSTRUED AS BROADLY AS POSSIBLE TO THE EXTENT THEY RELATE TO THE PENDING CLAIMS. WITHOUT LIMITING THE FOREGOING, EACH PARTY IS AWARE OF CALIFORNIA CIVIL CODE SECTION 1542, WHICH PROVIDES AS FOLLOWS:

“A general release does not extend to claims that the creditor or releasing party does not know or suspect to exist in his or her favor at the time of executing the release and that, if known by him or her, would have materially affected his or her settlement with the debtor or released party.”

EACH PARTY AGREES TO EXPRESSLY WAIVE ANY RIGHTS IT MAY HAVE UNDER THIS CODE SECTION OR UNDER NATIONAL, MULTINATIONAL, FEDERAL, STATE OR COMMON LAW STATUTES, JUDICIAL DECISIONS OR OTHER LAWS OF A SIMILAR NATURE, AND KNOWINGLY AND VOLUNTARILY WAIVES SUCH UNKNOWN CLAIMS.

SECTION VIII GENERAL PROVISIONS

8.1 Entire Agreement. This License Agreement contains the entire agreement between the Parties pertaining to the subject matter hereof, and supersedes any prior or contemporaneous negotiations, representations, agreements and understandings of the Parties with respect to such subject matter, whether written or oral, except for (a) the Prior CDAs which will continue to govern disclosures thereunder made prior to the Effective Date; (b) the Tolling Agreement between Genentech and Bioeq (as amended); and (c) the Tolling Agreement between Genentech and Coherus (as amended). The Parties acknowledge that they have not relied on any promise, representation or warranty, expressed or implied, not contained in or contemplated by this License Agreement.

8.2 Independent Parties. Each Party agrees that it will not seek to challenge or to have determined invalid, void or unenforceable any provision of this License Agreement. The Parties understand that this License Agreement provides for the relinquishment of legal rights and each has sought the advice of legal counsel, which each Party has encouraged the other to seek. Further, the Parties agree that none of them has reposed such trust or confidence in the other Party so as to create a fiduciary, agency or confidential relationship. Nothing in this License Agreement shall be deemed to create an agency, joint venture or partnership relationship between the Parties.

8.3 Amendment, Consent and Waivers. This License Agreement may be amended only in writing and signed by both Parties. No waiver of the performance of any provision of this License Agreement and no consent to any

default under this License Agreement shall be effective unless the same is in writing and properly executed by or on behalf of the Party against whom such waiver or consent is claimed. Waiver by any Party of any default by the other Party shall not be deemed a waiver of any other default. Failure of a Party to insist on performance of any term or condition of this License Agreement or to exercise any right or privilege hereunder shall not be construed as a continuing or future waiver of such term, condition, right or privilege. No course of dealing or failure of any Party to strictly enforce any term, right or condition of this License Agreement in any instance shall be construed as a general waiver or relinquishment of such term, right or condition.

8.4 Jointly Prepared Agreement. This License Agreement will be deemed to have been drafted jointly by the Parties and therefore no provision shall be construed against any Party on the theory that such Party drafted such provision.

8.5 Governing Law; Jurisdiction. This License Agreement shall be governed, interpreted and construed in accordance with the laws of the State of Delaware, without giving effect to choice of law principles. The Parties agree that the federal district court in the State of Delaware shall have exclusive jurisdiction to deal with any disputes arising out of or in connection with this License Agreement and that, accordingly, any proceedings arising out of or in connection with this License Agreement shall be brought in the United States District Court for the District of Delaware. Notwithstanding the foregoing, if there is any dispute for which the federal district court in the State of Delaware does not have subject matter jurisdiction, the state courts in the State of Delaware shall have jurisdiction. In connection with any dispute arising out of or in connection with this License Agreement, each Party hereby expressly consents and submits to the personal jurisdiction of the federal and state courts in the State of Delaware. The Parties' consent to jurisdiction set forth in this Section 8.5 shall apply irrespective of whether the activities giving rise to the dispute occur within or outside the United States, and the Parties agree to waive any defense relating to *forum non conveniens* with respect to any such dispute. The Parties agree, on behalf of themselves and their Affiliates, to abide, inside and outside of the United States, by any decision of any federal or state court in the State of Delaware with respect to any dispute arising out of or in connection with this License Agreement. Notwithstanding the foregoing, each Party shall have the right to institute judicial proceedings against any Party or anyone acting by, through or under such Party, in any court of competent jurisdiction inside or outside of the United States (a) if such Party is unable to bring such proceedings in any federal or state court in the State of Delaware or (b) in order to enforce any judgment issued by a federal or state court in the State of Delaware.

8.6 Counterparts; Signatures. This License Agreement may be executed simultaneously in any number of counterparts, each of which when shall be taken to be an original, but such counterparts shall together constitute but one and the same document. The Parties agree that electronic signatures (e.g., via DocuSign) will have the same force and effect as handwritten signatures.

8.7 Costs and Expenses. Each Party shall bear its own costs, fees and expenses in any way related to the negotiation, preparation, execution and delivery of this License Agreement and the performance of any obligations and releases contained herein.

8.8 Assignment. This License Agreement shall not be assignable in whole or in part by either of the Parties without the prior written consent of the other Party. Notwithstanding the foregoing:

(i) Coherus may assign this Agreement in its entirety without the prior written consent of Genentech: (i) to an Affiliate or (ii) to a Third Party who acquires all or substantially all of the assets or business of Coherus to which this License Agreement pertains (i.e., Marketing Licensed Product in the Licensed Territory), whether through a merger, consolidation, purchase or other transfer provided that such Affiliate or Third Party, as the case may be, agrees in writing for the benefit of Genentech to assume all of the obligations of Coherus hereunder.

(ii) Bioeq may assign this Agreement in its entirety without the prior written consent of Genentech: (i) to an Affiliate or (ii) to a Third Party who acquires all or substantially all of the assets or business of Bioeq to which this License Agreement pertains (i.e., Manufacturing Licensed Product for sale in the Licensed Territory), whether through a merger, consolidation, purchase or other transfer provided that such Affiliate or Third Party, as the case may be, agrees in writing for the benefit of Genentech to assume all of the obligations of Bioeq hereunder.

(iii) Genentech may assign this Agreement without the prior written consent of Coherus or Bioeq to any Affiliate or to any successor or assignee of the Licensed Patents or all or substantially all of the Lucentis® business generally, provided that in either case such Affiliate or successor, as the case may be, agrees in writing for the benefit of Coherus and Bioeq to assume all of the obligations of Genentech, as appropriate, in this License Agreement. For clarity, Genentech may not assign the Licensed Patents unless the assignee agrees in writing for the benefit of Coherus and Bioeq to assume all of the obligations of Genentech in respect of such Licensed Patents in this License Agreement.

Any purported assignment in violation of this Section 8.8 shall be void. This License Agreement shall be binding upon, and inure to the benefit of, the successors and permitted assigns of the Parties.

8.9 Severability. The Parties hereby agree that if any provision of this License Agreement is declared illegal, invalid or unenforceable by a court having competent jurisdiction, it is mutually agreed that this License Agreement shall endure, except that the provision declared illegal, invalid or unenforceable by order of such court, shall be deemed stricken from this License Agreement; provided, however, that in the event that the terms and conditions of this License Agreement are thereby materially altered, the Parties will, in good faith, renegotiate the terms and conditions of this License Agreement to reasonably replace such illegal, invalid or unenforceable provision to effectuate the intent of the Parties.

8.10 Construction. Headings in this License Agreement are for convenience of reference only and shall not affect their interpretation or construction. As used in this License Agreement, neutral pronouns and any variations thereof shall be deemed to include the feminine and masculine and all

terms used in the singular shall be deemed to include the plural, and vice versa, as the context may require. The words “herein,” “hereof” and “hereunder” and other words of similar import refer to this License Agreement as a whole, as the same may from time to time be amended or supplemented, and not to any particular subdivision contained herein. The word “including” when used herein is not intended to be exclusive, or to limit the generality of the preceding words, and means “including, without limitation”. Except where the context otherwise requires, the term “or” will be interpreted in the inclusive sense commonly associated with the term “and/or” and no inferences or conclusions of any sort shall be drawn from the fact that in some instances in this License Agreement, the word “or” is preceded by “and/” while in other instances it is not. The word “will” has the same meaning as the word “shall”. Where a Party’s consent is required hereunder, except as otherwise specified herein, such Party’s consent may be granted or withheld in such Party’s sole discretion.

8.11 Notices. All notices pursuant to this License Agreement shall be provided, by first class mail or express delivery service, with courtesy copy by email, as follows and shall be deemed effective upon receipt of same:

If to Genentech, to:

Genentech, Inc.
1 DNA Way
South San Francisco, CA 94080 Attn: General Counsel

Courtesy copy by email to: [***]

With a copy (which shall not constitute notice) to:

Paul, Weiss, Rifkind, Wharton & Garrison LLP
1285 Avenue of the Americas
New York, NY 10019-6064
Attn: [***]
Email: [***]

If to Coherus, to:

Coherus BioSciences, Inc.
333 Twin Dolphin Drive, Suite 600 Redwood Shores, CA 94065
Attn: Chief Business and Legal Officer

Courtesy copy by email to: [***]

With a copy (which shall not constitute notice) to:

Jenner & Block LLP
353 N. Clark Street
Chicago, IL 60654-3456
Attn: [***]
Email: [***]

If to Bioeq, to:
Bioeq GmbH
c/o Formycon AG Fraunhoferstr. 15
82152 Martinsried/Planegg Germany
Attn: Manager IP Biologics

Courtesy copy by email to: [***]

With a copy (which shall not constitute notice) to:
Robins Kaplan LLP
800 LaSalle Avenue Suite 2800
Minneapolis, MN 55402
Attn: [***]
Email: [***]

Any such notice shall be deemed to have been received on the date actually received.
Any Party may change its address by giving the other Party written notice, delivered in accordance with this Section 8.11.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties have each caused this License Agreement to be executed by their authorized representatives as of the Effective Date.

GENENTECH, INC.

By: /s/ Edward Harrington

Name: Edward Harrington

Title: Chief Financial Officer

COHERUS BIOSCIENCES, INC.

By: /s/ Christopher Slavinsky

Name: Christopher Slavinsky

Title: Chief Business & Legal Officer

BIOEQ AG

By: /s/ Marcel Schnarwiler

Name: Marcel Schnarwiler

Title: Board Member

By: /s/ Barbara Merz

Name: Barbara Merz

Title: Board Member

SCHEDULE 1

Licensed Patents

[***]

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements:

- (1) Registration Statements (Form S-3 Nos. 333-208625, 333-220590, 333-222698, and 333-268252) of Coherus BioSciences, Inc.,
- (2) Registration Statements (Form S-8 Nos. 333-200593, 333-203356, 333-209936, 333-216679, 333-222700, 333-229480, 333-236068, 333-251876, 333-262134, and 333-269291) 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, and
- (3) Registration Statements (Form S-8 Nos. 333-213077, 333-225616, 333-228274, 333-229479, 333-231329, 333-234601, 333-236065, 333-251877 and 333-262941) pertaining to the 2016 Employment Commencement Incentive Plan of Coherus BioSciences, Inc.;

of our reports dated March 6, 2023, 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) of Coherus BioSciences, Inc. for the year ended December 31, 2022.

/s/ Ernst & Young LLP

San Mateo, California
March 6, 2023

**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: March 6, 2023

/s/ Dennis M. Lanfear

Dennis M. Lanfear
President and Chief Executive Officer
(Principal Executive Officer)

**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, McDavid Stilwell, 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: March 6, 2023

/s/ McDavid Stilwell

McDavid Stilwell
Chief Financial Officer
(Principal Financial Officer)

**CERTIFICATIONS OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officers of Coherus BioSciences, Inc. (the "Registrant") certify that the Registrant's Annual Report on Form 10-K for the year ended December 31, 2022 (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: March 6, 2023

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

Date: March 6, 2023

By: /s/ McDavid Stilwell
Name: McDavid Stilwell
Title: Chief Financial Officer

This certification accompanies the Annual Report on 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.
