

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, 2024

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
(Address of principal executive offices)

94065
(Zip Code)

(650) 649-
3530

(Registrant's telephone number, including area code)

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 checked="" 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 28, 2024 (which was the last business day of the registrant's most recently completed second fiscal quarter) based upon the closing market price of such stock on the Nasdaq Global Market on that date, was approximately \$170.6 million. For purposes of this disclosure, shares of common stock held by each officer and director have been excluded in that such persons may be deemed to be "affiliates" as that term is defined under the Rules and Regulations of the Securities Exchange Act of 1934, as amended. 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, 2025 was 115,896,849.

DOCUMENTS INCORPORATED BY REFERENCE

Part III of this annual report on Form 10-K incorporates by reference certain information from the registrant's definitive proxy statement for the 2025 Annual Meeting of Stockholders, which will be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year ended December 31, 2024.

**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	24
<u>ITEM 1B.</u> Unresolved Staff Comments	71
<u>ITEM 1C.</u> Cybersecurity	71
<u>ITEM 2.</u> Properties	73
<u>ITEM 3.</u> Legal Proceedings	73
<u>ITEM 4.</u> Mine Safety Disclosures	73
<u>PART II</u>	
<u>ITEM 5.</u> Market for Registrant's Common Equity, Related Stockholder Matters, and Issuer Purchases of Equity Securities	73
<u>ITEM 6.</u> [Reserved]	74
<u>ITEM 7.</u> Management's Discussion and Analysis of Financial Condition and Results of Operations	74
<u>ITEM 7A.</u> Quantitative and Qualitative Disclosures About Market Risk	88
<u>ITEM 8.</u> Financial Statements and Supplementary Data	90
<u>ITEM 9.</u> Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	136
<u>ITEM 9A.</u> Controls and Procedures	136
<u>ITEM 9B.</u> Other Information	140
<u>ITEM 9C.</u> Disclosure Regarding Foreign Jurisdictions that Prevent Inspections	140
<u>PART III</u>	
<u>ITEM 10.</u> Directors, Executive Officers and Corporate Governance	140
<u>ITEM 11.</u> Executive Compensation	140
<u>ITEM 12.</u> Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	140
<u>ITEM 13.</u> Certain Relationships and Related Transactions, and Director Independence	140
<u>ITEM 14.</u> Principal Accounting Fees and Services	140
<u>PART IV</u>	
<u>ITEM 15.</u> Exhibits and Financial Statement Schedules	141
<u>ITEM 16.</u> Form 10-K Summary	141
Signatures	146

UDENYCA® and LOQTORZI®, 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](#)

As used in this Annual Report on Form 10-K, unless the context requires otherwise, references to “Coherus,” the “Company,” “we,” “us,” and “our,” and similar references refer to Coherus BioSciences, Inc. and its wholly owned subsidiaries.

FORWARD-LOOKING STATEMENTS

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 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 our product candidates;
- our expectations regarding the satisfaction of the conditions to the closing of the sale of our UDENYCA franchise, expected timing for the closing to occur; expected uses of proceeds received at the closing and our expected post-closing operations;
- 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 about the timing for our additional packaging and labeling CMO to commence commercial supply of UDENYCA;
- 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, projected future cash reserves, 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;
- our expectations about the number of our employees who may transfer to Accord BioPharma, Inc.;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our products and product candidates;
- 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;

[Table of Contents](#)

- *the cost, timing and outcomes of litigation involving our products and product candidates;*
- *our reliance on third-party contract research organizations to conduct clinical trials of our product candidates;*
- *the benefits of the use of our products and product candidates;*
- *our expectations about potential risks, disruptions and losses from future cyberattacks and security incidents;*
- *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 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 the continuation of the war in Ukraine and conflicts in the Middle East 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 immunotherapies to treat cancer. Our commercial portfolio includes our first product, UDENYCA® (pegfilgrastim-cbqv), a biosimilar to Neulasta, a long-acting granulocyte-colony stimulating factor (“G-CSF”) and LOQTORZI® (toripalimab-tpzi), a novel next-generation programmed death receptor-1 (“PD-1”) inhibitor. We are developing an innovative immunology pipeline that we expect to bring forward new potential indications for LOQTORZI in the U.S. and the development of new product candidates.

UDENYCA was launched commercially in a pre-filled syringe presentation in the United States in January 2019, followed by the launch of UDENYCA in an autoinjector presentation in May 2023 and the launch of UDENYCA ONBODY® in February 2024. On December 2, 2024, we and Intas Pharmaceuticals Ltd. (“Intas”), entered into an Asset Purchase Agreement (the “UDENYCA Purchase Agreement”), pursuant to which, and upon the terms and subject to the conditions thereof, we have agreed to divest the UDENYCA franchise (the “UDENYCA Business”) to Intas (the “UDENYCA Sale”). As consideration for the UDENYCA Sale, Intas has agreed to pay us \$483.4 million in cash, inclusive of \$118.4 million of UDENYCA product inventory (the “Inventory Target”), subject to downward adjustment by the amount of inventory delivered at the closing of the UDENYCA Sale less than the Inventory Target (the “Closing Consideration”). Intas has designated Accord BioPharma, Inc., an indirect wholly owned subsidiary of Intas (“Accord” and, together with Intas, the “Intas Parties”) to purchase the physical assets, including product inventory. In addition, the Company is also eligible to receive two additional payments of \$37.5 million each (the “Earnout Payments,” together with the Closing Consideration, the “Consideration”), provided that certain minimum UDENYCA net sales (as defined in the UDENYCA Purchase Agreement, “Net Sales”) thresholds are met during specified periods after the closing of the UDENYCA Sale. We anticipate the transactions contemplated by the UDENYCA Purchase Agreement to close late in the first quarter or early in the second quarter of 2025. We expect to use proceeds from the UDENYCA Sale (a) to fully repay our outstanding \$230.0 million in aggregate principal amount of 1.5% Convertible Senior Subordinated Notes due 2026 (the “2026 Convertible Notes”) and (b) to pay \$47.7 million, assuming a closing late in the first quarter or early in the second quarter of 2025, to buy out the right to receive royalties on net sales of UDENYCA in accordance with our Revenue Purchase and Sale Agreement (the “Revenue Purchase and Sale Agreement”) with Coduet Royalty Holdings, LLC and each buyer named in an annex thereto (collectively, the “Purchaser Group”), dated May 8, 2024. In addition, we will use the proceeds for working capital and general corporate purposes, in connection with our continued business.

On October 27, 2023, we announced that LOQTORZI was approved by the U.S. Food and Drug Administration (“FDA”) in combination with cisplatin and gemcitabine for the first-line treatment of adults with metastatic or recurrent locally advanced nasopharyngeal carcinoma (“NPC”), and as monotherapy for the treatment of adults with recurrent unresectable, or metastatic NPC with disease progression on or after platinum-containing chemotherapy. LOQTORZI is an anti-PD-1 antibody that we developed in collaboration with Junshi Biosciences Co., Ltd. (“Junshi Biosciences”) that is currently the only immune checkpoint inhibitor approved by the FDA for the treatment of these indications. We announced the launch of LOQTORZI in the U.S. on January 2, 2024. Further evaluation of LOQTORZI is expected through multiple current and planned clinical studies by us, Junshi Biosciences and our biopharma partners.

Our pipeline is comprised of earlier stage clinical and preclinical immuno-oncology programs that we plan to develop in combination with LOQTORZI as well as in partnership with other companies with immune activating or cancer agents. Our lead clinical stage product candidate is casdozokitug (CHS-388, formerly SRF388), an investigational antagonist antibody targeting IL-27, an immune regulatory cytokine, that is overexpressed in certain cancers, including hepatocellular, lung and renal cell carcinoma. Casdozokitug received orphan drug designation from the FDA for the treatment of hepatocellular carcinoma (“HCC”) in October 2020 and fast track designation from the FDA for the treatment of patients with HCC previously treated with standard therapies in November 2020. Casdozokitug is currently in three on-going clinical studies, including a Phase 1/2 study in patients with advanced solid tumors, including combination with toripalimab in non-small cell lung cancer (clinicaltrials.gov identifier# NCT04374877), and a Phase 2 study in HCC (clinicaltrials.gov identifier# NCT05359861). We initiated a randomized Phase 2 study in HCC evaluating casdozokitug in combination with toripalimab and bevacizumab in the fourth quarter of 2024 (clinicaltrials.gov identifier# NCT06679985).

Our second clinical-stage product candidate, CHS-114 (formerly SRF114), is an investigational IgG1 antibody targeting CCR8, a chemokine receptor highly expressed on regulatory T cells (“Treg cells”) in the tumor microenvironment (“TME”). We are enrolling patients with advanced solid tumors and head and neck squamous cell carcinoma (“HNSCC”) in the U.S. in a clinical trial evaluating safety and pharmacokinetics of CHS-114 with and without LOQTORZI (clinicaltrials.gov identifier# NCT05635643). We plan to initiate a Phase 1b clinical study of CHS-114 in combination with toripalimab in second-line HNSCC (clinicaltrials.gov identifier# NCT05635643) and to initiate

[Table of Contents](#)

a Phase 1b clinical study of CHS-114 in combination with toripalimab and/or other treatments in participants with advanced solid tumors with the first cohort evaluating gastric cancer (clinicaltrials.gov identifier# NCT06657144), each in the first quarter of 2025.

We also have an early-stage development candidate, CHS-1000, an investigational antibody targeting human ILT4, designed to improve anti-PD-1 clinical benefit by transforming an unfavorable TME to a more favorable TME. Our investigational new drug application (“IND”) for CHS-1000 was allowed to proceed by the FDA in the second quarter of 2024 and initiating the first-in-human clinical study remains subject to further evaluation in our portfolio prioritization process.

In addition, we have a product candidate, GSK4381562, which is exclusively licensed to GlaxoSmithKline Intellectual Property No. 4 Limited (“GSK”). Through September 2033, we have an obligation to pay 70% of all milestone- and royalty-based payments that we or our affiliates receive from GSK4381562 to the holders of contingent value rights (“CVRs”).

We have a depth of scientific expertise, an experienced and robust manufacturing know-how and oncology clinical, regulatory, market access, sales, key account management and medical affairs capabilities in the United States, which has supported the commercialization of LOQTORZI. We expect to further leverage these capabilities as we continue to advance our immuno-oncology franchise.

We primarily operate in the United States and partner with companies that operate in other countries.

Products and Product Candidates

Our portfolio includes the following products and product candidates:

Oncology

- UDENYCA was launched commercially in a pre-filled syringe presentation in the United States in January 2019, followed by the launch of UDENYCA in an autoinjector presentation in May 2023 and the launch of UDENYCA ONBODY in February 2024. On December 2, 2024, we and Intas entered into the UDENYCA Purchase Agreement, pursuant to which, and upon the terms and subject to the conditions thereof, we have agreed to divest the UDENYCA Business to Intas. We anticipate the transactions contemplated by the UDENYCA Purchase Agreement to close late in the first quarter or early in the second quarter of 2025.
- LOQTORZI was 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 receptor. 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. On October 27, 2023, we announced that LOQTORZI was approved by the FDA in combination with cisplatin and gemcitabine for the first-line treatment of adults with metastatic or recurrent locally advanced NPC, and as monotherapy for the treatment of adults with recurrent, unresectable, or metastatic NPC with disease progression on or after platinum-containing chemotherapy. LOQTORZI is an anti-PD-1 antibody that we developed in collaboration with Junshi Biosciences. We announced the launch of LOQTORZI in the U.S. on January 2, 2024.

On December 11, 2023 we announced that the National Comprehensive Cancer Network (“NCCN”) updated the clinical practice guidelines for NPC to include LOQTORZI as a preferred, category 1 first-line treatment option for adults with metastatic or recurrent locally advanced NPC when used in combination with cisplatin and gemcitabine. On November 26, 2024, NCCN made a further update to the clinical practice guidelines for NPC to specify that LOQTORZI is the only preferred category 1 first-line treatment option for adults with metastatic or recurrent locally advanced NPC when used in combination with cisplatin and gemcitabine. The guidelines also recommend LOQTORZI monotherapy as the only preferred treatment in subsequent lines of therapy if disease progression on or after a platinum-containing therapy.

Further evaluation of LOQTORZI is expected through multiple current and planned clinical studies by us and our partners. We have a postmarketing commitment study active and enrolling patients in locations in the U.S. and Canada in order to further evaluate the efficacy of toripalimab in combination with chemotherapy (cisplatin and gemcitabine) in patients with advanced NPC (clinicaltrials.gov identifier NCT06457503). Junshi Biosciences is currently enrolling in a multiregional Phase 3 clinical study evaluating the treatment of LOQTORZI with its investigational anti-BTLA antibody in limited-stage small cell lung cancer (“LS-SCLC”) (clinicaltrials.gov identifier NCT06095583). INOVIO Pharmaceuticals, Inc. plans a randomized Phase 3 study of INO-3112 and toripalimab in locally advanced, high risk HPV16/18+ oropharyngeal squamous cell carcinoma. Cancer Research Institute (“CRI”) plans to evaluate toripalimab in combination with ENB Therapeutics’ investigational agent ENB-003 in its

[Table of Contents](#)

Phase 2 trial titled, “Immunotherapy Platform Study in Platinum Resistant High Grade Serous Ovarian Cancer (IPROC)” (clinicaltrials.gov identifier NCT04918186) that is being performed in collaboration with Canadian Cancer Trials Group (“CCTG”). On June 27, 2024, we entered into an exclusive license and distribution agreement (the “Canada License Agreement”) with Apotex, Inc. (“Apotex”), pursuant to which, we granted to Apotex an exclusive license under our rights to toripalimab to commercialize toripalimab within Canada.

- Casdozokitug (CHS-388, formerly SRF388), is an investigational recombinant human IgG1 monoclonal antibody targeting IL-27, an immune regulatory cytokine, or protein that is overexpressed in certain cancers, including hepatocellular, lung and renal cell carcinoma. IL-27 is a cytokine secreted by macrophages and antigen presenting cells that plays an important physiologic role in suppressing the immune system, as evidenced by its ability to resolve tissue inflammation. In addition, IL-27 is highly expressed during pregnancy and its expression is correlated with maternal-fetal tolerance. Due to its immune regulatory nature, there is a rationale for inhibiting IL-27 to treat cancer, as this approach will influence the activity of multiple types of immune cells that are necessary to recognize and attack a tumor. Casdozokitug received orphan drug designation from the FDA for the treatment of HCC in October 2020 and fast track designation from the FDA for the treatment of patients with HCC previously treated with standard therapies in November 2020. Casdozokitug is currently in three on-going clinical studies, including a Phase 1/2 study in advanced solid tumors (clinicaltrials.gov identifier# NCT04374877), a Phase 2 study in HCC (clinicaltrials.gov identifier# NCT05359861) and a randomized Phase 2 study in HCC evaluating casdozokitug in combination with toripalimab and bevacizumab (clinicaltrials.gov identifier# NCT06679985).
- CHS-114 (formerly SRF114), is an investigational highly specific human afucosylated IgG1 monoclonal antibody selectively targeting CCR8, a chemokine receptor highly expressed on Treg cells in the TME. CHS-114 is designed as a cytolytic antibody to cause depletion of intra-tumoral Treg cells, important regulators of immune suppression and tolerance, through ADCC, or ADCP or both. CHS-114 has shown anti-tumor activity as monotherapy or in combination with anti-PD-1 antibodies in preclinical models. We are enrolling patients with advanced solid tumors and HNSCC in the U.S. in a clinical trial evaluating safety and pharmacokinetics of CHS-114 with and without LOQTORZI (clinicaltrials.gov identifier# NCT05635643). We plan to initiate a Phase 1b clinical study of CHS-114 in combination with toripalimab in second-line HNSCC (clinicaltrials.gov identifier# NCT05635643) and to initiate a Phase 1b clinical study of CHS-114 in combination with toripalimab and/or other treatments in participants with advanced solid tumors with the first cohort evaluating gastric cancer (clinicaltrials.gov identifier# NCT06657144), each in the first quarter of 2025.
- CHS-1000 is an investigational antibody targeting human ILT4, designed to improve anti-PD-1 clinical benefit by transforming an unfavorable TME to a more favorable TME. Our IND for CHS-1000 was allowed to proceed by the FDA in the second quarter of 2024 and initiating the first-in-human clinical study remains subject to further evaluation in our portfolio prioritization process.
- In addition, we have a product candidate, GSK4381562, which is exclusively licensed to GSK. GSK4381562 is an investigational antibody targeting CD112R (“PVRIG”), an inhibitory protein expressed on natural killer (“NK”) and T cells. GSK4381562 is designed to block the interaction of PVRIG with CD112, its binding partner that is expressed on tumor cells. GSK4381562 is designed to promote the activation of both NK and T cells, with potential to elicit a strong anti-tumor response and promote immunological memory. Through September 2033, we have an obligation to pay 70% of all milestone- and royalty-based payments that we or our affiliates receive from GSK4381562 to the holders of CVRs.

Immunology – Sold to Hong Kong King-Friend Industrial Company Ltd. (“HKF”) pursuant to the sale of our YUSIMRY franchise (the “YUSIMRY Sale”)

- YUSIMRY (adalimumab-aqvh), 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 launched in the United States in July 2023.

On June 26, 2024, we entered into an Asset Purchase Agreement (the “YUSIMRY Purchase Agreement”) with HKF, and we completed the sale of our YUSIMRY franchise for upfront, cash consideration of \$40.0 million and the assumption of \$17.0 million of inventory purchase commitments by HKF. We retained the rights to certain patents that were licensed to Pfizer

[Table of Contents](#)

Inc. (“Pfizer”) under the License and Settlement Agreement, dated as of October 21, 2019, between us and Pfizer (the “Pfizer License Agreement”).

Ophthalmology – Sold to Sandoz Inc. (“Sandoz”) pursuant to the sale of our CIMERLI ophthalmology franchise (the “CIMERLI Sale” and, together with the YUSIMRY Sale, the “Sale Transactions”)

- CIMERLI (ranibizumab-eqrn), a Lucentis biosimilar, was approved by the FDA on August 2, 2022 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 and we launched CIMERLI commercially in the United States on October 3, 2022.

On January 19, 2024, we entered into a Purchase and Sale Agreement (the “CIMERLI Purchase Agreement”) by and between us and Sandoz. Pursuant to the terms and subject to the conditions set forth in the CIMERLI Purchase Agreement, on March 1, 2024, we completed the divestiture of our CIMERLI ophthalmology franchise through the sale of our subsidiary, Coherus Ophthalmology LLC (“Coherus Ophthalmology”), to Sandoz for upfront, all-cash consideration of \$170.0 million plus an additional \$17.8 million for CIMERLI product inventory and prepaid manufacturing assets.

Oncology Franchise Market Opportunity

LOQTORZI Opportunity

According to Clarivate/Decision Resource Group, the HNSCC therapy market was expected to increase 10.6% annually over the 2023-2033 forecast period. In 2023, sales of HNSCC therapies in the major pharmaceutical markets under study (United States, France, Germany, Italy, Spain, United Kingdom, and Japan) totaled \$1.4 billion, and sales were expected to increase to almost \$4.8 billion in 2033. Fueling this growth is the label expansion of pembrolizumab in the locoregionally advanced setting, and the expected approval of four new therapies.

PD-1 inhibitors are expected by the Clarivate/Decision Resource Group to be the sales-leading drug class in 2033, garnering major-market sales of over \$1.4 billion, and we expect these agents to be approved for both non-nasopharyngeal and nasopharyngeal drug-treatable patient populations. By the end of 2033, we expect them to be prescribed mostly in the large and commercially lucrative locoregionally advanced and recurrent or metastatic first-line setting.

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.

On October 27, 2023, we announced that LOQTORZI was approved by the FDA in combination with cisplatin and gemcitabine for the first-line treatment of adults with metastatic or recurrent locally advanced NPC, and as monotherapy for the treatment of adults with recurrent, unresectable, or metastatic NPC with disease progression on or after platinum-containing chemotherapy. LOQTORZI is an anti-PD-1 antibody that we developed in collaboration with Junshi Biosciences. We announced the launch of LOQTORZI in the U.S. on January 2, 2024.

LOQTORZI is a novel next-generation PD-1 monoclonal antibody that blocks PD-1 ligands PD-L1 and PD-L2 with high potency at a unique site on the PD-1 receptor, enabling the immune system to activate and kill the tumor.

NPC is a type of aggressive cancer that starts in the nasopharynx, the upper part of the throat behind the nose and near the base of the skull. NPC is rare in the United States, with an annual incidence of fewer than one per 100,000 people. The five-year survival rate for all patients diagnosed with NPC is approximately 60%, however, those who are diagnosed with advanced disease have a five-year survival rate of approximately 49%.

Due to the location of the primary tumor, surgery is rarely an option, and, before the launch of LOQTORZI, patients with localized disease were treated primarily with radiation and chemotherapy. Patients treated with chemotherapy alone experience poor prognosis:

[Table of Contents](#)

only 20% experience one-year progression-free survival; up to 50% developed distant metastasis during their disease course; and low median overall survival (“OS”) of 29 months.

Based on SEER and DRG models, we estimate that the annual drug-treatable population in the United States for NPC is approximately 2,000 patients annually. Of this group, 60% have relapsed/metastatic disease and would be candidates for LOQTORZI. 40% have localized disease that can progress to relapsed/metastatic within a 12-24 month timeframe.

On December 11, 2023 we announced that NCCN updated the clinical practice guidelines for NPC to include LOQTORZI as a preferred, category 1 first-line treatment option for adults with metastatic or recurrent locally advanced NPC when used in combination with cisplatin and gemcitabine. On November 26, 2024, NCCN made a further update to the clinical practice guidelines for NPC to specify that LOQTORZI is the only preferred category 1 first-line treatment option for adults with metastatic or recurrent locally advanced NPC when used in combination with cisplatin and gemcitabine. The guidelines also recommend LOQTORZI monotherapy as the only preferred treatment in subsequent lines of therapy if disease progression on or after a platinum-containing therapy.

The NCCN recommendations were based on results of the JUPITER-02 Phase 3 study and the POLARIS-02 Phase 2 study. In the JUPITER-02 Phase 3 study, LOQTORZI combined with chemotherapy significantly improved progression-free survival, reducing the risk of disease progression or death by 48% compared to chemotherapy alone. LOQTORZI also demonstrated a statistically significant and clinically meaningful improvement in OS, with treatment resulting in a 37% reduction in the risk of death versus chemotherapy alone. In the POLARIS-02 clinical study, LOQTORZI demonstrated durable anti-tumor activity in patients with recurrent or metastatic NPC who failed previous chemotherapy, with an objective response rate of 20.5%, a disease control rate of 40%, and a median OS of 17.4 months with an acceptable safety profile.

LOQTORZI is the first FDA-approved therapy for NPC, and we believe could represent a new standard of care for treating the disease when used in combination with cisplatin and gemcitabine in the first line setting or as monotherapy in the second line or greater setting.

UDENYCA Biosimilar

We initiated United States sales of UDENYCA in January 2019, and in 2024 we recorded UDENYCA net product sales of \$206.0 million. UDENYCA is currently approved by the FDA in three presentations: pre-filled syringe (“PFS”), autoinjector (“AI”) and UDENYCA ONBODY.

On December 2, 2024, we and Intas entered into the UDENYCA Purchase Agreement, pursuant to which, and upon the terms and subject to the conditions thereof, we have agreed to divest the UDENYCA Business to Intas. We anticipate the transactions contemplated by the UDENYCA Purchase Agreement to close late in the first quarter or early in the second quarter of 2025.

Sales and Marketing

Our strategy, following the closing of the UDENYCA Sale, is to focus our research, development and commercial resources on our innovative immuno-oncology portfolio in combination with our commercial product LOQTORZI.

Following the FDA approval of LOQTORZI for NPC, the commercial launch commenced in January 2024 with our existing Oncology commercial and medical affairs teams. As the UDENYCA transaction process unfolds, we plan to focus on maintaining business continuity for both our UDENYCA and LOQTORZI customers and ensure patients continue to access our products without disruption. Post-UDENYCA Sale, we will maintain a more focused commercial team fully enabled to continue momentum of our LOQTORZI launch and to maximize the commercial opportunity for LOQTORZI along with meeting the requirements of the transition services agreement that we are required to enter into with Intas (the “UDENYCA TSA”).

Our overarching strategy with LOQTORZI is to establish a new standard of care for eligible patients with NPC and our execution plan is anchored on three growth drivers: accelerating new patient share through strong healthcare professional and patient identification, ensuring LOQTORZI messaging is delivered at the time of treatment decision, and optimizing the duration of LOQTORZI treatment.

After the closing of the UDENYCA Sale, we will maintain an experienced sales force for LOQTORZI. An experienced set of Sales and Marketing personnel will transfer to Accord. We will maintain a focused set of field facing sales representatives and strategic account managers to support LOQTORZI and work directly with the largest accounts including group purchasing organizations, integrated delivery networks, and large clinic customers.

[Table of Contents](#)

We have an experienced market access and patient services team that will continue to support LOQTORZI and a set of personnel will also transfer to Accord to ensure the continued success of UDENYCA. This team is responsible for negotiating payer coverage with national and regional health plans and pension benefit managers (via a team of National Account Directors), servicing account specific questions regarding the billing, coding and reimbursement of our products (via a team of Field Reimbursement Managers), and managing our Coherus Solutions patient services hub which provides product specific coverage, reimbursement and co-pay support for patients and providers.

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.”

Scientific, Clinical and Regulatory

The Company has a depth of scientific, oncology clinical and regulatory expertise in the United States, which has supported the commercialization of LOQTORZI. The Company expects to further leverage these capabilities as it continues to advance its immuno-oncology franchise.

Manufacturing

We have entered into agreements with several contract manufacturing organizations (“CMOs”) for the manufacture and clinical drug supply of our commercial products and product candidates. We continue to screen other contract manufacturers to meet our clinical, commercial and regulatory supply requirements on a product-by-product basis. On September 13, 2024, we announced that our third-party labeling and packaging CMO for UDENYCA delayed production of UDENYCA due to over-commitments and capacity constraints. These delays caused a temporary UDENYCA supply interruption that quickly took away our ability to sell our product UDENYCA, that makes up a large percentage of our total revenue, for a significant period of time. Production resumed in November 2024.

We have made significant progress in our efforts to diversify our labeling and packaging resources. An additional final packaging and labeling CMO started production testing and manufacturing saleable product. Commercial supply from that CMO is expected to commence late in the first quarter or early in the second quarter of 2025, subject to FDA authorization. For a discussion of risks related to manufacturing our products and our reliance on third parties, please see “Risk Factors—Risks Related to Manufacturing and Supply Chain” and “Risk Factors—Risks Related to Reliance on Third Parties.”

Competition

While we believe that our knowledge, experience and scientific resources provide us with competitive advantages, we face 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.

LOQTORZI faces 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, although not in NPC, including the following marketed products from several competitors: Keytruda® (pembrolizumab) from Merck & Co., 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, Libtayo® (cemiplimab-rwlc) from Regeneron Pharmaceuticals, Inc. (“Regeneron”), Jemperli (dostarlimab-gxly) from GlaxoSmithKline plc (“GlaxoSmithKline”) and TEVIMBRA® (tislelizumab-jsgr) from BeiGene, Ltd. In addition to LOQTORZI, 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 camrelizumab from Elevar Therapeutics, Inc. (in collaboration with Jiangsu Hengrui Pharmaceuticals Co., Ltd.). As the only immunotherapy approved by the FDA for the treatment of NPC, we believe LOQTORZI addresses a potentially high unmet need.

UDENYCA faces competition in the United States from Amgen, Biocon Biologics Inc. (“Biocon”), Sandoz International GmbH, Pfizer, Spectrum Pharmaceuticals, Inc. (“Spectrum”), Amneal Pharmaceuticals, Inc. (“Amneal”) and Fresenius Medical Care AG & Co. KGaA (“Fresenius”).

Casdozokitug is in development and is the only antagonist antibody in development known to us that is targeting the immune regulatory cytokine IL-27.

[Table of Contents](#)

CHS-114 is in development and, if approved, faces competition from programs in development specifically targeting CCR8, including those by BMS, Gilead Sciences, Inc. / Jounce Therapeutics, Inc., Shionogi Inc., AbbVie Inc. (“AbbVie”), Bayer AG, F. Hoffmann-La Roche Ltd, Amgen Inc. (“Amgen”), LaNova Medicines Ltd. and Nanjing Immunophage Biotech Co., Ltd.

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”) / Laboratio Gador S.A. (“Gador”)

In December 2012, we entered into a distribution agreement with Orox / Gador, for the commercialization of biosimilar versions of our internally developed biosimilars. Under this agreement, we granted to Orox / Gador an exclusive license to commercialize UDENYCA in Latin America, except Brazil and Argentina, and YUSIMRY (which we sold in 2024) and CHS-0214 (which we discontinued development in 2020) in Latin America, except Brazil. Under this agreement, Orox / Gador 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 / Gador.

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 / Gador’s activities under the agreement in its licensed territory. We are eligible to receive from Orox / Gador 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 / Gador 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 / Gador 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 / Gador if Orox / Gador challenges the licensed patents or commits a breach of specified provisions of the agreement.

Upon the closing of the UDENYCA Sale, all rights and benefits under our agreement with Orox / Gador will be assigned, conveyed, transferred and delivered to Intas.

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 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 Agreement”).

Under the terms of the Collaboration Agreement, we paid \$150.0 million upfront for exclusive rights to LOQTORZI 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 obtained the right to conduct all commercial activities of LOQTORZI in the United States and Canada. We are obligated to pay Junshi Biosciences up to an aggregate \$380.0 million in one-time payments for the achievement of various regulatory and sales milestones, of which \$12.5 million was paid as of December 31, 2024 and another \$12.5 million was paid in January 2025, and a royalty in the low twenty

[Table of Contents](#)

percent range on net sales of LOQTORZI. On June 27, 2024, we entered into the Canada License Agreement pursuant to which, we granted to Apotex an exclusive license under our rights to toripalimab to commercialize toripalimab within Canada.

In March 2022, we paid \$35.0 million for the exercise of our option to license CHS-006. Subsequent joint development consistent with the Collaboration Agreement commenced. On January 10, 2024, we announced that we had delivered a notice of termination of the TIGIT Program (as defined in the Collaboration Agreement) to Junshi Biosciences pursuant to the Collaboration Agreement. Under the Collaboration Agreement, we retain the right to collaborate in the development of LOQTORZI and the other licensed compounds and will pay for a portion of these co-development activities up to a maximum of \$25.0 million per licensed compound per year. Additionally, we are responsible for certain associated regulatory and technology transfer costs for LOQTORZI 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. As of December 31, 2023, we accrued a \$25.0 million milestone payment to Junshi Biosciences, of which we paid \$12.5 million in the second quarter of 2024 and \$12.5 million in January of 2025. The accrued royalty obligation to Junshi Biosciences was \$1.5 million as of December 31, 2024 and immaterial at December 31, 2023. The additional milestone payments 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.

Adimab Development and Option Agreement

In October 2018, Surface Oncology, Inc. (“Surface”), which we acquired in September 2023, and Adimab LLC (“Adimab”), entered into an amended and restated development and option agreement, (as amended by the amendments dated as of December 16, 2020, June 1, 2022 and July 18, 2022, the “A&R Adimab Agreement”), which amended and restated the development and option agreement with Adimab dated July 2014, as amended, (the “Original Adimab Agreement”), for the discovery and optimization of proprietary antibodies as potential therapeutic product candidates. Under the A&R Adimab Agreement, we will select biological targets against which Adimab will use its proprietary platform technology to research and develop antibody proteins using a mutually agreed upon research plan. The A&R Adimab Agreement, among other things, provided access to additional antibodies and expanded our right to evaluate and use antibodies that were modified or derived using Adimab technology for diagnostic purposes.

Adimab granted us an exclusive option to obtain a non-exclusive, worldwide, fully paid-up, sublicensable license under Adimab’s platform patents and other Adimab technology solely to research up to ten antibodies, chosen by us against a specific biological target for a specified period of time (the “Research Option”). In addition, Adimab granted us an exclusive option to obtain a worldwide, royalty-bearing, sublicensable license under Adimab platform patents and other Adimab technology to exploit, including commercially, 20 or more antibodies against specific biological targets (the “Commercialization Option”). Upon the exercise of a Commercialization Option, and payment of the applicable option fee to Adimab, Adimab will assign us the patents that cover the antibodies selected by such Commercialization Option. We will be required to use commercially reasonable efforts to develop, seek market approval of, and commercialize at least one antibody against the target covered by the Commercialization Option in specified markets upon the exercise of a Commercialization Option.

Under the A&R Adimab Agreement, we are obligated to make milestone payments and to pay specified fees upon the exercise of the Research Option or Commercialization Option. Upon exercise of a Research Option, we are obligated to pay a nominal research maintenance fee on each of the next four anniversaries of the exercise. Upon the exercise of each Commercialization Option, we will be required to pay an option exercise fee of a low seven-digit dollar amount, and we may be responsible for milestone payments of up to an aggregate of \$13.0 million for each licensed product that receives marketing approval. For any licensed product that is commercialized, we are obligated to pay Adimab tiered royalties of a low to mid single-digit percentage on worldwide net sales of such product. We may also partially exercise a Commercialization Option with respect to ten antibodies against a biological target by paying 65% of the option fee and later either (i) paying the balance and choosing additional antibodies for commercialization, up to the maximum number under the Commercialization Option, or (ii) foregoing the Commercialization Option entirely. For any Adimab diagnostic product that is used with or in connection with any compound or product other than a licensed antibody or licensed product, we are obligated to pay Adimab up to a low seven digits in regulatory milestone payments and low single-digit royalties on net sales. No additional payment is due with respect to any companion diagnostic or any diagnostic product that does not contain any licensed antibody. Any payments payable to Adimab as a result of any product candidates being developed pursuant to the license agreement between Surface and GSK, dated December 16, 2020, which was subsequently amended in August 2021 (as amended, the “GSK Agreement”), will be payable to Adimab directly by GSK.

GSK Out-licensing Agreement

In December 2020, Surface entered into the GSK Agreement. Pursuant to the GSK Agreement, Surface granted GSK a worldwide exclusive, sublicensable license to develop, manufacture and commercialize antibodies that target PVRIG, including the antibody GSK4381562 (the "Licensed Antibodies"). GSK is responsible for the development, manufacturing and commercialization of the Licensed Antibodies and a joint development committee was formed to facilitate information sharing. GSK is responsible for all costs and expenses of such development, manufacturing and commercialization and is obligated to provide us with updates on its development, manufacturing and commercialization activities through the joint development committee. In March 2022, Surface earned a \$30.0 million milestone payment from GSK upon the dosing of the first patient in the Phase 1 trial of GSK4381562. We are eligible to receive up to \$60.0 million in additional clinical milestones and \$155.0 million in regulatory milestones. In addition, we may receive up to \$485.0 million in sales milestone payments. We are also eligible to receive royalties on global net sales of any approved products based on the Licensed Antibodies, ranging in percentages from high single digits to mid-teens. Due to the uncertainty of pharmaceutical development and the historical failure rates generally associated with drug development, we may not receive any milestone payments or any royalty payments under the GSK Agreement. We have not recognized license-related revenue under the GSK Agreement to date.

Unless terminated earlier, the GSK Agreement expires on a licensed product-by-licensed product and country-by-country basis on the later of ten years from the date of first commercial sale or when there is no longer a valid patent claim or regulatory exclusivity covering such licensed product in such country. Either party may terminate the GSK Agreement for an uncured material breach by the other party or upon the bankruptcy or insolvency of the other party. GSK may terminate the GSK Agreement for its convenience. We may terminate the GSK Agreement if GSK institutes certain actions related to the licensed patents or if GSK ceases development activities, other than for certain specified technical or safety reasons. In the event of termination, we would regain worldwide rights to the terminated program.

License Agreement with Vaccinex

On March 23, 2021, Surface and Vaccinex, Inc. ("Vaccinex") entered into an exclusive product license agreement (the "Vaccinex License Agreement") to exclusively license certain antibodies, including CHS-114. Pursuant to the terms of the Vaccinex License Agreement, we have a worldwide, exclusive, sublicensable license to make, have made, use, sell, offer to sell, have sold, import and otherwise exploit licensed products that incorporate certain Vaccinex intellectual property which covers certain antibodies (each, a "Vaccinex Licensed Product"), including the antibody CHS-114 targeting CCR8.

Under the Vaccinex License Agreement, we are obligated to use commercially reasonable efforts to develop, clinically test, achieve regulatory approval, manufacture, market and commercialize at least one Vaccinex Licensed Product and have the sole right to develop, manufacture and commercialize the licensed products worldwide. We are responsible for all costs and expenses of such development, manufacturing and commercialization. Pursuant to the Vaccinex License Agreement, Surface paid Vaccinex a one-time fee of \$0.9 million. Vaccinex is eligible to receive up to an aggregate of \$3.5 million based on achievement of certain clinical milestones and up to an aggregate of \$11.5 million based on achievement of certain regulatory milestones per Vaccinex Licensed Product. We also owe low single-digit royalties on global net sales of any approved licensed products. Commencing on the third anniversary of the date of the Vaccinex License Agreement and continuing until the first dosing of a Vaccinex Licensed Product in a clinical trial, we will be required to pay Vaccinex a nominal yearly maintenance fee. Since a patient was dosed with a Vaccinex Licensed Product, CHS-114, in January 2023, no yearly maintenance fees are due under the Vaccinex License Agreement.

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

[Table of Contents](#)

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 European Union (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, such as FDA refusal to approve a pending biologics license application (“BLA”) or new drug application (“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 certain 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 PHSA (“original BLA”) or an NDA, as appropriate, satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug or biologic is produced, and FDA approval and review of the original BLA or NDA. Developing the data to satisfy FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation and toxicity, as well as, 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 allowance from the FDA to administer an investigational 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

[Table of Contents](#)

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. While the IND is active, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report, among other information, must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or in vitro testing suggesting a significant risk to humans, and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

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, optimal dosage, 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 and to preliminarily evaluate the efficacy of the product for specific targeted diseases.
- 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.

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.

[Table of Contents](#)

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, where the product candidate has received orphan drug designations for the sought indication 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 for a three-month period by the FDA to review additional information deemed a major amendment to the application.

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

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 ensure 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 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.

Expedited Development and Review Programs

The FDA has a number of programs intended to expedite the development or review of a marketing application for an investigational drug or biologic. For example, the fast track designation program is intended to expedite or facilitate the process for developing and reviewing product candidates that meet certain criteria. Specifically, investigational drugs and biologics are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. The sponsor of a fast track product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and, with regard to a fast track product candidate, the FDA may consider for review sections of the NDA or original BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA or original BLA, the FDA agrees to accept sections of the NDA or original BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA or original BLA.

A product candidate can also receive breakthrough therapy designation if preliminary clinical evidence indicates that the product candidate, alone or in combination with one or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the fast track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product candidate, including involvement of senior managers.

Separately, an NDA or original BLA is eligible for priority review if the product candidate is designed to treat a serious condition, and if approved, would provide a significant improvement in safety or efficacy compared to available therapies. The FDA will attempt to direct additional resources to the evaluation of a NDA or original BLA designated for priority review in an effort to facilitate the review. The FDA endeavors to review applications with priority review designations within six months of the filing date as compared to ten months for review of new molecular entity NDAs and original BLAs under its current PDUFA review goals.

In addition, depending on the design of the applicable clinical trials, a product candidate may be eligible for accelerated approval. Specifically, drugs and biologics intended to treat serious or life-threatening diseases or conditions may be eligible for accelerated approval upon a determination that the product candidate has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA generally requires that a sponsor of a drug or biologic receiving accelerated approval perform adequate and well-controlled confirmatory clinical trials, and may require that such confirmatory trials be underway prior to granting accelerated approval. Drugs or biologics receiving accelerated approval may be subject to expedited withdrawal procedures if the sponsor fails to conduct the required confirmatory trials in a timely manner or if such trials fail to verify the predicted clinical benefit. In addition, the FDA requires as a condition of accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Fast track designation, breakthrough therapy designation, priority review, and accelerated approval do not change the standards for approval but may expedite the development or approval process. Even if a product candidate qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Orphan drug designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States or, if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making the product available in the United States for this type of disease or condition will be recovered from sales of the product. Orphan designation must be requested before submitting an NDA or BLA. After the FDA grants orphan designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications –including full NDAs or BLAs– to market the same drug for the same disease or condition for seven years, except in limited circumstances,

[Table of Contents](#)

such as a showing of clinical superiority to the product with orphan exclusivity or inability to manufacture the product in sufficient quantities. The designation of such drug or biologic also entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. However, competitors, may receive approval of different products for the disease or condition for which the orphan product has exclusivity, or obtain approval for the same product but for a different disease or condition for which the orphan product has exclusivity. Orphan exclusivity also could block the approval of a competing product for seven years if a competitor obtains approval of the “same drug,” as defined by the FDA, or if the active ingredient of the product candidate is determined to be contained within the competitor’s product for the same disease or condition. In addition, if an orphan designated product receives marketing approval for a disease or condition broader than what is designated, it may not be entitled to orphan exclusivity.

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.

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

[Table of Contents](#)

- 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 developed, may be composed of components, such as drug components and device components that would normally be regulated under different types of regulatory 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;

[Table of Contents](#)

- 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 FDCA 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.

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, implementation of a REMS, and/or 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, manufacturing, 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,

[Table of Contents](#)

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 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

[Table of Contents](#)

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

Pharmaceutical Coverage, Pricing and Reimbursement

In the United States and other countries, sales of UDENYCA and LOQTORZI 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

[Table of Contents](#)

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 and LOQTORZI 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 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

[Table of Contents](#)

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, the IRA was signed into law. 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 manufacturer discounting program (which began 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. HHS has issued and will continue to issue guidance implementing the IRA. CMS has published the negotiated prices for the initial ten drugs, which will first be effective in 2026, and the list of the subsequent 15 drugs that will be subject to negotiation, although the Medicare drug price negotiation program is currently subject to legal challenges. 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, 2023, we had 306 full-time and part-time employees. In addition to our 35 former employees who transferred to Sandoz in connection with the closing of the CIMERLI Sale, on March 11, 2024 we committed to a plan to reduce our workforce (the “Plan”) by approximately 26 employees effective March 18, 2024 to focus resources on strategic priorities including the research, development and commercialization of innovative cancer treatments and the commercialization of our portfolio of FDA-approved oncology products. The Plan was completed in 2024.

As of December 31, 2024, we had 228 full-time and part-time employees. All were located in the United States and none of our employees were 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.

Pursuant to the UDENYCA Purchase Agreement, approximately 50 of our employees are expected to transfer employment to Accord, with the transfer of employment effective at the closing of the UDENYCA Sale, which we expect to occur late in the first quarter or early in the second quarter of 2025. None of our executive officers are expected to transfer to Intas.

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 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 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.

[Table of Contents](#)

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 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 valuing diversity in terms of gender, ethnicity, nationality, disability status, veteran status and other factors. 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 have an incident reporting plan to respond to injuries and emergencies on an ongoing basis to protect our employees and comply with all Occupational Safety and Health Administration requirements.

Training, Development and Engagement

Through our online learning platform, we deliver a variety of required learning modules, including those modules tied to our Code of Business Conduct, cybersecurity, unlawful harassment, workplace violence prevention and anti-corruption policies, which are completed periodically by all team members. We also have Performance Management, Leadership 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 reports 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 (<https://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 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 at <https://www.coherus.com>. Any waiver of our Code of Business Conduct and Ethics may be made only by our board of directors (“Board”). 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, one of which we have agreed to sell, and with multiple products that are not approved and still in development.
- 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.
- As we have in-licensed development and/or commercial rights to LOQTORZI, we rely on prior and ongoing preclinical, clinical, regulatory and manufacturing expertise of our collaborators in order to advance this product candidate 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, government shut-downs or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, and conduct 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 product faces significant competition from the reference product and from other biosimilar products or pharmaceuticals approved for the same indication as the originator products. LOQTORZI faces significant competition from other immuno-oncology biologics. If we fail to compete effectively, we may not achieve significant market penetration and expansion.
- We face intense competition and rapid technological change and the possibility that our competitors may develop therapies that are similar, more advanced or more effective than ours, which may adversely affect our financial condition and our ability to successfully commercialize our product candidates.
- If an improved version of an originator product, such as Neulasta, is developed or if the market for the originator product significantly declines, sales of our biosimilar product 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.

[Table of Contents](#)

- We are subject to a multitude of manufacturing risks and the risks of inaccurately forecasting sales of our products. We also need to make a determination of excess or obsolete inventory that requires judgment and may result in write-downs of inventory, charges related to firm purchase commitments, or both. Any adverse developments affecting the manufacturing operations of our products and product candidates could substantially increase our costs and limit supply for our products and product candidates.
- The continuation of the war between Russia and Ukraine and conflicts in the Middle East 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, one of which we have agreed to sell, and with multiple products that are not approved and still in development.

With the exception of generating net income of \$28.5 million, \$132.2 million and \$89.8 million in 2024, 2020 and 2019, respectively, we incurred net losses in each year from our inception in September 2010 through December 31, 2024, including net losses of \$237.9 million and \$291.8 million in 2023 and 2022, respectively. It is uncertain that we will be profitable in future periods, particularly if the UDENYCA Sale is consummated, 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, 2024, we had an accumulated deficit of \$1.6 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 commercial expenses for LOQTORZI, 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. The recent launch of this product and future work to advance our other product candidates through clinical development in combination with toripalimab will be expensive and could result in us continuing to experience future net losses.

[Table of Contents](#)

For UDENYCA and LOQTORZI, which are launched products, and if we obtain regulatory approval to market any other 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:

- 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 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;
- 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.

In addition, the UDENYCA Sale may make it more difficult or make it take more time for us to become profitable at any point in the future. UDENYCA is our largest product that contributes significantly more revenue to our business than LOQTORZI currently. LOQTORZI may not increase its revenue contribution to our business as quickly as we project or at all and for our clinical trials for our product candidates may be delayed, may be unsuccessful or may take more time and expense to complete than we currently anticipate. The inherent risk involved in divesting a major business could make it difficult for us to replace the revenue lost by selling UDENYCA or by becoming profitable in the future.

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.

[Table of Contents](#)

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, 2024, our cash, cash equivalents and marketable securities were \$126.0 million. We expect that our existing cash and cash equivalents, investments, cash collected from our product sales and cash proceeds from the UDENYCA Sale (assuming it is consummated) 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, divestitures, 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 consummate the UDENYCA Sale;
- our ability to continue to successfully commercialize our products;
- our ability to maintain continuity for the supply of 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;
- prior to the consummation of the UDENYCA Sale, the timing for us to receive FDA authorization to produce UDENYCA product at our additional packaging and labeling CMO's facility and the timing for our additional packaging and labeling CMO to make UDENYCA products available in a sufficient quantity to meet the demand from our customers;
- 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;
- if not otherwise resolved with proceeds from the UDENYCA Sale, 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 payment of interest, principal and royalties related to our financial liabilities; 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 the sales from time to time through our sales agreement dated November 8, 2022 (the "Sales Agreement") with Cowen and Company, LLC ("TD Cowen") pursuant to which we may issue and sell from time to time up to \$150.0 million of our common stock, including the common stock already sold, through or to TD Cowen as our sales agent or principal in an at-the-market offering ("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 (the "2029 Loan Agreement"), dated as of May 8, 2024 (the "2029 Term Loan Effective Date"), by and among us, Ankura Trust Company, LLC, as administrative agent (in such capacity, the "Agent"), and the lenders signatory thereto (collectively, the "2029 Lenders") governing the senior secured term loan facility of up to \$38.7 million (the "2029 Term Loan") we entered into on the 2029 Term Loan Effective Date, 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 such as a financial covenant which requires us to maintain certain levels of cash and cash equivalents. We could also be required to seek funds through arrangements with collaborative partners or otherwise at an earlier stage or for a lower

[Table of Contents](#)

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.

Risks Related to Launch and Commercialization of our Products and our Product Candidates

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 are UDENYCA and LOQTORZI 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 approvals necessary to commercialize, one or more of our product pipeline candidates, which include:

- CHS-1000
- casdozokitug;
- CHS-114; and
- toripalimab in non-NPC indications.

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 all three UDENYCA product presentations and LOQTORZI;
- competing against numerous current and future pegfilgrastim 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 biosimilar product;
- obtaining additional regulatory 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;

Table of Contents

- 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, which 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 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 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 product LOQTORZI, 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;
- relative convenience, ease of administration and any real or perceived benefit from administration at home as opposed to in the clinic;
- 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;

[Table of Contents](#)

- 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;
- the potential impact of the IRA on the pharmaceutical industry and the market for our products;
- 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 (prior to the UDENYCA Sale) and LOQTORZI, 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 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.

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 competing products. If our products or any of our future product candidates, are not covered or adequately reimbursed by third-party payers, including

[Table of Contents](#)

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. 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 current 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 PHS Act, Section 351(k) BLA or marketing authorization application ("MAA"). Accordingly, we and others with whom we work must continue to spend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Any regulatory approvals that we or our collaboration partners receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval or may contain requirements for potentially costly additional clinical trials and surveillance to monitor the safety and efficacy of the product candidate. We will be required to report certain adverse events and production problems, if any, to the FDA and comparable foreign regulatory authorities. Any new legislation addressing drug safety issues could result in delays in product development or commercialization or increased costs to ensure 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;

[Table of Contents](#)

- 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, staffing limitations, government shut-downs or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, and conduct 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, government shut-downs, 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 or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the United States 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. If a prolonged government shutdown occurs, or if funding shortages, staffing limitations or further global health concerns emerge, such events could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Risks Related to Competitive Activity

Our biosimilar product faces significant competition from the reference product and from other biosimilar products or pharmaceuticals approved for the same indication as the originator products. Our product LOQTORZI and product candidate CHS-114, 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, and marketing resources, with additional benefits of mergers and acquisitions.

[Table of Contents](#)

LOQTORZI entered 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, although not in NPC, 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, Libtayo® (cemiplimab-rwlc) from Regeneron, Jemperli (dostarlimab-gxly) from GlaxoSmithKline and TEVIMBRA® (tislelizumab-jsgr) from BeiGene, Ltd. In addition to LOQTORZI, 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 camrelizumab from Elevar Therapeutics, Inc. (in collaboration with Jiangsu Hengrui Pharmaceuticals Co., Ltd.). As the only immunotherapy approved by the FDA for the treatment of NPC, we believe LOQTORZI addresses a potentially high unmet need.

UDENYCA faces competition in the United States from Amgen, Biocon, Sandoz, Pfizer, Spectrum, Amneal and Fresenius.

Casdozokitug is in development and is the only antagonist antibody in development known to us that is targeting the immune regulatory cytokine IL-27.

CHS-114 is in development and, if approved, faces competition from programs in development specifically targeting CCR8, including those by Bristol-Myers Squibb Company, Gilead/Jounce, Shionogi, AbbVie, Bayer, F. Hoffmann-La Roche Ltd, Amgen, LaNova and Immunophage;

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 product 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 pharmacy benefit managers, payers and their third-party administrators, integrated delivery networks 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.

Many of our competitors have substantially greater financial, technical and other resources, including larger research and development, marketing and manufacturing organizations. Additionally, 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. 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 competitors to toripalimab (in indications besides those approved for LOQTORZI), casdozokitug, CHS-1000 and CHS-114 are approved and successfully commercialized before toripalimab (in indications besides those approved for LOQTORZI), casdozokitug, CHS-1000 and CHS-114, our business would suffer.

There are a number of companies that currently commercialize PD-1/PD-L1 blocking antibodies or are developing such compounds for commercialization in the United States. If other competitors to toripalimab (in indications besides those approved for LOQTORZI), casdozokitug, CHS-1000 and CHS-114 are successfully commercialized before toripalimab (in indications besides those approved for LOQTORZI), casdozokitug, CHS-1000 and CHS-114, 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, is developed or if the market for the originator product significantly declines, sales of our biosimilar product may suffer.

Originator companies may develop improved versions of a reference product as part of a life cycle extension strategy and may obtain regulatory approval of the improved version under a new or supplemental BLA submitted to the applicable regulatory authority. Should the originator company succeed in obtaining an approval of an improved biologic product, it may capture a significant share of the collective reference product market in the applicable jurisdiction and significantly reduce the market for the reference product and thereby the potential size of the market for our biosimilar product. 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 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, 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 for our biosimilar product. 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 casdozokitug, CHS-1000 and CHS-114, subjects us to additional risks relating to biosimilar competition. In particular, under the Biologics Price Competition and Innovation Act of 2009 (“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 LOQTORZI does, and any of our 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.

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. The majority of our outstanding options have exercise prices that are above our current stock price. See the tables describing our outstanding stock options in Note 12. Stock-Based Compensation and Employee Benefits to our financial statements included in our Annual Report for the Fiscal Year ended December 31, 2024. 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 experience difficulties in managing changes in our number of employees, particularly due to employees departing due to divestitures, reductions in force and turnover, which could disrupt our operations.

As of December 31, 2024, we had 228 full-time and part-time employees, which represented a decrease of 78 full-time and part-time employees since December 31, 2023. As our development and commercialization plans and strategies develop and evolve from time

[Table of Contents](#)

to time we face difficulty managing these changes as we experience changes in our number of employees, including due to divestitures, like the potential employee transfers to Accord in the UDENYCA Sale, reductions in force and turnover. We may not be able to effectively manage during a period of significant change in our number of employees, which may result in weaknesses in our infrastructure, operational mistakes, loss of business opportunities and reduced productivity and morale among remaining employees. If our management is unable to effectively manage the changes in our number of employees, our expenses may increase more than expected and our ability to generate or grow revenue could be reduced. Our future financial performance and our ability to commercialize product candidates and compete effectively will depend, in part, on our ability to effectively manage changes in our number of employees.

Risks Related to Reliance on Third Parties

We rely on third parties, and in some cases a single third party, to manufacture nonclinical, clinical and commercial drug supplies of our products and product candidates and to store critical components of our products and product candidates for us. Our business could be harmed if those third parties fail to provide us with sufficient quantities of products and 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 products and product candidates for use in our nonclinical and clinical studies, and we lack the resources and the capability to manufacture any of our products and product candidates on a clinical or commercial scale. We rely on third-party manufacturers to manufacture and supply us with our products and product candidates for our preclinical and clinical studies as well as to maintain commercial supplies of our products. Successfully transferring complicated manufacturing techniques to contract manufacturing organizations and scaling up these techniques for commercial quantities is time consuming and we may not be able to achieve such transfer or do so in a timely manner. Moreover, the availability of contract manufacturing services for protein-based therapeutics is highly variable and there are periods of relatively abundant capacity alternating with periods in which there is little available capacity. If our need for contract manufacturing services increases during a period of industry-wide production capacity shortage, we may not be able to produce our product candidates on a timely basis or on commercially viable terms. Although we will plan accordingly and generally do not begin a clinical study unless we believe we have a sufficient supply of a product candidate to complete such study, any significant delay or discontinuation in the supply of a product candidate for an ongoing clinical study due to the need to replace a third-party manufacturer could considerably delay completion of our clinical studies, product testing and potential regulatory approval of our product candidates, which could harm our business and results of operations.

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

On September 13, 2024, we announced that our third-party labeling and packaging CMO for UDENYCA delayed production of UDENYCA due to over-commitments and capacity constraints. These delays caused a temporary UDENYCA supply interruption that quickly took away our ability to sell our product UDENYCA, that makes up a large percentage of our total revenue, for a significant period of time. Production resumed in November 2024. The Company announced in January 2025 that due to strong demand in Q4 2024 and into Q1 2025, all three presentations of UDENYCA were being temporarily allocated. Based on individual distributor historical purchasing patterns, supply allocations to wholesalers for all three presentations of UDENYCA were removed between the end of January 2025 and the end of February 2025. The temporary UDENYCA supply interruption had a significant impact on our business, relationships with customers and affected the negotiations with potential counterparties in the UDENYCA Sale. Similar circumstances to the temporary UDENYCA supply interruption could arise in the future, which would have an adverse impact on our financial statements and reputation.

[Table of Contents](#)

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. 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 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 contract 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 good laboratory practices (“GLP”), which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the EEA and comparable foreign regulatory authorities for all of our product candidates in clinical development. Regulatory authorities enforce these regulations through periodic inspections 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 CROs or any other participating parties violate federal or state fraud and abuse or false claims laws and regulations or healthcare or data 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 are dependent on Junshi Biosciences and Orox / Gador 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 an exclusive license from Junshi Biosciences to develop and commercialize LOQTORZI in the United States and Canada. Our licensors are responsible for supplying us with drug substance and final drug products.

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

[Table of Contents](#)

Our licenses with Junshi Biosciences, Orox / Laboratorio Gador S.A., 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 could substantially divert the attention of our senior management from other business activities and may 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 the UDENYCA Sale and our future operations following the UDENYCA Sale

The announcement and pendency of the UDENYCA Sale, whether or not consummated, may adversely affect our business.

The announcement and pendency of the UDENYCA Sale, whether or not consummated, may adversely affect the trading price of our common stock, our business or our relationships with customers, suppliers and employees. In addition, pending the completion of the UDENYCA Sale, we may be unable to attract and retain key personnel and the focus and attention of our management and employee resources may be diverted from operational matters during the pendency of the UDENYCA Sale.

The closing of the UDENYCA Sale is subject to multiple conditions beyond our control. Failure to complete the UDENYCA Sale could materially and adversely affect our future business, results of operations, financial condition and stock price.

The closing of the UDENYCA Sale is subject to the satisfaction or waiver of various conditions, including FDA authorization of commercial supply from our additional packaging and labeling CMO for UDENYCA. We cannot predict whether and when the conditions will be satisfied. If one or more of these conditions is not satisfied, and as a result, we do not complete the UDENYCA Sale, or in the event the UDENYCA Sale is not completed or is delayed for any other reason, we and investors in our common stock may be harmed. If we are unable to satisfy the closing conditions in Intas' favor or if other mutual closing conditions are not satisfied, Intas will not be obligated to complete the UDENYCA Sale. In the event that the UDENYCA Sale is not completed, the announcement of the termination of the UDENYCA Purchase Agreement may adversely affect the trading price of our common stock, our business and operations or our relationships with our employees. Any delay in completing the UDENYCA Sale may significantly reduce the benefits that we expect to achieve if we successfully complete the UDENYCA Sale within the expected timeframe.

The UDENYCA Purchase Agreement limits our ability to pursue alternatives to the UDENYCA Sale.

The UDENYCA Purchase Agreement contains customary "no-shop" restrictions on our ability to solicit alternative acquisition proposals from third parties for the UDENYCA Business and to provide information to, and participate and engage in discussions or negotiations with, third parties regarding any alternative acquisition proposals. These restrictions are subject to a customary "fiduciary out" provision that allows us, under certain specified circumstances, to provide information to, and participate or engage in discussions or negotiations with and afford access to, third parties with respect to an acquisition proposal if our Board determines in good faith (after consultation with its financial advisor and outside legal counsel) that such alternative acquisition proposal either constitutes a superior

[Table of Contents](#)

proposal or would be reasonably likely to result in a superior proposal, and our Board determines in good faith (after consultation with its outside legal counsel) that the failure to take such actions would be inconsistent with its fiduciary duties pursuant to applicable law.

There is no guarantee that we will receive either of the Earnout Payments under the UDENYCA Purchase Agreement.

A portion of the Consideration potentially payable to us under the UDENYCA Purchase Agreement is in the form of two Earnout Payments of \$37.5 million each. The first such payment is payable by Intas to us if Net Sales of UDENYCA for four consecutive fiscal quarters within the first five full fiscal quarters following the consummation of the UDENYCA Sale are equal to or greater than \$300 million, and the second such payment is payable by Intas to us if Net Sales of UDENYCA for four consecutive fiscal quarters within the first seven full fiscal quarters following the consummation of the UDENYCA Sale are equal to or greater than \$350 million. However, there is no guarantee that we will receive either of the Earnout Payments, and we may not receive more than the Closing Consideration for selling the UDENYCA Business. If we do not receive the Earnout Payments the total consideration paid to us for the sale of UDENYCA will be significantly lower, which could be harmful to our future financial position.

Our stockholders should not assume that they will receive any of the proceeds of the UDENYCA Sale.

The proceeds from the UDENYCA Sale will be paid directly to us and not to our stockholders. We intend to use substantially all of the proceeds to pay off certain financial liabilities and for working capital and general corporate purposes in connection with its continued business which is focused on the research, development and commercialization of innovative immunotherapies to treat cancer and the development of an innovative immuno-oncology pipeline. We have never declared or paid any cash dividends on our common stock and the Board does not currently expect to declare a special dividend of any UDENYCA Sale proceeds to our stockholders.

We have incurred and will continue to incur significant expenses in connection with the UDENYCA Sale, regardless of whether the UDENYCA Sale is completed.

We have incurred and expect to continue to incur significant expenses related to the UDENYCA Sale. These expenses are substantial and include, but are not limited to, financial advisory and opinion fees and expenses, legal fees and expenses, accounting fees and expenses, certain employee expenses, filing fees, printing expenses and other related fees and expenses. Many of these expenses have already been incurred by us and will be payable by us regardless of whether the UDENYCA Sale is completed.

Immediately following the UDENYCA Sale, we will be a commercial-stage biopharmaceutical company focused on the research, development and commercialization of innovative immunotherapies to treat cancer.

Upon the closing of the UDENYCA Sale, we will no longer operate the UDENYCA Business, other than certain transition activities for a temporary period of time to transition the UDENYCA Business to Intas pursuant to the UDENYCA TSA, and will be focused on the research, development and commercialization of innovative immunotherapies to treat cancer and the commercialization of LOQTORZI for the treatment of NPC patients in the U.S. We expect to continue to generate revenue by sales of our commercial product LOQTORZI and otherwise expect to devote substantial resources to our research, development and commercialization efforts for our pipeline product candidates. However, there is no guarantee that these efforts will ever result in any meaningful revenue for us, and revenue generated from these immunotherapies alone or in combination with revenue generated by LOQTORZI may never equal or surpass revenue generated by the UDENYCA Business. If our stock price decreases after the closing of the UDENYCA Sale because our revenue is lower than when we operated the UDENYCA Business or for other reasons it could result in the delisting of our shares from The Nasdaq Global Market or other adverse consequences that would materially harm our business and prospects.

We have discretion in the use of the proceeds from the UDENYCA Sale and our choices about the use of proceeds may not be effective.

If the UDENYCA Sale is consummated, we will receive the Closing Consideration proceeds from the UDENYCA Sale. We announced that we plan to use a portion of the proceeds of the UDENYCA Sale to pay off the \$230 million in aggregate principal amount of convertible notes due April 2026 and to buy out the right to receive royalties on net sales of UDENYCA, which is expected to be \$47.7 million, assuming a close late in the first quarter or early in the second quarter of 2025, in accordance with the Revenue Purchase and Sale Agreement. We plan to use the remainder for working capital and general corporate purposes, in connection with our continued business, which is focused on the research, development and commercialization of innovative immunotherapies to treat cancer and the development of an innovative immuno-oncology pipeline and the commercialization of LOQTORZI for the treatment of NPC patients in the U.S. We will have broad discretion in the application of the proceeds from the UDENYCA Sale and our planned use of proceeds described above may not improve our results of operations or enhance the value of our common stock. If our planned use of proceeds is not effective it could result in financial losses that could have a material adverse effect on our business and cause the price of our common stock to decline. Pending their use, we may invest the proceeds in a manner that does not produce income or that loses value. Although our Board will evaluate various alternatives regarding the use of the proceeds from the UDENYCA Sale, it has made no decision with respect to the specific use of

[Table of Contents](#)

proceeds other than as described above and has not committed to making any such decision by a particular date. This uncertainty may negatively impact the value and liquidity of our common stock.

There are risks and uncertainties associated with the transition services agreement that will be entered into between us and Intas at or before the date of the closing of the UDENYCA Sale, one or more of which could have a material adverse effect on our business, financial condition, results of operations, cash flows or stock price.

In connection with the UDENYCA Sale, we are required to enter into the UDENYCA TSA pursuant to which we expect to be required to provide certain business support services to Intas for a defined transition period of time. There are a number of risks and uncertainties associated with the UDENYCA TSA, which could have a material adverse effect on our business, financial condition, results of operations, cash flows or stock price, including, among other things:

- the need to expend our management and employee time and attention on the UDENYCA TSA that could be spent on other areas of our business;
- the need to provide significant support services under the UDENYCA TSA on behalf of Intas, such as logistics, payments, accounting, finance, commercial, regulatory and manufacturing support;
- the exposure to the financial status of Intas for any payments due to us under the UDENYCA TSA, which may be significant; and
- potential unanticipated costs to us under the UDENYCA TSA.

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. We also need to make a determination of excess or obsolete inventory that requires judgment and may result in write-downs of inventory, charges related to firm purchase commitments, or both. Any adverse developments affecting the manufacturing operations of our products and product candidates could substantially increase our costs and limit supply for our products and 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 conflicts in Ukraine and the Middle East.

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 products and product candidates resulting in delays prior to our taking corrective action. Additionally, if microbial, viral or other contaminations are discovered in our products or product candidates or in the manufacturing facilities in which our products or 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 products and product candidates, including due to sudden or long-term changes in weather patterns or conflicts in particular geographic areas, may result in shipment delays, inventory shortages, lot failures, withdrawals or recalls or other interruptions in the supply of our products and product candidates. We also need to make a determination of excess or obsolete inventory that requires judgment and includes 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 statements 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.

We may have to take inventory write-downs and incur other charges and expenses, such as charges related to firm purchase commitments, 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 UDENYCA inventory that was at risk of expiration and during the fourth quarter of 2023, we recorded a \$47.0 million charge for the write-down of slow moving YUSIMRY inventory and the related partial recognition of certain firm purchase commitments. 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-downs, 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.

On September 13, 2024, we announced that our third-party labeling and packaging CMO for UDENYCA delayed production of UDENYCA due to over-commitments and capacity constraints. These delays caused a temporary UDENYCA supply interruption that quickly took away our ability to sell our product UDENYCA, that makes up a large percentage of our total revenue, for a significant period of time. Production resumed in November 2024. The Company announced in January 2025 that due to strong demand in Q4 2024 and into Q1 2025, all three presentations of UDENYCA were being temporarily allocated. Based on individual distributor historical purchasing patterns, supply allocations to wholesalers for all three presentations of UDENYCA were removed between the end of January 2025 and the end of February 2025. The temporary UDENYCA supply interruption had a significant impact on our business, relationships with customers and affected the negotiations with potential counterparties in the UDENYCA Sale. Similar circumstances to the temporary UDENYCA supply interruption could arise in the future, which would have an adverse impact on our financial statements and reputation.

We currently engage single suppliers for manufacture, clinical trial services, formulation development and product testing of our products and 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. 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 make any assurances 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 products and 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.

For example, on September 13, 2024, we announced that our third-party labeling and packaging CMO for UDENYCA delayed production of UDENYCA due to over-commitments and capacity constraints. These delays caused a temporary UDENYCA supply interruption that quickly took away our ability to sell our product UDENYCA, that makes up a large percentage of our total revenue, for a significant period of time. Production resumed in November 2024. The Company announced in January 2025 that due to strong demand in Q4 2024 and into Q1 2025, all three presentations of UDENYCA were being temporarily allocated. Based on individual distributor historical purchasing patterns, supply allocations to wholesalers for all three presentations of UDENYCA were removed between the end of January 2025 and the end of February 2025. The temporary UDENYCA supply interruption had a significant impact on our business, relationships with customers and affected the negotiations with potential counterparties in the UDENYCA Sale. Similar circumstances to the temporary UDENYCA supply interruption could arise in the future, which would have an adverse impact on our financial statements and reputation.

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

[Table of Contents](#)

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 successfully complete a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates or any of our other potential products. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. Although we oversee the contract manufacturers, we cannot control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements. If these facilities do not successfully complete 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 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 a manufacturer cannot meet the supply demand, supply from an alternative manufacturer would require the submission of a BLA/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. For example, on September 13, 2024, we announced that our third-party labeling and packaging CMO for UDENYCA delayed production of UDENYCA due to over-commitments and capacity constraints. These delays caused a temporary UDENYCA supply interruption that quickly took away our ability to sell our product UDENYCA, that makes up a large percentage of our total revenue, for a significant period of time. Production resumed in November 2024. The Company announced in January 2025 that due to strong demand in Q4 2024 and into Q1 2025, all three presentations of UDENYCA were being temporarily allocated. Based on individual distributor historical purchasing patterns, supply allocations to wholesalers for all three presentations of UDENYCA were removed between the end of January 2025 and the end of February 2025.

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 maintain regulatory approval for our biosimilar product.

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 continuing to develop our biosimilar product 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 are 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 cannot assure that our product liability coverage will cover in full claims to which we are exposed. We may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. A successful product liability claim or series of claims brought against us could adversely affect our results of operations and business. In addition, regardless of merit or eventual outcome, product liability claims may result in impairment of our business reputation, withdrawal of clinical study participants, costs due to related litigation, distraction of management's attention from our primary business, initiation of investigations by regulators, substantial monetary awards to patients or other claimants, the inability to commercialize our product candidates and decreased demand for our product candidates, if approved for commercial sale.

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including but not limited to:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label;

[Table of Contents](#)

- 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.

For our products and 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, other biosimilars of such originator product or other anti-PD-1 or PD-L1 antibody product may negatively affect our business.

In the event that use of an originator product, other biosimilar for such originator product, or anti-PD-1 or PD-L1 antibody product results in unanticipated side effects or other adverse events, it is likely that our product will be viewed comparably and may become subject to the same scrutiny and regulatory sanctions as the originator product, other biosimilar, or other anti-PD-1 or PD-L1 antibody product, 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, other biosimilar, or other anti-PD-1 or PD-L1 antibody product, as applicable, if and until we are able to demonstrate to the satisfaction of our regulators that our product is not subject to the same issues leading to the regulatory action as the originator product or other biosimilar, or other anti-PD-1 or PD-L1 antibody product, 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 company that originated the product for which we introduced a biosimilar version, such as Amgen, 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 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.

[Table of Contents](#)

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 or unenforceable, and we may not be able to do this. Proving that a patent is invalid or unenforceable is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Also, in proceedings before courts in Europe, the burden of proving invalidity of the patent usually rests on the party alleging invalidity. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on us. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

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

In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference, 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 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

[Table of Contents](#)

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

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

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

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

We employ individuals, retain independent contractors and consultants and members on our board of directors or scientific advisory board who were previously employed at universities or other pharmaceutical companies, including our competitors or potential competitors. For example, our Chief Executive Officer, Dennis M. Lanfear is a former employee of Amgen. Mr. Lanfear was employed at Amgen during periods when Amgen's operations included the development and commercialization of Neulasta. Senior members of our commercial team and medical affairs team who were responsible for the 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 Amgen and

[Table of Contents](#)

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, until the closing of the UDENYCA Sale, and from July 1, 2019 to July 1, 2024 we paid a mid-single digit royalty to Amgen.

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 that are important to our business, and we expect to enter into additional license agreements in the future. Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty and other obligations on us. If we fail to comply with our obligations under these agreements or we are subject to a bankruptcy, we may be required to make certain payments to the licensor, we may lose the license or the licensor may have the right to terminate the license, in which event we would not be able to develop or market products covered by the license. Additionally, the milestone and other payments associated with these licenses will make it less profitable for us to develop our product candidates.

In the event we breach any of our obligations related to such agreements, we may incur significant liability to our licensing partners. Disputes may arise regarding intellectual property subject to a licensing agreement, including but not limited to:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patents and other rights;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our collaborators; and
- the priority of invention of patented technology.

If disputes over intellectual property and other rights that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates and that could have a material adverse effect on our business.

We may not be successful in obtaining or maintaining necessary rights to our products and 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 and commercialize our products and 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,

[Table of Contents](#)

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. We may also get into disputes or litigation with third parties from whom we license intellectual property rights necessary for the sale of our products.

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.

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 invest substantial 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 two approved products: UDENYCA and LOQTORZI.

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. Other than certain pharmacokinetic 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. Neither we nor any collaboration partner has obtained regulatory approval for any of our products and product candidates, other than UDENYCA, which has

[Table of Contents](#)

received approval from the FDA and EMA, and LOQTORZI, which has received approval from the FDA and is also approved for use in China, and it is possible that none of our other current or future product candidates will ever obtain additional regulatory approvals.

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, which may be unavailable to us on acceptable terms or at all.

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:

[Table of Contents](#)

- 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;
- delays in patients completing participation in a study or return for post-treatment follow-up, or patients dropping out of a study;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- the cost of clinical studies of our product candidates being greater than we anticipate;
- clinical studies of our product candidates producing negative or inconclusive results, which may result in us deciding or regulators requiring us to conduct additional clinical studies or abandon product development programs; and
- delays in manufacturing, testing, releasing, validating or importing/exporting and/or distributing sufficient stable quantities of our product candidates and originator products for use in clinical studies or the inability to do any of the foregoing.

Any inability to successfully complete nonclinical and clinical development could result in additional costs to us or impair our ability to continue 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.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

Patient enrollment is a significant factor in the timing of clinical trials, and the timing of our clinical trials will depend, in part, on the speed at which we can recruit patients to participate in our trials, as well as completion of required follow-up periods. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials to such trial's conclusion as required by the FDA or other comparable regulatory authorities. Some of the conditions for which we may plan to evaluate our product candidates are rare diseases with limited patient pools from which to draw for clinical trials. The eligibility criteria of our clinical trials, once established, may further limit the pool of available trial participants.

Patient enrollment in clinical trials may be affected by other factors, including:

- size and nature of the targeted patient population;
- severity of the disease or condition under investigation;
- availability and efficacy of approved therapies for the disease or condition under investigation;
- patient eligibility criteria for the trial in question as defined in the protocol;
- perceived risks and benefits of the product candidate under study;

[Table of Contents](#)

- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any products that may be approved for, or any product candidates under investigation for, the indications we are investigating;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- proximity and availability of clinical trial sites for prospective patients;
- continued enrollment of prospective patients by clinical trial sites; and
- the risk that patients enrolled in clinical trials will drop out of such trials before completion.

Additionally, other pharmaceutical companies targeting these same diseases are recruiting clinical trial patients from these patient populations, which may make it more difficult to fully enroll any clinical trials. We also rely on, and will continue to rely on, CROs and clinical trial sites to ensure proper and timely conduct of our clinical trials and preclinical studies. Though we have entered into agreements governing their services, we will have limited influence over their actual performance. Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates and jeopardize our ability to obtain regulatory approval for the sale of our product candidates.

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 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 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) are determined to be interchangeable and our biosimilar product is 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 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. For example, recent U.S. legislative proposals have sought to reduce or altogether eliminate the statutory and regulatory distinctions between interchangeable products and conventional biosimilars. Such efforts, if successful, could reduce or eliminate any competitive or regulatory advantages currently afforded to interchangeable products.

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 LOQTORZI and UDENYCA in the United States, and subject to product approvals and relevant patent and settlement agreement expirations, we intend to market our other 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 / Gador for the commercialization of a biosimilar version of pegfilgrastim (Neulasta) in certain Caribbean and Latin American countries. We intend to market our products in the United States and may seek to partner commercially all products outside the United States, such as our Canada License Agreement with Apotex in Canada for LOQTORZI.

[Table of Contents](#)

In order to market our products in the E.U., the United States and other jurisdictions, we and our collaboration partners must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The EMA is responsible for the centralized procedure for the regulation and approval of human medicines. This procedure results in a single marketing authorization that is valid in all E.U. countries, as well as in Iceland, Liechtenstein and Norway. The time required to obtain approval abroad may differ from that required to obtain FDA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval and we may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by 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; 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 average manufacturer price (“AMP”) definition under the Medicaid Drug Rebate Program (“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.

[Table of Contents](#)

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 eliminated the statutory cap on the Medicaid drug rebate beginning January 1, 2024. The rebate was previously capped at 100% of a drug's AMP.

Most significantly, on August 16, 2022, the IRA was signed into law. 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. HHS has and will continue to issue and update guidance as these programs are implemented. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. For that and other reasons, the impact of the IRA on our business and the pharmaceutical industry cannot yet be fully determined. 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. Additionally, in response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the Center for Medicare and Medicaid Innovation which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future.

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, drug price reporting and other transparency measures, and, in some cases, measures designed to encourage importation from other countries and bulk purchasing. Some states have enacted legislation creating so-called prescription drug affordability boards, which ultimately may attempt to impose price limits on certain drugs in these states. 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, 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 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

[Table of Contents](#)

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 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-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 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

[Table of Contents](#)

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 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 make any assurances 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 \$0.66 to \$38.10 per share during the period from November 6, 2014 through December 31, 2024 and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include those discussed in the “Risk Factors” section of this Annual Report on Form 10-K and others such as:

- adverse results or delays in preclinical or clinical studies;
- the risk of deterioration in our financial conditions, such as reduced collection of cash and increased costs in the future;
- any inability to obtain additional funding;
- any delay or inability to satisfy the conditions to closing of the UDENYCA Sale or failure to receive either of the Earnout Payments after the closing;
- 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 products;
- 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;
- future outbreaks of COVID-19 and other viral pandemics;
- any inability to obtain adequate product supply for our products and product candidates or the inability to do so at acceptable prices;
- adverse regulatory decisions;
- introduction of new products, services or technologies by our competitors;
- failure to meet or exceed financial projections we may provide to the public;
- failure to meet or exceed the financial projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;

[Table of Contents](#)

- announcements of significant acquisitions, dispositions, 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 our biosimilar product;
- 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 company or 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 intended as a biosimilar to such originator products; and
- changes in 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.

We have identified a material weakness in our internal control over financial reporting and may identify additional material weaknesses in the future or otherwise fail to maintain effective internal control over financial reporting, which may result in a material misstatement of our consolidated financial statements or cause us to fail to meet our periodic reporting obligations.

Effective internal controls are necessary to provide reliable financial reports and to assist in the effective prevention of fraud. Any inability to provide reliable financial reports or prevent fraud could harm our business. We regularly review and update our internal controls, disclosure controls and procedures, and corporate governance policies. In addition, we are required under the Sarbanes-Oxley Act of 2002 to report annually on our internal control over financial reporting. Any system of internal controls, however well designed and operated, is based in part on certain assumptions and can provide only reasonable, not absolute, assurances that the objectives of the system are met.

As discussed below in Item 9A, "Controls and Procedures," of this Annual Report on Form 10-K, we have identified a material weakness in the operating effectiveness of our procedures related to documentation and review of certain inventory account reconciliations. The lack of sufficient evidence of the review performed over these accounting records did not allow for the testing and validation that the relevant internal controls operated, and thus it resulted in the material weakness. This material weakness related to documentation and did not result in a misstatement with respect to our financial statements included in this Form 10-K. As a result of this material weakness, our management concluded that our internal control over financial reporting was not effective as of December 31, 2024. Notwithstanding this material weakness, our management concluded the consolidated financial statements included in this Annual Report on Form 10-K present fairly, in all material respects, our financial condition, results of operations and cash flows for the periods covered by this report and our external auditors have issued an unqualified opinion on our consolidated financial statements as of and for the year ended December 31, 2024.

Following identification of this material weakness, and as part of our commitment to strengthen our internal control over financial reporting, we are implementing remedial actions to address this deficiency. The remediation measures include additional training and enhancement of our documentation and retention procedures, particularly as they relate to our inventory account reconciliations. This

[Table of Contents](#)

remediation is in progress and will require validation and testing of operating effectiveness of internal controls over multiple financial reporting cycles.

We will continue to monitor the design and operating effectiveness of these and other processes, procedures and controls and make any further changes management determines are appropriate. While we are undertaking efforts to remediate this material weakness, the material weakness will not be considered remediated until our remediation plan has been fully implemented, the applicable controls operate for a sufficient period of time, and we have concluded, through testing, that the newly implemented and enhanced controls are operating effectively. At this time, we cannot predict the success of such efforts or the outcome of our assessment of the remediation efforts. We can give no assurance that our efforts will remediate this material weakness in our internal control over financial reporting, or that additional material weaknesses will not be identified in the future. The effectiveness of our internal control over financial reporting is subject to various inherent limitations, including judgments used in decision making, assumptions about the likelihood of future events, the possibility of human error and the risk of fraud. If we are unable to remediate the material weakness, our ability to maintain compliance with the covenants contained in our 2029 Loan Agreement, record, process and report financial information accurately, and to prepare the consolidated financial statements within the time periods specified by the rules and regulations of the SEC, could be adversely affected which, in turn, may adversely affect our reputation and business and the trading price of our common stock.

Any failure to implement new or improved controls, or difficulties encountered in their implementation, could result in errors in our consolidated financial statements and could cause us to fail to meet our reporting obligations, any of which could diminish investor confidence in us and cause a decline in the price of our common stock. In addition, any such failures could result in litigation or regulatory actions by the SEC or other regulatory authorities, loss of investor confidence, delisting of our common stock, harm to our reputation or diversion of management resources from the operation of our business.

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, 2024, our executive officers, directors, five percent stockholders and their affiliates beneficially owned approximately 32.3% 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;
- increasing our need to meet minimum net sales requirements when our future sales are uncertain;
- 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 entered into the 2029 Loan Agreement that contains affirmative and negative covenants that restrict our operations, including, among other restrictions, the requirement to maintain

[Table of Contents](#)

certain levels of cash and cash equivalents. Further, the 2029 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. We may need to request waivers from time to time with respect to the 2029 Loan Agreement and if we are unable to obtain a waiver that we need it could materially impact our business and financial results.

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, 2024, there were 115,614,548 shares of our common stock outstanding.

In addition, as of December 31, 2024, approximately 37.2 million shares of common stock that are either subject to outstanding options and restricted stock units or reserved for future issuance under our equity incentive plans were eligible or may become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold or if it is perceived that they will be sold in the public market, the market price of our common stock could decline.

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

We have needed and anticipate we will need additional capital in the future to continue our planned operations. To the extent that we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. Similar to prior or ongoing financing transactions like the ATM Offering or the exchange of our shares for shares of outstanding stock of Surface as part of the acquisition of Surface, 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 Amended and Restated 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. Any increase in the number of shares available for future grant under the 2014 Plan must be approved by our stockholders. 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 were automatically increased 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. Pursuant to our 2016 Employment Commencement Incentive Plan (the “2016 Plan”), our management was authorized to grant stock options and other equity-based awards to our new employees, however in connection with the approval of the 2014 Plan in 2024, we agreed that we would not make any new awards under the 2016 Plan after the effective date of the 2014 Plan.

In April 2020, we issued and sold \$230.0 million aggregate principal amount of our 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. 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. We plan to use a portion of the proceeds of the UDENYCA Sale to fully repay the entirety of the 2026 Convertible Notes.

Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults, or non-performance by financial institutions or transactional counterparties, could adversely affect our business operations, financial condition, results of operations and prospects.

Our cash and cash equivalents are deposited or invested with several banks and other financial institutions. Actual events involving reduced or limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds, have in the past and may in the future lead to market-wide liquidity problems. For example, in March 2023, Silicon Valley Bank was closed and taken over by the Federal Deposit Insurance Corporation and subsequently had all of its customer deposits and other liabilities and

[Table of Contents](#)

substantially all loans and other assets acquired by First-Citizens Bank & Trust Company. We had approximately \$126.0 million of cash, cash equivalents and marketable securities as of December 31, 2024 with the majority held by custodians or in money market mutual funds that are not bank deposits. Our bank deposits are primarily held in accounts at three large banks that we believe to be stable at this time. Actual and perceived stability of banks can change from time to time and adverse perceptions by customers or investors about the banks where we deposit money could result in a material and adverse effect on our ability to access necessary cash. Investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources, could, among other risks, adversely impact our ability to access funds for our basic operating expenses, financial obligations, payroll or fulfill our other important obligations. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity, business operations, financial condition, results of operations and prospects.

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 potential return to stockholders will therefore be limited to the appreciation of their stock, if any.

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.

[Table of Contents](#)

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

We depend on a limited number of wholesalers for a significant amount of our total revenue, and if we lose any of our significant wholesalers, our business could be harmed.

We sell our products to wholesalers and distributors and the wholesalers and distributors then resell to hospitals and clinics pursuant to contracts with us. The majority of our revenue comes from a limited number of wholesalers. In 2024, three wholesalers individually comprised approximately 42%, 38%, and 18%, respectively, of our total gross product revenue. We expect that revenue from a limited number of wholesalers will continue to account for a large portion of our revenue in the future. The loss by us of any of these wholesalers, or a material reduction in their purchases or their market pricing, could harm our business, results of operations, financial condition and prospects. In addition, if any of these wholesalers were to fail to pay us in a timely manner, it could harm our cash flow.

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

We currently have limited international operations of our own and have 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:

- 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;
- foreign CMOs may be subject to U.S. legislation, sanctions, trade restrictions, new or increasing tariffs, retaliatory trade actions due to recent or future trade tension and other regulatory requirements which could increase the cost or reduce the supply of material available to us, delay the procurement or supply of such material or have an adverse effect on our ability to secure commitments from governments to purchase our products;
- 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;

[Table of Contents](#)

- expose us to sanctions, such as the sanctions levied by United States, E.U. and Russian regulatory bodies in connection with the war between Russia and Ukraine; 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.

Although the degree of focus on these factors may change in the future, there is continued scrutiny 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 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 any new ESG regulations, for example, the SEC's proposed climate disclosure rules 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 pipeline candidates and thereby cause

[Table of Contents](#)

significant market entry delay, defeat our ability to market our products or cause us to abandon development or commercialization of a molecule.

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 products and 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,

[Table of Contents](#)

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 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.

In June 2023, the European Unitary Patent system and the European Unified Patent Court (“UPC”) were launched. European patent applications now have the option, upon grant of a patent, of becoming a Unitary Patent which is subject to the jurisdiction of the UPC. In addition, conventional European patents, both already granted at the time the new system began and granted thereafter, are subject to the jurisdiction of the UPC, unless actively opted out. This was a significant change in European patent practice, and deciding whether to opt-in or opt-out of Unitary Patent practice entails strategic and cost considerations. The UPC provides third parties with a new forum to centrally revoke our European patents and makes it possible for a third party to obtain pan-European injunctions against us. It will be several years before we will understand the scope of patent rights that will be recognized and the strength of patent remedies that will be provided by the UPC. While we have the right to opt our patents out of the UPC over the first seven years of the court’s existence, doing so may preclude us from realizing the benefits of the UPC. Moreover, the decision whether to opt-in or opt-out of Unitary Patent status will require coordinating with co-applicants, if any, adding complexity to any such decision.

We have issued patents and have filed patent applications, which are currently pending, covering various aspects of our products and 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 and methods of making it. 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 would cover the 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 products will avoid infringement of third-party patents.

[Table of Contents](#)

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 products and 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

[Table of Contents](#)

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 on may be adversely affected by earthquakes, wildfires 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, wildfires and other natural disasters. Wildfires have been increasing in intensity and frequency in recent years. We do not carry earthquake insurance. Earthquakes, wildfires 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 and conflicts in the Middle East may exacerbate certain risks we face.

The war between Russia and Ukraine and the global response, including the imposition of sanctions by the United States and other countries, could create or exacerbate risks facing our business. Conflicts in the Middle East may also increase the risks facing our business. We have evaluated our operations and partner contracts, and we currently do not expect either conflict to directly have a significant effect on our financial condition or results of operations. However, if the war between Russia and Ukraine or conflicts in the Middle East escalate or expand, 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, and adverse impacts on, 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 conflicts, which could adversely affect our ability to maintain or enhance our cybersecurity measures. These and other risks are described more fully in this “Risk Factors” section.

[Table of Contents](#)

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. For example, as described elsewhere in this Annual Report on Form 10-K, our management concluded that our internal control over financial reporting was not effective as of December 31, 2024 due to a material weakness in the operating effectiveness of our procedures related to our documentation and review of certain inventory account reconciliations. We are taking steps to remediate this material weakness and to strengthen our internal control over financial reporting, which include additional training and enhancement of our documentation and retention procedures, particularly as they relate to our inventory account reconciliations. However, this remediation is in progress and will require validation and testing of operating effectiveness of internal controls over multiple financial reporting cycles and we cannot make any assurances as to when or whether the material weakness will be remediated.

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 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 or conflicts in the Middle East, may create a heightened risk of cyberattacks.

We collect and maintain information in digital form that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure to operate our business. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information, preclinical and clinical trial data, and personal information (collectively, "Confidential Information") of customers and our employees and contractors. It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such Confidential Information.

[Table of Contents](#)

Despite the implementation of security measures, our 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, misconfigurations, “bugs” or other vulnerabilities, “phishing” attacks, malware, ransomware, denial of service and other cyberattacks or disruptive incidents that could result in unauthorized access to, use or disclosure of, corruption of, or loss of Confidential Information, and could subject us to significant liabilities and regulatory and enforcement actions, and reputational damage.

In addition, geopolitical tensions or conflicts, such as the war between Russia and Ukraine or the conflicts in the Middle East, 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 Confidential 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. There can also be no assurance that our and our service providers’ cybersecurity risk management program and processes, including policies, controls or procedures, will be fully implemented, complied with or effective in protecting our systems, networks and Confidential Information.

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 continued hybrid working environment has generally increased 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 incidents, is increasing. 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 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 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

[Table of Contents](#)

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 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. The FTC has authority to initiate enforcement actions against entities that make deceptive statements about privacy and data sharing in privacy policies, fail to limit third-party use of personal health information, fail to implement policies to protect personal health information or engage in other unfair practices that harm customers or that may violate Section 5(a) of the FTC Act. Additionally, federal and state consumer protection laws are increasingly being applied by the FTC and states’ attorneys general to regulate the collection, use, storage, and disclosure of personal information, through websites or otherwise, and to regulate the presentation of website content.

In addition, state laws govern the privacy and security of personal 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 as amended by the California Privacy Rights Act (collectively, the “CCPA”), which requires covered businesses that process the personal information of California residents to, among other things: (i) provide certain disclosures to California residents regarding the business’s collection, use, and disclosure of their personal information; (ii) receive and respond to requests from California residents to access, delete, and correct their personal information, or to opt out of certain disclosures of their personal information; and (iii) enter into specific contractual provisions with service providers that process California resident personal information on the business’s behalf. Similar laws have passed in other states and are continuing to be proposed at the state and 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 or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our business and financial condition.

In addition, the regulatory framework for the receipt, collection, processing, use, safeguarding, sharing and transfer of personal 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 General Data Protection Regulation (“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. 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; and the efficacy and longevity of current transfer mechanisms between the EEA and the United States remains uncertain. Case law from the Court of Justice of the European Union (“CJEU”) states that reliance on the standard contractual clauses - a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism - alone may not necessarily be sufficient in all circumstances and that transfers must be assessed on a case-by-case basis. On July 10, 2023, the European Commission adopted its Adequacy Decision in relation to the new EU-US Data Privacy Framework (“DPF”) rendering the DPF effective as a GDPR transfer mechanism to U.S. entities self-certified under the DPF. We expect the existing legal complexity and uncertainty regarding international personal data transfers to continue. In particular, we expect the DPF Adequacy Decision to be challenged and international transfers to the United States and to other jurisdictions more generally to continue to be subject to enhanced scrutiny by regulators. As a result, we may have to make certain

[Table of Contents](#)

operational changes and we will have to implement revised standard contractual clauses and other relevant documentation for existing data transfers within required time frames. Penalties and fines for failure to comply with GDPR are significant, including fines of up to €20 million or 4% of the total worldwide annual turnover of a non-compliant undertaking, whichever is higher. In addition to fines, a breach of the GDPR may result in regulatory investigations, reputational damage, orders to cease/ change our data processing activities, enforcement notices, assessment notices (for a compulsory audit) and/ or civil claims (including class actions).

Further, since the beginning of 2021, we have also been subject to the United Kingdom General Data Protection Regulation and Data Protection Act 2018, which collectively 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 undertaking's global annual revenue for the preceding financial year, whichever is greater. On October 12, 2023, the U.K. Extension to the DPF came into effect (as approved by the U.K. government), as a data transfer mechanism from the U.K. to U.S. entities self-certified under the DPF. 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. 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 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 1C. Cybersecurity

Cybersecurity Risk Management and Strategy

We have developed and implemented a cybersecurity risk management program intended to protect the confidentiality, integrity, and availability of our critical systems and information. Our cybersecurity risk management program is designed to align with industry standards and incorporates best practices such as the National Institute of Standards and Technology (“NIST”) Cybersecurity Framework. This does not imply that we meet any particular technical standards, specifications, or requirements, only that we use the NIST as a guide to help us identify, assess, and manage cybersecurity risks relevant to our business.

We have also established an interdisciplinary Cybersecurity Incident Response Team (“CIRT”), which is responsible for our incident response plan, our security controls, and for assessing incidents reported by our information technology security team. In addition, our cybersecurity risk management program includes:

- Monitoring and evaluation of our vulnerability performance.
- Implementation of processes to oversee and identify risks from cybersecurity threats associated with our use of third-party service providers that have access to our critical systems and information. For any agreements with service providers that do not contain acceptable protections, we are working to put them in place on an ongoing basis.
- Risk assessments designed to help identify material cybersecurity risks to our critical systems, information, products, services, and our broader enterprise information technology environment. We use a third-party consultant to provide us with advisory, project execution, and operational support in connection with cybersecurity and to conduct NIST assessments and vulnerability evaluations.
- Cybersecurity awareness training of our employees, contractors, incident response personnel, and senior management.

We have not identified risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected or are reasonably likely to materially affect us, including our operations, business strategy, results of operations, or financial condition. For more information, see the section titled “Risk Factor— 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 or conflicts in the Middle East, may create a heightened risk of cyberattacks.”

Cybersecurity Governance

Risk assessment and oversight are an integral part of our governance and management processes. Our Board of Directors encourages management to promote a culture that incorporates risk management into our corporate strategy and day-to-day business operations. Our Board considers cybersecurity risk as part of its risk oversight function and oversees management’s implementation of our cybersecurity risk management program.

Management discusses strategic and operational risks at regular management meetings and conducts specific strategic planning and review sessions throughout the year. Throughout the year, senior management reviews these risks, including with respect to cybersecurity, with the Board of Directors at board meetings from time to time as part of management presentations that focus on particular business functions, operations or strategies and presents the steps taken by management to mitigate or eliminate such risks. We have implemented a risk-based approach to identify and assess the cybersecurity threats that could adversely affect our business, data or information systems that we use or own.

Our Vice President of Information Technology, as head of our information technology team, leading our cybersecurity efforts, oversees the day-to-day administration of our cybersecurity program. Our CIRT has members that include our Chief Executive Officer, Chief Financial Officer, Vice President, Corporate & Securities Law, and Vice President of Information Technology. As key members of our management team, our Chief Executive Officer, Chief Financial Officer, and Vice President of Information Technology have approximately a combined 48 years of risk management experience and are responsible for assessing and managing our material risks from cybersecurity threats. The team has primary responsibility for our overall cybersecurity risk management program and supervises both our internal cybersecurity personnel and our retained external cybersecurity consultants. Key members of our information technology management team collectively possess over 16 years of hands-on experience in implementing a diverse array of cybersecurity initiatives. Their expertise

[Table of Contents](#)

spans both cloud and on-premise IT infrastructure and applications/systems, cultivated through extensive engagement across various regulated environments.

Our management team supervises efforts to prevent, detect, mitigate, and remediate cybersecurity risks and incidents through various means, which may include briefings from internal security personnel; threat intelligence and other information obtained from governmental, public or private sources, including external consultants engaged by us; and alerts and reports produced by security tools deployed in the information technology environment.

Item 2. *Properties*

Our headquarters are located in Redwood City, California, where we occupy office space under a lease that was amended in October 2023. Pursuant to the lease amendment, we extended the term of the lease through September 30, 2027 for approximately 27,532 square feet of office space.

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 9. “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, 2025, there were approximately 81 stockholders of record of our common stock.

Dividends

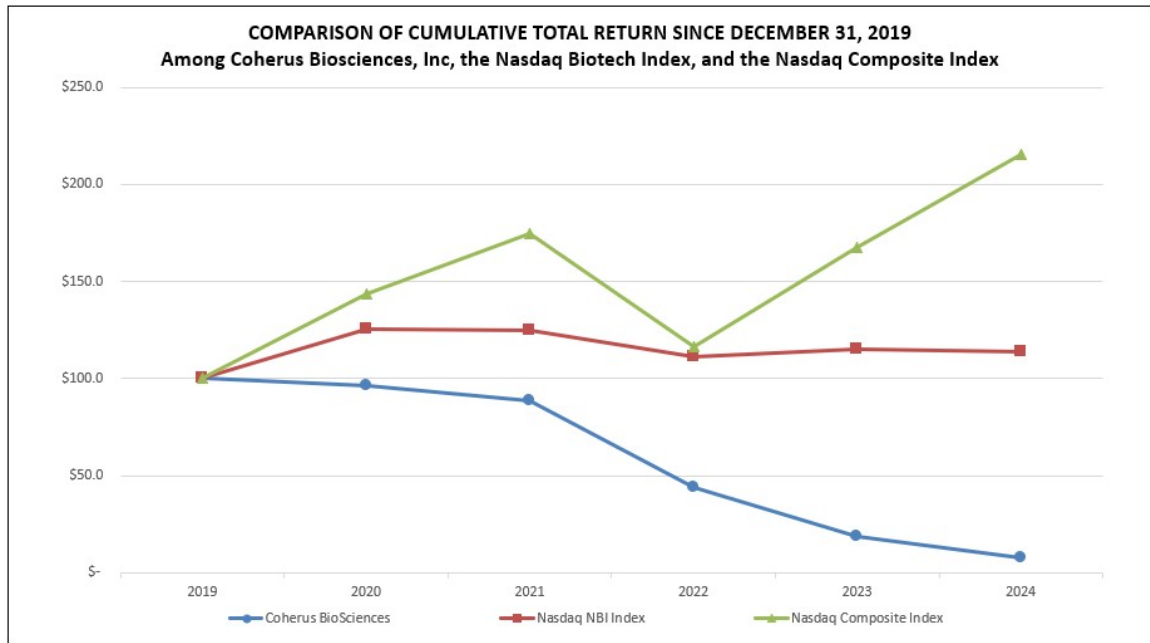
We have never declared or paid any cash dividends on our capital stock and do not anticipate paying cash dividends in the foreseeable future.

Stock Performance Graph

The following graph shows the total stockholder’s return on an investment of \$100 in cash at market close on December 31, 2019 through December 31, 2024 for (i) our common stock, (ii) the Nasdaq Composite Index and (iii) the Nasdaq Biotechnology Index. Pursuant to applicable Securities and Exchange Commission rules, all values assume reinvestment of the full amount of all dividends, however, no dividends have been declared on our common stock to date. The stockholder return shown on the graph below is not necessarily indicative of future performance, and we do not make or endorse any predictions as to future stockholder return. This graph shall not be deemed “soliciting material” or be deemed “filed” for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities under that

[Table of Contents](#)

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, 2024 through December 31, 2024, 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, 2024. A total of 10,807 shares were surrendered to Coherus in the fourth quarter of 2024, 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 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 2024 and 2023 items and year-to-year comparisons between 2024 and 2023. Discussions of 2022 items and year-to-year comparisons between 2023 and 2022 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, 2023, filed with the SEC on March 15, 2024.

Overview

We are a commercial-stage biopharmaceutical company focused on the research, development and commercialization of innovative immunotherapies to treat cancer. Our commercial portfolio includes our first product, UDENYCA (pegfilgrastim-cbqv), a biosimilar to Neulasta, a long-acting G-CSF, and LOQTORZI, a novel next-generation PD-1 inhibitor. We are developing an innovative immuno-oncology pipeline that is expected to bring forward new potential indications for LOQTORZI in the U.S. and the development of new product candidates.

UDENYCA was launched commercially in a pre-filled syringe presentation in the United States in January 2019, followed by the launch of UDENYCA in an autoinjector presentation in May 2023 and the launch of UDENYCA ONBODY in February 2024. On December 2, 2024, we and Intas entered into the UDENYCA Purchase Agreement, pursuant to which, and upon the terms and subject to the conditions thereof, we have agreed to divest the UDENYCA Business to Intas. As consideration for the UDENYCA Sale, Intas has agreed to pay us \$483.4 million in cash, inclusive of \$118.4 million of UDENYCA product inventory, subject to downward adjustment by the amount of inventory delivered at the closing of the UDENYCA Sale less than the Inventory Target. Intas has designated Accord to purchase the physical assets, including product inventory. In addition, the Company is also eligible to receive two Earnout Payments of \$37.5 million each, provided that certain minimum UDENYCA Net Sales thresholds are met during specified periods after the closing of the UDENYCA Sale. We anticipate the transactions contemplated by the UDENYCA Purchase Agreement to close late in the first quarter or early in the second quarter of 2025. We expect to use proceeds from the UDENYCA Sale (a) to fully repay our outstanding \$230.0 million in aggregate principal amount of 2026 Convertible Notes and (b) to pay \$47.7 million to buy out the right to receive royalties on net sales of UDENYCA in accordance with our Revenue Purchase and Sale Agreement. In addition, we will use the proceeds for working capital and general corporate purposes, in connection with our continued business.

On October 27, 2023, we announced that LOQTORZI was approved by the FDA in combination with cisplatin and gemcitabine for the first-line treatment of adults with metastatic or recurrent locally advanced NPC, and as monotherapy for the treatment of adults with recurrent unresectable, or metastatic NPC with disease progression on or after platinum-containing chemotherapy. LOQTORZI is an anti-PD-1 antibody that we developed in collaboration with Junshi Biosciences that is currently the only immune checkpoint inhibitor approved by the FDA for the treatment of these indications. We announced the launch of LOQTORZI in the U.S. on January 2, 2024. Further evaluation of LOQTORZI is expected through multiple current and planned clinical studies by us, Junshi Biosciences and our biopharma partners.

Our pipeline is comprised of earlier stage clinical and preclinical immuno-oncology programs that we plan to develop in combination with LOQTORZI as well as in partnership with other companies with immune activating or cancer agents. Our lead clinical stage product candidate is casdozokitug (CHS-388, formerly SRF388), an investigational antagonist antibody targeting IL-27, an immune regulatory cytokine, that is overexpressed in certain cancers, including hepatocellular, lung and renal cell carcinoma. Casdozokitug received orphan drug designation from the FDA for the treatment of HCC in October 2020 and fast track designation from the FDA for the treatment of patients with HCC previously treated with standard therapies in November 2020. Casdozokitug is currently in three on-going clinical studies, including a Phase 1/2 study in patients with advanced solid tumors, including in combination with toripalimab in non-small cell lung cancer (clinicaltrials.gov identifier# NCT04374877), and a Phase 2 study in HCC (clinicaltrials.gov identifier# NCT05359861). We initiated a randomized Phase 2 study in HCC evaluating casdozokitug in combination with toripalimab and bevacizumab in the fourth quarter of 2024 (clinicaltrials.gov identifier# NCT06679985).

Our second clinical-stage product candidate, CHS-114 (formerly SRF114), is an investigational IgG1 antibody targeting CCR8, a chemokine receptor highly expressed on Treg cells in the TME. We are enrolling patients with advanced solid tumors and HNSCC in the U.S. in a clinical trial evaluating safety and pharmacokinetics of CHS-114 with and without LOQTORZI (clinicaltrials.gov identifier# NCT05635643). We plan to initiate a Phase 1b clinical study of CHS-114 in combination with toripalimab in second-line HNSCC (clinicaltrials.gov identifier# NCT05635643) and initiate a Phase 1b clinical study of CHS-114 in combination with toripalimab and/or other treatments in participants with advanced solid tumors with the first cohort evaluating gastric cancer (clinicaltrials.gov identifier# NCT06657144), each in the first quarter of 2025.

We also have an early-stage development candidate, CHS-1000, an investigational antibody targeting human ILT4, designed to improve anti-PD-1 clinical benefit by transforming an unfavorable TME to a more favorable TME. Our IND for CHS-1000 was allowed to proceed by the FDA in the second quarter of 2024 and initiating the first-in-human clinical study remains subject to further evaluation in our portfolio prioritization process.

In addition, we have a product candidate, GSK4381562, which is exclusively licensed to GSK. Through September 2033, we have an obligation to pay 70% of all milestone- and royalty-based payments that we or our affiliates receive from GSK4381562 to the holders of CVRs.

[Table of Contents](#)

We have a depth of scientific expertise, an experienced and robust manufacturing know-how and oncology clinical, regulatory, market access, sales, key account management and medical affairs capabilities in the United States, which has supported the commercialization of LOQTORZI. We expect to further leverage these capabilities as we continue to advance our immuno-oncology franchise.

We primarily operate in the United States and partner with companies that operate in other countries.

Business Update

UDENYCA Sale

On December 2, 2024, we entered into the UDENYCA Purchase Agreement by and between us and Intas. Pursuant to the terms and subject to the conditions set forth in the UDENYCA Purchase Agreement, we have agreed to divest the UDENYCA Business to Intas for \$483.4 million in cash, inclusive of \$118.4 million of UDENYCA product inventory, subject to downward adjustment by the amount of inventory delivered at the closing of the UDENYCA Sale less than the Inventory Target. In addition, we are also eligible to receive two additional Earnout Payments of \$37.5 million each, provided that certain minimum UDENYCA Net Sales thresholds are met during specified periods after the closing of the UDENYCA Sale. The first such payment is payable by Intas to us if net sales of UDENYCA for four consecutive fiscal quarters within the first five full fiscal quarters following the consummation of the UDENYCA Sale are equal to or greater than \$300 million, and the second such payment is payable by Intas to us if net sales of UDENYCA for four consecutive fiscal quarters within the first seven full fiscal quarters following the consummation of the UDENYCA Sale are equal to or greater than \$350 million.

Our board of directors unanimously approved and declared the UDENYCA Purchase Agreement and the transactions contemplated thereby, including the UDENYCA Sale, to be in the best interest of the Company and its stockholders, and resolved to recommend that the our stockholders adopt the UDENYCA Purchase Agreement. There was a vote of our stockholders at a special stockholder meeting on March 11, 2025 where our stockholders approved the UDENYCA Sale, the UDENYCA Purchase Agreement and the other transactions and ancillary documents contemplated by the Asset Purchase Agreement.

Closing of the UDENYCA Sale is not subject to a financing condition, but is subject to closing conditions, including (i) approval of our stockholders, which has occurred, (ii) the expiration or earlier termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, which has occurred, (iii) clearance from Committee on Foreign Investment in the United States or any member agency thereof acting in its capacity as a member agency, which has occurred, and (iv) certain additional closing conditions related to packaging by our packaging and labeling CMOs for UDENYCA and FDA authorization of commercial supply from our additional packaging and labeling CMO for UDENYCA.

Assuming the satisfaction of the conditions set forth in the UDENYCA Purchase Agreement, we anticipate the transactions contemplated thereby to close late in the first quarter or early in the second quarter of 2025.

UDENYCA Supply Interruption

On September 13, 2024, we announced that our third-party labeling and packaging CMO for UDENYCA delayed production of UDENYCA due to over-commitments and capacity constraints. These delays caused a temporary UDENYCA supply interruption that quickly took away our ability to sell our product UDENYCA, that makes up a large percentage of our total revenue, for a significant period of time. Production resumed in November 2024. The Company announced in January 2025 that due to strong demand in Q4 2024 and into Q1 2025, all three presentations of UDENYCA were being temporarily allocated. Based on individual distributor historical purchasing patterns, supply allocations to wholesalers for all three presentations of UDENYCA were removed between the end of January 2025 and the end of February 2025.

We have made significant progress in our efforts to diversify our labeling and packaging resources. An additional labeling and packaging CMO started production testing and manufacturing saleable product. Commercial supply from that CMO is expected to commence late in the first quarter or early in the second quarter of 2025, subject to FDA authorization. For a discussion of risks related to manufacturing our products and our reliance on third parties, please see “Risk Factors—Risks Related to Manufacturing and Supply Chain” and “Risk Factors—Risks Related to Reliance on Third Parties.”

Products and Product Candidates

Our portfolio includes the following products and product candidates:

Oncology

- UDENYCA was launched commercially in a pre-filled syringe presentation in the United States in January 2019, followed by the launch of UDENYCA in an autoinjector presentation in May 2023 and the launch of UDENYCA ONBODY in February 2024. On December 2, 2024, we and Intas entered into the UDENYCA Purchase Agreement, pursuant to which, and upon the terms and subject to the conditions thereof, we have agreed to divest the UDENYCA Business to Intas. We anticipate the transactions contemplated by the UDENYCA Purchase Agreement to close late in the first quarter or early in the second quarter of 2025.
- LOQTORZI was 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 receptor. 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. On October 27, 2023, we announced that LOQTORZI was approved by the FDA in combination with cisplatin and gemcitabine for the first-line treatment of adults with metastatic or recurrent locally advanced NPC, and as monotherapy for the treatment of adults with recurrent, unresectable, or metastatic NPC with disease progression on or after platinum-containing chemotherapy. LOQTORZI is an anti-PD-1 antibody that we developed in collaboration with Junshi Biosciences. We announced the launch of LOQTORZI in the U.S. on January 2, 2024.

On December 11, 2023 we announced that NCCN updated the clinical practice guidelines for NPC to include LOQTORZI as a preferred, category 1 first-line treatment option for adults with metastatic or recurrent locally advanced NPC when used in combination with cisplatin and gemcitabine. On November 26, 2024, NCCN made a further update to the clinical practice guidelines for NPC to specify that LOQTORZI is the only preferred category 1 first-line treatment option for adults with metastatic or recurrent locally advanced NPC when used in combination with cisplatin and gemcitabine. The guidelines also recommend LOQTORZI monotherapy as the only preferred treatment in subsequent lines of therapy if disease progression on or after a platinum-containing therapy.

Further evaluation of LOQTORZI is expected through multiple current and planned clinical studies by us and our partners. We have a postmarketing commitment study active and enrolling patients in locations in the U.S. and Canada in order to further evaluate the efficacy of toripalimab in combination with chemotherapy (cisplatin and gemcitabine) in patients with advanced NPC (clinicaltrials.gov identifier NCT06457503). Junshi Biosciences is currently enrolling in a multiregional Phase 3 clinical study evaluating the treatment of LOQTORZI with its investigational anti-BTLA antibody in LS-SCLC (clinicaltrials.gov identifier NCT06095583). INOVIO Pharmaceuticals, Inc. plans a randomized Phase 3 study of INO-3112 and toripalimab in locally advanced, high risk HPV16/18+ oropharyngeal squamous cell carcinoma. CRI plans to evaluate toripalimab in combination with ENB Therapeutics' investigational agent ENB-003 in its Phase 2 trial titled, "Immunotherapy Platform Study in Platinum Resistant High Grade Serous Ovarian Cancer (IPROC)" (clinicaltrials.gov identifier NCT04918186) that is being performed in collaboration with CCTG. On June 27, 2024, we entered into the Canada License Agreement with Apotex, pursuant to which, we granted to Apotex an exclusive license under our rights to toripalimab to commercialize toripalimab within Canada.

- Casdozokitug (CHS-388, formerly SRF388), is an investigational recombinant human IgG1 monoclonal antibody targeting IL-27, an immune regulatory cytokine, or protein that is overexpressed in certain cancers, including hepatocellular, lung and renal cell carcinoma. IL-27 is a cytokine secreted by macrophages and antigen presenting cells that plays an important physiologic role in suppressing the immune system, as evidenced by its ability to resolve tissue inflammation. In addition, IL-27 is highly expressed during pregnancy and its expression is correlated with maternal-fetal tolerance. Due to its immune regulatory nature, there is a rationale for inhibiting IL-27 to treat cancer, as this approach will influence the activity of multiple types of immune cells that are necessary to recognize and attack a tumor. Casdozokitug received orphan drug designation from the FDA for the treatment of HCC in October 2020 and fast track designation from the FDA for the treatment of HCC in November 2020. Casdozokitug is currently in three on-going clinical studies, including a Phase 1/2 study in advanced solid tumors (clinicaltrials.gov identifier# NCT04374877), a Phase 2 study in HCC (clinicaltrials.gov identifier# NCT05359861) and a randomized Phase 2 study in HCC evaluating casdozokitug in combination with toripalimab and bevacizumab (clinicaltrials.gov identifier# NCT06679985).

- CHS-114 (formerly SRF114), is an investigational highly specific human afucosylated IgG1 monoclonal antibody selectively targeting CCR8, a chemokine receptor highly expressed on Treg cells in the TME. CHS-114 is designed as a cytolytic antibody to cause depletion of intra-tumoral Treg cells, important regulators of immune suppression and tolerance, through ADCC, or ADCP or both. CHS-114 has shown anti-tumor activity as monotherapy or in combination with anti-PD-1 antibodies in preclinical models. We are enrolling patients with advanced solid tumors and HNSCC in the U.S. in a clinical trial evaluating safety and pharmacokinetics of CHS-114 with and without LOQTORZI (clinicaltrials.gov identifier# NCT05635643). We plan to initiate a Phase 1b clinical study of CHS-114 in combination with toripalimab in second-line HNSCC (clinicaltrials.gov identifier# NCT05635643) and to initiate a Phase 1b clinical study of CHS-114 in combination with toripalimab and/or other treatments in participants with advanced solid tumors with the first cohort evaluating gastric cancer (clinicaltrials.gov identifier# NCT06657144), each in the first quarter of 2025.
- CHS-1000 is an investigational antibody targeting human ILT4, designed to improve anti-PD-1 clinical benefit by transforming an unfavorable TME to a more favorable TME. Our IND for CHS-1000 was allowed to proceed by the FDA in the second quarter of 2024 and initiating the first-in-human clinical study remains subject to further evaluation in our portfolio prioritization process.
- GSK4381562 is exclusively licensed to GSK. GSK4381562 is an investigational antibody targeting PVRIG, an inhibitory protein expressed on NK and T cells. GSK4381562 is designed to block the interaction of PVRIG with CD112, its binding partner that is expressed on tumor cells. GSK4381562 is designed to promote the activation of both NK and T cells, with potential to elicit a strong anti-tumor response and promote immunological memory. Through September 2033, we have an obligation to pay 70% of all milestone- and royalty-based payments that we or our affiliates receive from GSK4381562 to the holders of CVRs.

Immunology – Sold to HKF pursuant to the YUSIMRY Sale

- YUSIMRY (adalimumab-aqvh), a biosimilar of Humira (adalimumab), is 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 launched in the United States in July 2023.

On June 26, 2024, we entered into the YUSIMRY Purchase Agreement with HKF and we completed the sale of our YUSIMRY franchise for upfront, cash consideration of \$40.0 million and the assumption of \$17.0 million of inventory purchase commitments by HKF. We retained the rights to certain patents that were licensed to Pfizer under the Pfizer License Agreement.

Ophthalmology – Sold to Sandoz pursuant to the CIMERLI Sale

- CIMERLI (ranibizumab-eqrn), a Lucentis biosimilar, was approved by the FDA on August 2, 2022 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 and we launched CIMERLI commercially in the United States on October 3, 2022.

On January 19, 2024, we entered into the CIMERLI Purchase Agreement by and between us and Sandoz. Pursuant to the terms and subject to the conditions set forth in the CIMERLI Purchase Agreement, on March 1, 2024, we completed the divestiture of our CIMERLI ophthalmology franchise through the sale of our subsidiary, Coherus Ophthalmology, to Sandoz for upfront, all-cash consideration of \$170.0 million plus an additional \$17.8 million for CIMERLI product inventory and prepaid manufacturing assets.

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 LOQTORZI, 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 LOQTORZI 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

[Table of Contents](#)

next-generation engineered IL-2 cytokine, and certain negotiation rights to two undisclosed preclinical immuno-oncology drug candidates. We obtained the right to conduct all commercial activities of LOQTORZI in the United States and Canada. We are obligated to pay Junshi Biosciences up to an aggregate \$380.0 million in one-time payments for the achievement of various regulatory and sales milestones, of which we have already paid \$25.0 million, and a royalty in the low twenty percent range on net sales of LOQTORZI. On June 27, 2024, we entered into the Canada License Agreement pursuant to which, we granted to Apotex an exclusive license under our rights to toripalimab to commercialize toripalimab within Canada.

In March 2022, we paid \$35.0 million for the exercise of our option to license CHS-006. Subsequent joint development consistent with the Collaboration Agreement commenced. On January 10, 2024, we announced that we had delivered a notice of termination of the TIGIT Program (as defined in the Collaboration Agreement) to Junshi Biosciences pursuant to the Collaboration Agreement. Under the Collaboration Agreement, we retain the right to collaborate in the development of LOQTORZI and the other licensed compounds and will pay for a portion of these co-development activities up to a maximum of \$25.0 million per licensed compound per year. Additionally, we are responsible for certain associated regulatory and technology transfer costs for LOQTORZI 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. As of December 31, 2024, we had an accrued expense of \$12.5 million for a milestone payable to Junshi Biosciences, which was paid in January 2025, as well as \$1.5 million for our royalty obligation. The additional milestone payments 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.

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 launched in the United States in July 2023. On August 2, 2022, the FDA approved CIMERLI, which we launched in the United States in October 2022. LOQTORZI was approved in October 2023, and we launched LOQTORZI in the United States in January 2024. We stopped receiving revenue from CIMERLI sales on March 1, 2024 as a result of the CIMERLI Sale. We stopped receiving revenue from YUSIMRY sales on June 26, 2024 as a result of the YUSIMRY Sale. On June 27, 2024, Apotex paid us an upfront payment of \$6.3 million which has been classified as net revenue in the consolidated statements of operations for the year ended December 31, 2024 pursuant to the terms of the Canada License Agreement. Our total net revenues were \$267.0 million and \$257.2 million in 2024 and 2023, respectively.

On December 2, 2024, we entered into the UDENYCA Purchase Agreement by and between us and Intas. Pursuant to the terms and subject to the conditions set forth in the UDENYCA Purchase Agreement, we have agreed to divest the UDENYCA Business to Intas for \$483.4 million in cash, inclusive of \$118.4 million of UDENYCA product inventory, subject to downward adjustment by the amount of inventory delivered at the closing of the UDENYCA Sale less than the Inventory Target. In addition, we are also eligible to receive two additional Earnout Payments of \$37.5 million each, provided that certain minimum UDENYCA Net Sales thresholds are met during specified periods after the closing of the UDENYCA Sale. The first such payment is payable by Intas to us if net sales of UDENYCA for four consecutive fiscal quarters within the first five full fiscal quarters following the consummation of the UDENYCA Sale are equal to or greater than \$300 million, and the second such payment is payable by Intas to us if net sales of UDENYCA for four consecutive fiscal quarters within the first seven full fiscal quarters following the consummation of the UDENYCA Sale are equal to or greater than \$350 million.

Cost of Goods Sold

Cost of goods sold consists primarily of third-party manufacturing, distribution, certain overhead costs, and royalties on certain products. On May 2, 2019, we settled a trade secret action brought by Amgen. As a result, cost of goods sold for the five-year period ending on July 1, 2024 reflects a mid-single digit royalty on UDENYCA net product revenue. Additionally, until the CIMERLI Sale on March 1, 2024, we shared a percentage of gross profits on sales of CIMERLI in the United States with Bioeq AG ("Bioeq") in the low- to mid-fifty percent range. Cost of goods sold includes a royalty in the low twenty percent range on net sales of LOQTORZI.

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

[Table of Contents](#)

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

- expense incurred under agreements with 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
- option 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 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, 2024	Year Ended December 31, 2024	2023
External costs incurred by product candidate:			
Casdozokitug	Clinical trials ⁽¹⁾	\$ 16,588	\$ 4,129
CHS-114	Clinical trials ⁽¹⁾	7,847	1,429
CHS-1000	IND approved	2,773	7,105
LOQTORZI	Approved ⁽²⁾	13,290	17,192
UDENYCA	Approved ⁽³⁾	3,612	4,476
YUSIMRY	Divested ⁽⁴⁾	545	7,273
CIMERLI	Divested ⁽⁵⁾	699	683
Other discontinued projects	Discontinued ⁽⁶⁾	2,305	5,856
Other research and development expenses		1,430	2,143
Internal costs		<u>44,247</u>	<u>59,150</u>
Total research and development expenses		<u>\$ 93,336</u>	<u>\$ 109,436</u>

(1) We acquired casdozokitug and CHS-114 in connection with the acquisition of Surface (the "Surface Acquisition") in September 2023.

(2) In October 2023, LOQTORZI was approved by the FDA in combination with cisplatin and gemcitabine for the first-line treatment of adults with metastatic or recurrent locally advanced NPC, and for LOQTORZI as monotherapy for the treatment of adults with recurrent, unresectable, or metastatic NPC with disease progression on or after platinum-containing chemotherapy.

(3) Expenses related primarily to development efforts and manufacturing process approval to obtain the prior approval supplement for additional presentations of UDENYCA. We anticipate the transactions contemplated by the UDENYCA Purchase Agreement to close late in the first quarter or early in the second quarter of 2025.

[Table of Contents](#)

- (4) YUSIMRY 2024 and 2023 expenses were primarily related to manufacturing efforts for new formulations and clinical studies. On June 26, 2024, we entered into the YUSIMRY Purchase Agreement with HKF and completed the sale of our YUSIMRY franchise.
- (5) On March 1, 2024, we completed the sale of our CIMERLI franchise pursuant to the CIMERLI Purchase Agreement with Sandoz.
- (6) These expenses primarily relate to our remaining obligations under the TIGIT Program (as defined in the Collaboration Agreement), which we terminated in January 2024.

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, certain transaction costs, and costs associated with establishing commercial capabilities in support of the commercialization of UDENYCA and LOQTORZI and the commercialization of CIMERLI and YUSIMRY up until the CIMERLI Sale and the YUSIMRY Sale, respectively. Personnel costs consist of salaries, benefits and stock-based compensation.

Interest Expense

Interest expense consists primarily of interest incurred on our outstanding indebtedness, our Revenue Purchase and Sale Agreement, and non-cash interest related to the amortization of debt discount and debt issuance costs associated with our outstanding debt agreements.

Gain on Sale Transactions, net

Gain on Sale Transactions, net consists of cash proceeds received from the CIMERLI Sale, net of assets sold (primarily CIMERLI product inventory and prepaid manufacturing assets), other assets derecognized (goodwill and intangible assets), net of related transaction costs, retention bonuses and stock-based compensation expense incurred, and the YUSIMRY Sale, net of assets sold (primarily YUSIMRY product inventory and prepaid manufacturing assets), other assets and liabilities derecognized (primarily purchase commitments and an intangible asset), and related transaction costs.

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 and cash equivalents, non-cash accretion of discount on our investments in marketable securities, foreign exchange gains (losses) resulting from currency fluctuations, gains (losses) from financial instruments including the change in fair value of the embedded derivative contained in the Revenue Purchase and Sale Agreement that meets the criteria to be bifurcated and accounted for separately from the Revenue Purchase and Sale Agreement (the "Royalty Fee Derivative Liability"), gains (losses) from disposal of long-lived assets, and income related to services provided under transition service agreements.

Results of Operations

Comparison of Years Ended December 31, 2024 and 2023

Revenue

(in thousands)	Year Ended December 31,		
	2024	2023	Change
Products			
UDENYCA ⁽¹⁾	\$ 205,951	\$ 127,064	\$ 78,887
CIMERLI - divested March 1, 2024	27,079	125,388	(98,309)
YUSIMRY - divested June 26, 2024	7,541	3,574	3,967
LOQTORZI	19,131	554	18,577
Total net product revenue	259,702	256,580	3,122
Other revenue	7,258	664	6,594
Total net revenue	<u>\$ 266,960</u>	<u>\$ 257,244</u>	<u>\$ 9,716</u>

- (1) We anticipate the transactions contemplated by the UDENYCA Purchase Agreement to close late in the first quarter or early in the second quarter of 2025.

[Table of Contents](#)

UDENYCA net revenue increased \$78.9 million primarily due to increased market share driven by sales of UDENYCA ONBODY, launched in February 2024, offset by a change in UDENYCA segment mix and the impact of the fourth quarter temporary UDENYCA supply interruption. The \$98.3 million decrease in net revenues of CIMERLI was primarily the result of the CIMERLI Sale. LOQTORZI net revenue reflects initial sales beginning in December 2023 following FDA approval. Other revenue in 2024 included \$6.3 million for the sale to Apotex of rights to commercialize toripalimab within Canada on June 27, 2024.

Following the stockholder approval obtained in March 2025, the contemplated UDENYCA Sale was determined to represent a strategic shift. Thus, beginning with the Quarterly Report on Form 10-Q for the first quarter of 2025, net revenues for the UDENYCA franchise and the previously divested CIMERLI and YUSIMRY franchises will be presented as discontinued operations, including comparative prior periods which will be recast. Our remaining product, LOQTORZI, will continue to be reflected in net product revenue, and we anticipate LOQTORZI's net product revenue will increase in 2025 compared to 2024.

Cost of Goods Sold

(in thousands)	Year Ended December 31,		
	2024	2023	Change
Cost of goods sold	\$ 117,553	\$ 158,992	\$ (41,439)
Gross margin	56 %	38 %	

The decrease in cost of goods sold in 2024 compared to 2023 was primarily due to a decrease of \$56.9 million in costs from CIMERLI, which was divested during the first quarter of 2024, and a \$47.0 million charge in the fourth quarter of 2023 related to slow moving YUSIMRY inventory. These decreases were partially offset by a \$34.3 million increase due to higher volumes of UDENYCA and LOQTORZI in 2024, \$14.1 million in charges in 2024 for the write-down of UDENYCA inventory that did not meet acceptance criteria, the \$7.3 million impact of the sales in 2023 of certain UDENYCA units having no carrying value following a prior period write-down, and \$4.4 million in connection with a CMO contract change in 2024.

Following the stockholder approval obtained in March 2025, the contemplated UDENYCA Sale was determined to represent a strategic shift. Thus, beginning with the Quarterly Report on Form 10-Q for the first quarter of 2025, cost of goods sold for the entire biosimilar business, inclusive of the UDENYCA, CIMERLI and YUSIMRY franchises, will be presented as discontinued operations, including comparative prior periods which will be recast, and cost of goods sold will only reflect costs for our remaining product, LOQTORZI.

Research and Development Expense

(in thousands)	Year Ended December 31,		
	2024	2023	Change
Research and development	\$ 93,336	\$ 109,436	\$ (16,100)

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

- a net decrease of \$14.5 million in personnel costs including stock-based compensation expense, primarily due to a decrease in headcount and restructuring charges of \$3.6 from our reduction in force in the first quarter of 2023;
- a decrease of \$7.4 million in co-development costs for toripalimab and CHS-006 resulting from reducing the scope of the development plan for toripalimab in the United States beginning in 2023 and the termination of the TIGIT Program announced in January 2024;
- a decrease of \$6.7 million in external costs related to YUSIMRY; and
- a decrease of \$4.3 million for fewer expenditures during the period for the development of CHS-1000.

The decrease was partially offset by the following:

- an increase of \$12.5 million for the development of casdozokitug; and
- an increase of \$6.4 million for the development of CHS-114.

[Table of Contents](#)

Following the stockholder approval obtained in March 2025, the contemplated UDENYCA Sale was determined to represent a strategic shift. Thus, beginning with the Quarterly Report on Form 10-Q for the first quarter of 2025, research and development for the entire biosimilar business, inclusive of the UDENYCA, CIMERLI and YUSIMRY franchises, will be presented as discontinued operations, including comparative prior periods which will be recast. Notwithstanding the retrospective reporting for discontinued operations, we expect our research and development expense in 2025 to increase as compared to 2024 due to continued investments in our immuno-oncology pipeline.

Selling, General and Administrative Expense

(in thousands)	Year Ended December 31,		
	2024	2023	Change
Selling, general and administrative	\$ 167,738	\$ 192,015	\$ (24,277)

The decrease in selling, general and administrative expense was driven primarily by lower headcount, including reductions of \$21.3 million in employee, consultant and travel costs, \$9.8 million in stock-based compensation, and decreased operating costs following divestitures. These decreases were partially offset by the \$6.8 million net impairment charge in 2024 relating to the full write-off of the out-license intangible asset of \$10.6 million and the final remeasurement of the CVR liability of \$3.8 million related to NZV930 to its fair value of zero.

Following the stockholder approval obtained in March 2025, the contemplated UDENYCA Sale was determined to represent a strategic shift. Thus, beginning with the Quarterly Report on Form 10-Q for the first quarter of 2025, selling, general and administrative expense for the entire biosimilar business, inclusive of the UDENYCA, CIMERLI and YUSIMRY franchises, will be presented as discontinued operations, including comparative prior periods which will be recast. Notwithstanding the retrospective reporting for discontinued operations, we expect our selling, general and administrative expense for the full year 2025 to be lower than the full year 2024 primarily as a result of decreased operating costs and headcount due to the divestitures.

Interest Expense

(in thousands)	Year Ended December 31,		
	2024	2023	Change
Interest expense	\$ 27,158	\$ 40,542	\$ (13,384)

The decrease in interest expense in 2024 was primarily due to fully paying off the \$250.0 million principal amount due under our senior secured term loan facility that was entered into on January 5, 2022 (as amended on April 7, 2022, February 6, 2023, and February 5, 2024, the "2027 Term Loans") in the second quarter of 2024, partially offset by interest on the 2029 Term Loan and the Revenue Purchase and Sale Agreement, both commencing May 8, 2024.

Following the stockholder approval obtained in March 2025, the contemplated UDENYCA Sale was determined to represent a strategic shift. Thus, beginning with the Quarterly Report on Form 10-Q for the first quarter of 2025, revenue and expenses for the entire biosimilar business, inclusive of the UDENYCA, CIMERLI and YUSIMRY franchises, will be presented as discontinued operations, including comparative prior periods which will be recast. As a result, interest on the 2026 Convertible Notes and a portion of the Revenue Purchase and Sale Agreement will be reported as discontinued operations. Notwithstanding the retrospective presentation of discontinued operations, we expect our interest expense for the full year 2025 to be lower than the full year 2024 primarily as a result of fully repaying the \$250.0 million principal amount of the 2027 Term Loans during the second quarter of 2024 and our plan to use a portion of the proceeds of the UDENYCA Sale, which we anticipate to close late in the first quarter or early in the second quarter of 2025, to pay off the 2026 Convertible Notes and to buy out the right to receive royalties on net sales of UDENYCA.

Gain on Sale Transactions, net

(in thousands)	Year Ended December 31,		
	2024	2023	Change
Gain on Sale Transactions, net	\$ 176,589	\$ —	\$ 176,589

The Gain on Sale Transactions, net for 2024 includes net gains for the first quarter CIMERLI Sale and second quarter YUSIMRY Sale. The net gain of \$153.8 million on the CIMERLI Sale includes the cash receipts of \$187.8 million less assets transferred to Sandoz, other assets derecognized, transaction costs of \$7.2 million, and other related employee transition expenses. The net gain of \$22.8 million on

[Table of Contents](#)

the YUSIMRY Sale to HKF includes the cash receipts of \$40.0 million less assets transferred to HKF, other assets and liabilities derecognized, and transaction costs of \$1.0 million.

Loss on Debt Extinguishment

(in thousands)	Year Ended December 31,		
	2024	2023	Change
Loss on debt extinguishment	\$ 12,630	\$ —	\$ 12,630

The \$12.6 million loss on debt extinguishment in 2024 resulted from the payoff of the 2027 Term Loans in May 2024, and included the write-off of the unamortized portion of debt discount and debt issuance costs, and the prepayment premium fee, the make-whole interest payment and lender fees.

Other Income (Expense), Net

(in thousands)	Year Ended December 31,		
	2024	2023	Change
Other income (expense), net	\$ 3,373	\$ 5,469	\$ (2,096)

Other income (expense), net in 2024 changed unfavorably compared to 2023 primarily due to the change in fair value of the Royalty Fee Derivative Liability of \$4.4 million and a reduction of \$1.4 million in investment and interest income, partially offset by an increase in income from transition service agreements of \$2.5 million and an increase in foreign exchange gains of \$1.9 million.

Income Tax Provision (Benefit)

No income tax provision or benefit was recognized for the year ended December 31, 2024. In 2023, income tax provision (benefit) consists of the change in deferred tax balances resulting from the recognition of a deferred tax liability related to the Surface Acquisition, and we recognized \$0.4 million of income tax benefit for the year ended December 31, 2023.

Liquidity and Capital Resources

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

(in thousands)	December 31,	
	2024	2023
Financial assets		
Total Cash, cash equivalents and marketable securities	\$ 125,987	\$ 117,748
Financial liabilities⁽¹⁾:		
2029 Term Loan	\$ 36,698	\$ —
Revenue Purchase and Sale Agreement	28,743 ⁽²⁾	—
2027 Term Loans	—	246,481
2026 Convertible Notes	228,229 ⁽²⁾	226,888
Total Financial liabilities	\$ 293,670	\$ 473,369

(1) See "Note 8. Financial Liabilities" in the Notes to Consolidated Financial Statements contained in Part II, Item 8 of this Annual Report on Form 10-K.

(2) We plan to use a portion of the proceeds of the Udenyca Sale, which we anticipate to close late in the first quarter or early in the second quarter of 2025, to pay off the \$230.0 million in aggregate principal amount of the 2026 Convertible Notes and to buy out certain royalty obligations related to UDENYCA comprising the majority of the balance of the Revenue Purchase and Sale Agreement.

As of December 31, 2024, we had cash and cash equivalents of \$126.0 million and an accumulated deficit of \$1.6 billion. We have generated significant operating losses in all years since our inception with the exceptions of net income of \$28.5 million in 2024, primarily due to the Sale Transactions in March 2024 and June 2024, \$132.2 million net income in 2020, and \$89.8 million net income in 2019.

On December 2, 2024, we announced the UDENYCA Sale for \$483.4 million in cash, inclusive of \$118.4 million of UDENYCA product inventory, subject to other requirements.

[Table of Contents](#)

We have funded our operations primarily through sales of our common stock, issuance and incurrence of convertible and term debt, the Revenue Purchase and Sale Agreement, the Sale Transactions and sales of our products. The following is a summary of recent liquidity events and financing transactions:

- We currently have an ATM Offering which offers the sale of our common stock up to \$92.5 million. As of December 31, 2024, we had approximately \$64.9 million of our common stock remaining available for sales under the ATM Offering, providing continued financial flexibility.
- On May 18, 2023, we completed a public offering and received net proceeds of approximately \$53.6 million, after deducting the underwriters' discounts and commissions and offering expenses.
- On September 8, 2023, we obtained \$28.8 million of cash, cash equivalents and marketable securities as part of the Surface Acquisition.
- On March 1, 2024, we sold our CIMERLI ophthalmology franchise to Sandoz for \$170.0 million in cash plus an additional \$17.8 million for CIMERLI product inventory and prepaid manufacturing assets.
- On April 1, 2024, \$175.0 million of the cash from the CIMERLI Sale was used to repay \$175.0 million of the total principal balance of \$250.0 million of the 2027 Term Loans.
- On May 8, 2024, we entered into the 2029 Term Loan for the principal amount of \$38.7 million, with proceeds of \$37.5 million, net of original issuance discount, which was used as part of the full repayment of the 2027 Term Loans. For a summary of the material terms of our 2029 Term Loan, please refer to "Note 8. Financial Liabilities" in the Notes to Consolidated Financial Statements contained in Part II, Item 8 of this Annual Report on Form 10-K.
- On May 8, 2024, we entered into the Revenue Purchase and Sale Agreement, receiving \$37.5 million by selling rights to receive future payments based on a percentage of U.S. net sales of UDENYCA and LOQTORZI. The proceeds were used as part of the full repayment of the 2027 Term Loans.
- On June 26, 2024, we sold our YUSIMRY immunology franchise to HKF for \$40.0 million in cash and the assumption of \$17.0 million of inventory purchase commitments by HKF.
- On June 27, 2024, we sold to Apotex an exclusive license under our rights to toripalimab to commercialize toripalimab within Canada for \$6.3 million.
- On September 13, 2024, we announced that our third-party labeling and packaging CMO for UDENYCA delayed production of UDENYCA due to over-commitments and capacity constraints, causing a prolonged supply interruption that quickly took away our ability to sell our product UDENYCA in the fourth quarter of 2024. Production resumed in November 2024 and due to strong demand in the fourth quarter of 2024 and into the first quarter of 2025, all three presentations of UDENYCA were being temporarily allocated. Based on individual distributor historical purchasing patterns, supply allocations to wholesalers for all three presentations of UDENYCA were removed between the end of January 2025 and the end of February 2025.

Irrespective of whether the UDENYCA Sale is consummated, we believe that our available cash, cash equivalents, and cash collected from product sales and services provided under transition service agreements will be sufficient to fund our planned expenditures and meet our obligations for at least the twelve months following the date of this Annual Report on Form 10-K.

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:

[Table of Contents](#)

- cash proceeds from product sales;
- the payment of interest, principal and royalties related to our financial liabilities;
- the costs of manufacturing, distributing and marketing our products;
- the cost of manufacturing clinical drug supplies and establishing commercial supplies of our product candidates and products;
- the timing for our packaging and labeling CMOs to make UDENYCA products available in a sufficient quantity to meet the demand from our customers;
- the percentage of customers that continue to purchase our products and that do not switch to products made by our competitors;
- the terms and timing of any other collaborative, licensing and other arrangements that we have established or may establish;
- the timing, receipt and amount of sales, profit sharing or royalties, if any, from any product candidates that are approved in the future;
- the number and characteristics of product candidates that we pursue;
- the scope, rate of progress, results and cost of our clinical trials, preclinical testing and other related activities;
- the costs of acquiring originator comparator materials and manufacturing preclinical study and clinical trial supplies and other materials from CMOs and related costs associated with release and stability testing;
- the cost, timing and outcomes of regulatory approvals; and
- the extent to which we acquire or invest in businesses, products or technologies.

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.”

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. With the exception of \$12.5 million for the second half of a milestone payment to Junshi Biosciences that was paid in January of 2025, as of December 31, 2024, no other milestones were accrued because their probability of achievement had not reached the threshold for recognition.

The following presents a summary of our active partnerships and collaborations that have contingent regulatory and sales milestones as of December 31, 2024:

Counterparty	Description	Remaining Potential Aggregate Milestone Amount
Junshi Biosciences	LOQTORZI	\$355.0 million ⁽¹⁾
Adimab	Casdozokitug	\$13.0 million
Vaccinex	CHS-114	\$15.0 million

(1) \$290.0 million relates to sales milestones and \$65.0 million relates to regulatory milestones for indications that are not currently the subject of our clinical trials. These amounts exclude the \$25.0 million milestone that Junshi Biosciences became entitled to upon the approval by the FDA of LOQTORZI for NPC, of which we paid \$12.5 million in the second quarter of 2024 and \$12.5 million in January of 2025.

Contingent Value Rights

We have recorded a contingent consideration liability for the fair value of the potential payments under the Contingent Value Rights Agreement, dated September 8, 2023, by and among the Company and Computershare Inc. and its affiliate Computershare Trust Company, N.A., together, as the rights agent thereunder (the “CVR Agreement”) in connection with the Surface Acquisition. These potential payments during the 10-year period following September 8, 2023 are only due if we first receive milestone- or royalty-based payments under certain license agreements or upfront payments pursuant to ex-U.S. licensing agreements. Payments to holders of CVRs can be in the form of cash, stock or a combination of cash and stock. The CVR liability associated with GSK and contingent consideration are recorded in other

[Table of Contents](#)

liabilities, non-current on the consolidated balance sheets at December 31, 2024. For further details, see “Note 6. Acquisition and Dispositions” in the Notes to Consolidated Financial Statements contained in Part II, Item 8 of this Annual Report on Form 10-K.

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 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, 2024 were \$86.5 million, as outlined in “Note 9. Commitments and Contingencies” in the Notes to Consolidated Financial Statements contained in Part II, Item 8 of this Annual Report on Form 10-K. The substantial majority of these purchase commitments are expected to transfer to the Intas Parties in conjunction with the UDENYCA Sale, if the transaction closes as anticipated.

Leases

We lease office and laboratory facilities through arrangements treated as operating leases. Refer to “Note 10. Leases” in the Notes to Consolidated Financial Statements contained in Part II, Item 8 of this Annual Report on Form 10-K for additional information to our leases. Our total non-cancelable contractual obligations arising from these agreements as of December 31, 2024 was \$5.8 million, with \$2.2 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,	
	2024	2023
Net cash used in operating activities	\$ (20,440)	\$ (174,884)
Net cash provided by investing activities	230,321	144,640
Net cash (used in) provided by financing activities	(186,974)	69,600
Net increase in cash, cash equivalents and restricted cash	\$ 22,907	\$ 39,356

Net cash used in operating activities

Cash used in operating activities of \$20.4 million in 2024 was primarily the result of net adjustments of \$104.8 million against our net income of \$28.5 million plus changes in our operating assets and liabilities of \$55.9 million.

Cash used in operating activities of \$174.9 million in 2023 was primarily due to the net loss of \$237.9 million adjusted for non-cash items including net inventory write-downs of \$52.6 million, stock-based compensation expense of \$43.1 million and other non-cash adjustments of \$4.1 million, partially offset by the changes in our operating assets and liabilities of \$36.8 million.

Net cash provided by investing activities

Cash provided by investing activities of \$230.3 million in 2024 was primarily due to \$187.8 million of cash acquired from the CIMERLI Sale, \$40.0 million of cash received from the YUSIMRY Sale, proceeds from the sale of investments in marketable securities of \$8.7 million and proceeds from maturities of investments in marketable securities of \$6.2 million, partially offset by the milestone payment to Junshi Biosciences of \$12.5 million.

Cash provided by investing activities of \$144.6 million in 2023 was primarily due to proceeds from maturities of investments in marketable securities of \$144.4 million, proceeds from sale of investments in marketable securities of \$13.3 million, and \$7.0 million of cash acquired as part of the Surface Acquisition, partially offset by purchases of investments in marketable securities of \$19.5 million.

Net cash (used in) provided by financing activities

Cash used in financing activities of \$187.0 million in 2024 was primarily due to \$260.4 million in payments to fully repay the 2027 Term Loans (excluding interest which is presented as an operating activity) and \$2.5 million in tax payments related to net share settlement of RSUs. These payments were partially offset by \$37.0 million of proceeds on the 2029 Term Loan, net of debt discount and issuance

[Table of Contents](#)

costs, \$36.5 million of proceeds from the Revenue Purchase and Sale Agreement, net of issuance costs, and \$1.5 million in proceeds from the ATM Offering, net of issuance costs.

Cash provided by financing activities of \$69.6 million in 2023 was primarily due to proceeds of \$53.6 million from the Public Offering, net of issuance costs, \$18.1 million proceeds from the ATM Offering, net of issuance costs, and \$1.8 million proceeds from purchase under the ESPP. These were partially offset by \$3.6 million in tax payments related to net share settlement.

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 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 2024, 2023 and 2022, total sales deductions to gross product sales were 83%, 77% and 73%, 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 2024 and 2023. A change of 10% in our total provisions for product sales discounts and allowances as of December 31, 2024, would have resulted in a change of our pre-tax earnings in 2024 by approximately \$27.6 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.

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

We are exposed to market risk related to changes in interest rates. As of December 31, 2024, we had cash and cash equivalents of \$126.0 million. Our primary exposure to market risk is interest rate sensitivity. Due to the short-term duration of our cash and cash equivalents, we believe that our exposure to interest rate risk 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

[Table of Contents](#)

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, 2024, we had \$38.7 million principal outstanding on our 2029 Term Loan that accrues interest at 8.0% per annum, plus the three-month SOFR, with a floor of 1.0%. We currently do not hedge our variable interest rate debt. The interest rate during the first quarter of 2025 will be 12.33%. A hypothetical 100 basis point increase in the interest rate on our variable rate debt could result in up to a \$0.4 million increase in the annual interest expense that we pay.

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 for these notes. 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 sheets at face value less the unamortized discount and issuance costs, and we present the fair value for required disclosure purposes only. We plan to use a portion of the proceeds of the UDENYCA Sale to fully repay the entirety of the 2026 Convertible Notes.

Substantially all of our sales are denominated in U.S. dollars, and since the CIMERLI Sale, we do not have any material exposure to the exchange rate between the U.S. Dollar and the Euro.

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)	91
Audited Consolidated Financial Statements	
Consolidated Balance Sheets	93
Consolidated Statements of Operations	94
Consolidated Statements of Comprehensive Income (Loss)	95
Consolidated Statements of Stockholders' Deficit	96
Consolidated Statements of Cash Flows	97
Notes to Consolidated Financial Statements	98

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, 2024 and 2023, the related consolidated statements of operations, comprehensive income (loss), stockholders' deficit and cash flows for each of the three years in the period ended December 31, 2024, 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, 2024 and 2023, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2024, 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, 2024, 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 17, 2025 expressed an adverse opinion thereon.

Basis for Opinion

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

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

Critical Audit Matter

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

Estimate of Reserves for Chargebacks and Rebates

Description of the Matter As described in Note 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 \$110.8 million at December 31, 2024. Estimated rebates are presented within accrued rebates, fees and reserves on the consolidated balance sheet and totaled \$123.7 million at December 31, 2024.

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, 2024, management is required to estimate the portion of product that is expected to be subject to a chargeback and rebate as well as the applicable discount rate.

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

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

/s/ Ernst & Young LLP

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

San Mateo, California
March 17, 2025

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

	December 31,	
	2024	2023
Assets		
Current assets:		
Cash and cash equivalents	\$ 125,987	\$ 102,891
Investments in marketable securities	—	14,857
Trade receivables, net	111,324	260,522
TSA receivables, net (Note 6)	11,010	—
Inventory	70,094	62,605
Prepaid manufacturing	11,636	23,657
Other prepaids and current assets	11,532	11,099
Total current assets	341,583	475,631
Property and equipment, net	2,837	5,119
Inventory, non-current	43,776	67,495
Intangible assets, net	53,646	71,673
Other assets, non-current	6,691	9,686
Total assets	<u>\$ 448,533</u>	<u>\$ 629,604</u>
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	\$ 28,456	\$ 35,219
Accrued rebates, fees and reserves	164,867	169,645
TSA payables and other accrued liabilities (Note 6)	11,026	—
Accrued compensation	18,344	21,521
Accrued and other current liabilities	60,288	105,386
Total current liabilities	282,981	331,771
Term loans, non-current	36,698	246,481
Convertible notes	228,229	226,888
Lease liabilities, non-current	3,286	5,328
Other liabilities, non-current	29,329	12,561
Total liabilities	580,523	823,029
Commitments and contingencies (Note 9)		
Stockholders' deficit:		
Preferred stock (\$0.0001 par value; shares authorized: 5,000,000; shares issued and outstanding: 0 at December 31, 2024 and 2023)		
Common stock (\$0.0001 par value; shares authorized: 300,000,000; shares issued and outstanding: 115,614,548 and 112,215,260 at December 31, 2024 and 2023, respectively)	12	11
Additional paid-in capital	1,419,266	1,386,312
Accumulated other comprehensive loss	(275)	(248)
Accumulated deficit	(1,550,993)	(1,579,500)
Total stockholders' deficit	(131,990)	(193,425)
Total liabilities and stockholders' deficit	<u>\$ 448,533</u>	<u>\$ 629,604</u>

See accompanying notes.

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

	Year Ended December 31,		
	2024	2023	2022
Net revenue	\$ 266,960	\$ 257,244	\$ 211,042
Costs and expenses:			
Cost of goods sold	117,553	158,992	70,083
Research and development	93,336	109,436	199,358
Selling, general and administrative	167,738	192,015	198,481
Total costs and expenses	378,627	460,443	467,922
Loss from operations	(111,667)	(203,199)	(256,880)
Interest expense	(27,158)	(40,542)	(32,474)
Gain on Sale Transactions, net (Note 6)	176,589	—	—
Loss on debt extinguishment	(12,630)	—	(6,222)
Other income (expense), net	3,373	5,469	3,822
Income (loss) before income taxes	28,507	(238,272)	(291,754)
Income tax provision (benefit)	—	(380)	—
Net income (loss)	\$ 28,507	\$ (237,892)	\$ (291,754)
Net income (loss) per share:			
Basic	\$ 0.25	\$ (2.53)	\$ (3.76)
Diluted	\$ 0.25	\$ (2.53)	\$ (3.76)
Weighted-average number of shares used in computing net income (loss) per share:			
Basic	114,553,537	94,162,637	77,630,020
Diluted	114,830,462	94,162,637	77,630,020

See accompanying notes.

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

	Year Ended December 31,		
	2024	2023	2022
Net income (loss)	\$ 28,507	(237,892)	\$ (291,754)
Other comprehensive income (loss):			
Unrealized gain (loss) on available-for-sale securities, net of tax	(24)	2	22
Foreign currency translation adjustments, net of tax	(3)	(1)	(1)
Comprehensive income (loss)	<u>\$ 28,480</u>	<u>\$ (237,891)</u>	<u>\$ (291,733)</u>

See accompanying notes.

Coherus BioSciences, Inc.
Consolidated Statements of Stockholders' 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, 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 to Junshi Biosciences, 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	78,851,516	8	1,204,431	(249)	(1,341,608)	(137,418)
Net loss	—	—	—	—	(237,892)	(237,892)
Issuance of common stock upon exercise of stock options	430,504	—	694	—	—	694
Issuance of common stock upon vesting of RSUs	1,280,901	—	—	—	—	—
Issuance of common stock under the ESPP	630,348	—	1,809	—	—	1,809
Issuance of common stock in connection with Surface Acquisition: ⁽¹⁾						
Issuance to Surface shareholders for acquisition	11,971,460	1	58,540	—	—	58,541
Accelerated vesting of equity awards	261,239	—	1,053	—	—	1,053
Taxes paid related to net share settlement of equity awards	(65,732)	—	(347)	—	—	(347)
Issuance of common stock under ATM Offering, net of issuance costs	3,559,761	1	18,316	—	—	18,317
Issuance of common stock under Public Offering, net of issuance costs	13,529,411	1	53,624	—	—	53,625
Issuance of common stock under Optional Stock Purchase Agreement	2,225,513	—	8,179	—	—	8,179
Taxes paid related to net share settlement of RSUs	(459,661)	—	(3,527)	—	—	(3,527)
Stock-based compensation expense	—	—	43,540	—	—	43,540
Other comprehensive gain, net of tax	—	—	—	1	—	1
Balances at December 31, 2023	112,215,260	11	1,386,312	(248)	(1,579,500)	(193,425)
Net income	—	—	—	—	28,507	28,507
Issuance of common stock upon exercise of stock options	174,651	—	291	—	—	291
Issuance of common stock upon vesting of RSUs	816,876	—	—	—	—	—
Issuance of common stock under the ESPP	852,222	—	926	—	—	926
Issuance of common stock - partial payout of 2023 bonus in RSUs	1,976,750	1	4,407	—	—	4,408
Issuance of common stock under ATM Offering, net of issuance costs	650,005	—	1,455	—	—	1,455
Taxes paid related to net share settlement of RSUs	(1,071,216)	—	(2,476)	—	—	(2,476)
Stock-based compensation expense	—	—	28,351	—	—	28,351
Other comprehensive loss, net of tax	—	—	—	(27)	—	(27)
Balances at December 31, 2024	115,614,548	\$ 12	\$ 1,419,266	\$ (275)	\$ (1,550,993)	\$ (131,990)

(1) See Note 6 for further discussion.

See accompanying notes.

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

	Years Ended December 31,		
	2024	2023	2022
Operating activities			
Net income (loss)	\$ 28,507	\$ (237,892)	\$ (291,754)
Adjustments to reconcile net income (loss) to net cash used in operating activities:			
Depreciation and amortization	5,276	3,791	3,699
Stock-based compensation expense	27,802	43,110	50,737
Impairment of out-license asset and remeasurement of CVR liability, net	6,772	—	—
Loss on debt extinguishment	12,630	—	6,222
Gain on Sale Transactions, net (Note 6)	(176,589)	—	—
Inventory write-downs, net	14,143	52,595	26,000
Non-cash interest expense from amortization of debt and other financial liabilities discount and issuance costs	4,159	2,407	6,431
Non-cash operating lease expense	1,394	2,476	2,503
Option payment to Junshi Biosciences	—	—	35,000
Change in fair value of derivatives	5,043	375	—
Other non-cash adjustments, net	(5,471)	(4,920)	(705)
Changes in operating assets and liabilities:			
Trade receivables, net	149,350	(150,683)	13,052
Inventory	(31,952)	(46,734)	(47,348)
Prepaid manufacturing	4,664	2,027	(4,214)
Other prepaid, current and non-current assets	(838)	16,155	(13,424)
Accounts payable	(3,938)	23,760	(4,548)
Accrued rebates, fees and reserves	(6,065)	113,105	(24,566)
Accrued compensation	1,549	(5,373)	596
Accrued and other current and non-current liabilities	(56,876)	10,917	1,195
Net cash used in operating activities	(20,440)	(174,884)	(241,124)
Investing activities			
Proceeds from maturities of investments in marketable securities	6,200	144,360	—
Proceeds from sale of investments in marketable securities	8,688	13,282	—
Cash received from CIMERLI Sale (Note 6)	187,823	—	—
Cash received from YUSIMRY Sale (Note 6)	40,000	—	—
Cash and cash equivalents acquired as part of the Surface Acquisition	—	6,997	—
Milestone and option payments to Junshi Biosciences	(12,500)	—	(35,000)
Purchases of investments in marketable securities	—	(19,507)	(127,382)
Other investing activities, net	110	(492)	(4,468)
Net cash provided by (used in) investing activities	230,321	144,640	(166,850)
Financing activities			
Proceeds from 2029 Term Loan, net of debt discount and issuance costs	36,979	—	—
Proceeds from Revenue Purchase and Sale Agreement, net of issuance costs	36,486	—	—
Proceeds from issuance of common stock under ATM Offering, net of issuance costs	1,455	18,093	6,358
Proceeds from issuance of common stock under Public Offering, net of issuance costs	—	53,625	—
Proceeds from issuance of common stock upon exercise of stock options	291	694	691
Proceeds from purchase under the employee stock purchase plan	926	1,809	2,320
Taxes paid related to net share settlement	(2,476)	(3,587)	(3,744)
Proceeds from 2027 Term Loans, net of debt discount and issuance costs	—	—	240,679
Repayment of 2022 Convertible Notes and premiums	—	—	(109,000)
Repayment of 2025 Term Loan, premiums and exit fees	—	—	(81,750)
Repayment of 2027 Term Loans, premiums and make-whole	(260,387)	—	—
Other financing activities	(248)	(1,034)	(1,228)
Net cash (used in) provided by financing activities	(186,974)	69,600	54,326
Net increase (decrease) in cash, cash equivalents and restricted cash	22,907	39,356	(353,648)
Cash, cash equivalents and restricted cash at beginning of period	103,343	63,987	417,635
Cash, cash equivalents and restricted cash at end of period	\$ 126,250	\$ 103,343	\$ 63,987
Supplemental disclosure of cash flow information			
Cash paid for interest	\$ 25,376	\$ 37,857	\$ 34,878
Income taxes paid (refunded), net	\$ (114)	\$ (118)	\$ 40
Supplemental disclosures of non-cash activities			
Capitalized and accrued milestone payment during the period to Junshi Biosciences	\$ —	\$ 25,000	\$ —
Stock issued under Optional Stock Purchase Agreement	\$ —	\$ 8,179	\$ —
Non-cash employee bonuses settled in common stock	\$ 4,408	\$ —	\$ —

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 immunotherapies to treat cancer. The Company’s commercial portfolio includes its first product, UDENYCA, a biosimilar to Neulasta, a long-acting G-CSF, and LOQTORZI, a novel next-generation PD-1 inhibitor. The Company is developing an innovative immuno-oncology pipeline that is expected to bring forward new potential indications for LOQTORZI in the U.S. and the development of new product candidates.

UDENYCA was launched commercially in a pre-filled syringe presentation in the United States in January 2019, followed by the launch of UDENYCA in an autoinjector presentation in May 2023 and the launch of UDENYCA ONBODY in February 2024. On December 2, 2024, the Company and Intas entered into the UDENYCA Purchase Agreement, pursuant to which, and upon the terms and subject to the conditions thereof, the Company has agreed to divest the UDENYCA Business to Intas. As consideration for the UDENYCA Sale, Intas has agreed to pay the Company \$483.4 million in cash, inclusive of \$118.4 million of UDENYCA product inventory, subject to downward adjustment by the amount of inventory delivered at the closing of the UDENYCA Sale less than the Inventory Target. Intas has designated Accord to purchase the physical assets, including product inventory. In addition, the Company is also eligible to receive two Earnout Payments of \$37.5 million each, provided that certain minimum UDENYCA Net Sales thresholds are met during specified periods after the closing of the UDENYCA Sale. The Company anticipates the transactions contemplated by the UDENYCA Purchase Agreement to close late in the first quarter or early in the second quarter of 2025.

On October 27, 2023, the Company announced that LOQTORZI was approved by the FDA in combination with cisplatin and gemcitabine for the first-line treatment of adults with metastatic or recurrent locally advanced NPC, and as monotherapy for the treatment of adults with recurrent unresectable, or metastatic NPC with disease progression on or after platinum-containing chemotherapy. LOQTORZI is an anti-PD-1 antibody that the Company developed in collaboration with Junshi Biosciences that is currently the only immune checkpoint inhibitor approved by the FDA for the treatment of these indications. The Company announced the launch of LOQTORZI in the U.S. on January 2, 2024. Further evaluation of LOQTORZI is expected through multiple current and planned clinical studies by the Company, Junshi Biosciences and the Company’s biopharma partners.

The Company’s pipeline is comprised of earlier stage clinical and preclinical immuno-oncology programs that it plans to develop in combination with LOQTORZI as well as in partnership with other companies with immune activating or cancer agents. The Company’s lead clinical stage product candidate is casdozokitug (CHS-388, formerly SRF388), an investigational antagonist antibody targeting IL-27, an immune regulatory cytokine, that is overexpressed in certain cancers, including hepatocellular, lung and renal cell carcinoma. Casdozokitug received orphan drug designation from the FDA for the treatment of HCC in October 2020 and fast track designation from the FDA for the treatment of patients with HCC previously treated with standard therapies in November 2020. Casdozokitug is currently in three on-going clinical studies, including a Phase 1/2 study in patients with advanced solid tumors, including combination with toripalimab in non-small cell lung cancer (clinicaltrials.gov identifier# NCT04374877), and a Phase 2 study in HCC (clinicaltrials.gov identifier# NCT05359861). The Company initiated a randomized Phase 2 study in HCC evaluating casdozokitug in combination with toripalimab and bevacizumab in the fourth quarter of 2024 (clinicaltrials.gov identifier# NCT06679985).

The Company’s second clinical-stage product candidate, CHS-114 (formerly SRF114), is an investigational IgG1 antibody targeting CCR8, a chemokine receptor highly expressed on Treg cells in the TME. The Company is enrolling patients with advanced solid tumors and HNSCC in the U.S. in a clinical trial evaluating safety and pharmacokinetics of CHS-114 with and without LOQTORZI (clinicaltrials.gov identifier# NCT05635643). The Company plans to initiate a Phase 1b clinical study of CHS-114 in combination with toripalimab in second-line HNSCC and initiate a Phase 1b clinical study of CHS-114 in combination with toripalimab and/or other treatments in participants with advanced solid tumors with the first cohort evaluating gastric cancer (clinicaltrials.gov identifier# NCT06657144), each in the first quarter of 2025.

The Company also has an early-stage development candidate, CHS-1000, an investigational antibody targeting human ILT4, designed to improve anti-PD-1 clinical benefit by transforming an unfavorable TME to a more favorable TME. The Company’s IND for CHS-1000 was allowed to proceed by the FDA in the second quarter of 2024 and initiating the first-in-human clinical study remains subject to further evaluation in the Company’s portfolio prioritization process.

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, 2024 and 2023.

Investments in Marketable Securities

Investments in marketable securities primarily consist of U.S. Treasury securities, government agency securities, commercial paper, corporate bonds and market money funds. 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 re-evaluates 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 2024, 2023 and 2022, interest income was \$4.5 million, \$2.8 million and \$1.9 million, respectively, and is included in other income (expense), net, in the consolidated statements of operations.

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. During 2024 and 2023, the products sold by the Company were UDENYCA, CIMERLI, YUSIMRY and LOQTORZI. Net revenue for product sales of YUSIMRY and CIMERLI effectively ceased following the disposition of these two product lines on June 26, 2024 and March 1, 2024, respectively (see Note 6. Acquisition and Dispositions). During 2022, UDENYCA and CIMERLI were the only products sold by the Company.

Business Combination Accounting & Valuation of Acquired Assets

The Company accounts for acquisitions of entities that include inputs and processes and have the ability to create outputs as business combinations. Judgment is required in assessing whether the acquired processes or activities, along with their inputs, meet the criteria to constitute a business, as defined by U.S. GAAP.

The acquisition method of accounting requires the recognition of assets acquired and liabilities assumed at their acquisition date fair values. The excess of the fair value of consideration transferred over the fair value of the net assets acquired is recorded as goodwill,

[Table of Contents](#)

or when there is an excess of the fair values of these identifiable assets and liabilities over the fair value of purchase consideration, a bargain purchase gain is recorded in the consolidated statements of operations. The estimations of fair values are based on non-observable inputs that are included in valuation models. An income approach, which generally relies upon projected cash flow models, is used in estimating the fair value of the acquired intangible assets. These cash flow projections are based on management's estimates of economic and market conditions including the estimated future cash flows from revenues of acquired assets, the timing and projection of costs and expenses and the related profit margins, tax rates, and discount rate.

During the measurement period, which occurs before finalization of the purchase price allocation, changes in assumptions and estimates that result in adjustments to the fair values of assets acquired and liabilities assumed, if based on facts and circumstances existing at the acquisition date, are recorded on a retroactive basis as of the acquisition date, with the corresponding offset to goodwill or bargain purchase gain (See Note 6. Acquisition and Dispositions).

Foreign Currency

Monetary assets and liabilities denominated in foreign currency are remeasured at period-end exchange rates. 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' 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 experienced material foreign currency transaction gains and losses for any of the 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 2024, 2023 and 2022, the Company recorded \$14.1 million, \$52.6 million and \$26.0 million in inventory write-downs, respectively, within cost of goods sold in the consolidated statements of operations. The 2024 charge was primarily for the write-down of UDENYCA inventory that did not meet acceptance criteria. The 2023 charge was primarily for the write-down of slow moving YUSIMRY inventory and the related partial recognition of certain firm purchase commitments. The 2022 charge was due to the competitive environment and lower demand for UDENYCA resulting in certain inventory becoming at risk of expiration.

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 statements 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 incurs expenses for the manufacture of drug products 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, 2024 relates to UDENYCA and LOQTORZI. The Company began to capitalize inventory costs associated with UDENYCA, CIMERLI and LOQTORZI after receiving final regulatory approval in November 2018, August 2022, and October 2023, 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

[Table of Contents](#)

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.

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 commence amortization over the useful life of the intangible asset, which will generally be determined by the period in which the substantial majority of the cash flows are expected to be generated. The Company evaluates IPR&D for impairment on an annual basis, during the fourth quarter, or more frequently if impairment indicators exist.

Finite-lived intangible assets are generally amortized on a straight-line basis over their estimated economic life and are reviewed periodically for impairment. The amortization expense related to capitalized milestone payments under license agreements and the amortization expense from out-licenses are recorded as a component of cost of goods sold in the consolidated statements of operations. The estimated life for capitalized milestone payments is ten years, and the life for acquired out-licenses is fifteen years.

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.

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.

Revenue Purchase and Sale Agreement

The Revenue Purchase and Sale Agreement (see Note 8. Financial Liabilities) contains the Royalty Fee Derivative Liability that meets the criteria to be bifurcated and accounted for separately from the Revenue Purchase and Sale Agreement. The Royalty Fee Derivative Liability was recorded at fair value upon entering into the Revenue Purchase and Sale Agreement and is subsequently remeasured to fair value at each reporting period with the corresponding change in fair value recognized in other income (expense), net in the consolidated statements of operations. The Revenue Purchase and Sale Agreement was initially valued and is remeasured using Monte Carlo simulation models to perform the "with-and-without" method, which involves valuing the Revenue Purchase and Sale Agreement with the embedded derivative and then valuing it without the embedded derivative. The difference between values is determined to be the estimated fair value of the Royalty Fee Derivative Liability. Refer to Note 3. Fair Value Measurements for details regarding the fair value.

[Table of Contents](#)

The Revenue Purchase and Sale Agreement is accounted for as a liability net of a discount comprising issuance costs and the fair value of the embedded derivative requiring bifurcation. The Company imputes interest expense associated with this liability using the effective interest rate method on a prospective basis. The effective interest rate is calculated based on the rate that would enable the liability to be repaid in full over the anticipated life of the arrangement. Interest expense is recognized over the estimated term on the consolidated statement of operations. The interest rate on this revenue participation liability may vary during the term of the agreement depending on a number of factors, including the level of actual and forecasted net sales. Increases or decreases in forecasted net sales could have a significant impact on the revenue participation liability, interest expense, and the time period for repayment. If the UDENYCA Sale is consummated, the Company plans to use a portion of the proceeds to pay off the 2026 Convertible Notes and buy out certain royalty obligations related to UDENYCA pursuant to the Revenue Purchase and Sale Agreement.

Contingent Consideration

Contingent consideration primarily relates to the potential payments to holders of the CVRs that are contingent upon the achievement of the Company and certain third-parties meeting product development or financial performance milestones. For transactions accounted for as business combinations, the Company records contingent consideration at fair value at the date of the acquisition based on the consideration expected to be transferred. Liabilities for contingent consideration are remeasured each reporting period and subsequent changes in fair value are recognized within loss from operations in the consolidated statements of operations. The assumptions utilized in the calculation of the fair values include probability of success and the discount rates. Contingent consideration involves certain assumptions requiring significant judgment and actual results may differ from estimated amounts.

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 80 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 and non-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.

[Table of Contents](#)

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 limited product return rights, which are principally based upon whether the product is damaged or defective, or the product's expiration date.

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

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 immaterial 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, certain overhead costs, royalties on certain products, and charges for inventory write-downs.

On May 2, 2019, the Company and Amgen settled a trade secret action brought by Amgen. As a result, cost of goods sold reflected a mid-single digit royalty on Udenyca net product revenue from July 1, 2019 to July 1, 2024. Additionally, prior to the Cimerli Sale, the Company shared a percentage of gross profits on sales of the Company's biosimilar version of ranibizumab (Lucentis) in certain dosage forms in both a vial and pre-filled syringe presentation (the "Bioeq Licensed Products") in the United States with Bioeq in the low- to mid-fifty percent range. The Company incurs royalties on net sales of Loqtorzi in the low twenty percent range and, prior to the Yusimry Sales Transaction, incurred royalties on net sales of Yusimry in the mid-single digit range. Pursuant to the license agreement with Genentech and Bioeq dated June 22, 2022, the Company incurred a royalty that was a low single-digit percentage of net sales of Cimerli through the end of 2023.

In 2024, 2023 and 2022, cost of goods sold included inventory write-downs, net of \$14.1 million, \$52.6 million and \$26.0 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;

[Table of Contents](#)

- 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
- option and certain 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 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 \$10.9 million, \$10.9 million and \$10.5 million in 2024, 2023 and 2022, respectively.

Stock-Based Compensation

The Company's compensation programs include stock-based awards. For awards other than condition-based performance stock options, the fair values are recognized as compensation expense on a straight-line basis over the vesting period. For condition-based performance stock options, expense is recognized only when performance conditions are considered probable of being achieved and is recognized over the period from the grant date through the time the milestone is expected to be achieved. The related costs are 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. The Company accounts for stock issued in connection with business combinations based on the fair value of the Company's common stock on the date of issuance.

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 2025.

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") were 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. As of December 31, 2024, the Company has fully satisfied its finance lease obligations and no longer has any related right-of-use assets or lease liabilities on its consolidated balance sheets.

The operating 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 or the lease modification date, as applicable, in determining the lease liabilities as the Company's leases generally do not provide an implicit rate.

Net Income (Loss) Per Share

Basic net income (loss) per share is calculated by dividing the net income (loss) 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 computed by dividing the net income by the weighted average number of common shares outstanding for the period plus any diluted potential common shares outstanding for the period determined using the treasury stock method for options, PSOs, restricted stock units ("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 14. Net Income (Loss) Per Share).

Comprehensive Income (Loss)

Comprehensive income (loss) includes the following two components: net income (loss) and other comprehensive income (loss). Other comprehensive income (loss) refers to gains and losses that are recorded as an element of stockholders' equity (deficit), but are excluded from net income (loss). The Company's other comprehensive income (loss) includes the unrealized gain (loss) on available-for-sale securities and foreign currency translation adjustments in 2024, 2023 and 2022.

Restructuring Charges

On March 3, 2023, the Company committed to a plan to reduce its workforce to focus resources on strategic priorities including the commercialization of its diversified product portfolio and development of innovative immuno-oncology product candidates. The reduction in force impacted approximately 50 full-time and part-time employees, effective March 10, 2023 for most of these employees. In the first quarter of 2023, non-recurring restructuring charges associated with the reduction in force consisted of \$3.9 million in cash expenses related to personnel expenses such as salaries, severance payments and other benefits; and \$1.5 million in non-cash stock-based compensation related to acceleration of vesting and extension of the stock option exercise windows for two impacted executives; partially offset by \$0.5 million in non-cash stock-based compensation forfeiture credits. The reduction in force was completed during the second quarter of 2023.

For the year ended December 31, 2023, the consolidated statements of operations included \$3.6 million in research and development expense and \$1.3 million in selling, general and administrative expense related to the reduction in force.

Reclassifications

Certain amounts in prior years' financial statements have been reclassified to conform with the current year presentation in 2024, including amounts in the consolidated statements of cash flows. There were no changes to net cash used in operating activities and net cash provided by (used in) investing activities in the consolidated statements of cash flows for the prior years as a result.

Recent Accounting Pronouncements

In November 2023, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2023-07, *Segment Reporting (Topic 280) Improvements to Reportable Segment Disclosures*, which expands annual and interim disclosure requirements for reportable segments, primarily through enhanced disclosures about significant segment expenses. ASU 2023-07 was adopted on a retrospective basis as of December 31, 2024, and it did not change the way that the Company identifies its reportable segments. The adoption did not have a material impact on the Company’s segment-related disclosures.

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

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, which provides qualitative and quantitative updates to the rate reconciliation and income taxes paid disclosures, among others, in order to enhance the transparency of income tax disclosures, including consistent categories and greater disaggregation of information in the rate reconciliation and disaggregation by jurisdiction of income taxes paid. The new standard is effective for the Company for annual periods beginning after December 15, 2024, with early adoption permitted. The amendments in this ASU should be applied prospectively; however, retrospective application is also permitted. The Company is currently evaluating the impact this ASU may have on its financial statement disclosures.

In November 2024, the FASB issued ASU 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation (Subtopic 220-40): Disaggregation of Income Statement Expenses*, which requires public entities to disclose certain disaggregated costs and expenses on an annual and interim basis in the notes to the financial statements. It also requires disclosure of the total amount of selling expenses, and the Company’s definition of selling expenses. The new standard is effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. Early adoption is permitted and is effective on either a prospective or retrospective basis. The Company is currently evaluating the impact this ASU may have on its financial statement disclosures.

In November 2024, the FASB issued ASU 2024-04, *Debt - Debt with Conversion and Other Options (Subtopic 470-20): Induced Conversions of Convertible Debt Instruments*, which clarifies the requirements for determining whether certain settlements of convertible debt instruments should be accounted for as an induced conversion or extinguishments of convertible debt. The new standard is effective for annual reporting periods beginning after December 15, 2025, and interim periods within those annual reporting periods. The Company is currently evaluating the impact this ASU may have on its financial statement disclosures.

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

2. Revenue

The Company launched LOQTORZI in December 2023, YUSIMRY in July 2023 and CIMERLI in October 2022. Net revenue for sales of YUSIMRY and CIMERLI effectively ceased following the disposition of these two product lines on June 26, 2024 and March 1, 2024, respectively (see Note 6. Acquisition and Dispositions). All net product revenue was generated in the United States, and the Company’s net revenue was as follows:

(in thousands)	Year Ended December 31,		
	2024	2023	2022
Products			
UDENYCA	\$ 205,951	\$ 127,064	\$ 203,814
CIMERLI	27,079	125,388	6,946
YUSIMRY	7,541	3,574	—
LOQTORZI	19,131	554	—
Total net product revenue	259,702	256,580	210,760
Other revenue	7,258	664	282
Total net revenue	\$ 266,960	\$ 257,244	\$ 211,042

Gross product revenues by significant customer as a percentage of total gross product revenues were as follows:

	Year Ended December 31,		
	2024	2023	2022
McKesson Corporation	42 %	40 %	38 %
Cencora (previously known as AmeriSource-Bergen Corporation)	38 %	43 %	44 %
Cardinal Health, Inc.	18 %	15 %	17 %

Product Sales Discounts and Allowances

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 on the accompanying consolidated balance sheets.

In connection with the Sale Transactions, the Company retained and will continue to be responsible for sales discounts and allowance liabilities incurred related to shipments prior to March 1, 2024 for CIMERLI and June 26, 2024 for YUSIMRY. Sales discounts and allowances incurred on behalf of the respective counterparties following the close of the Sale Transactions in accordance with the Company's Transition Services Agreement with Sandoz (the "CIMERLI TSA") in March 2024 for CIMERLI and the Company's Transition Services Agreement with HKF (the "YUSIMRY TSA" and, together with the CIMERLI TSA, collectively the "TSA") in June 2024 for YUSIMRY are reflected within TSA receivables, net and TSA payables and other accrued liabilities in the consolidated balance sheets and are excluded from the below table (see Note 6. Acquisition and Dispositions).

The activities and ending reserve balances for each significant category of sales discounts and allowances, which constitute variable consideration, are as follows:

(in thousands)	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 - increase (decrease)	(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	42,677	38,713	19,113	100,503
Provision related to sales made in:				
Current period	590,772	143,370	110,183	844,325
Prior period - increase (decrease)	(1,361)	1,424	3,744	3,807
Payments and customer credits issued	(558,135)	(62,370)	(83,245)	(703,750)
Balances at December 31, 2023	73,953	121,137	49,795	244,885
Provision related to sales made in:				
Current period	912,079	189,309	145,533	1,246,921
Prior period - increase (decrease)	(990)	7,391	(2,571)	3,830
Payments and customer credits issued	(874,264)	(194,099)	(151,628)	(1,219,991)
Balances at December 31, 2024	\$ 110,778	\$ 123,738	\$ 41,129	\$ 275,645

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.

[Table of Contents](#)

- Level 2 — Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The fair values of cash equivalents approximate their carrying values due to the short-term nature of such financial instruments.

In connection with the Surface Acquisition on September 8, 2023 (see Note 6. Acquisition and Dispositions), the Company recorded contingent consideration liabilities related to CVRs. The fair value of the CVR liabilities were determined using a Monte Carlo simulation-based model discounted to present value and represents a Level 3 measurement within the fair value hierarchy. Assumptions used in this calculation include estimated revenue, discount rate and various probability factors. If different assumptions were used for the various inputs, the estimated fair value could be significantly higher or lower than the fair value the Company determined. For example, increases in discount rates and the time to payment may result in lower fair value measurements. There is no assurance that any of the conditions for payment of the CVR liabilities will be met. During the three months ended March 31, 2024, the Company impaired its historical out-licensed partnership program with Novartis Institutes for Biomedical Research, Inc. (“Novartis Institutes”) (NZV930), which resulted in a net impairment charge of \$6.8 million in selling, general and administrative expenses in the consolidated statements of operations relating to the write-off of the net carrying value of the Novartis Institutes out-license intangible asset of \$10.6 million and the final remeasurement of the CVR liability related to NZV930 of \$3.8 million to its fair value of zero. The remaining CVR liability associated with GSK of \$0.5 million and other contingent consideration are recorded in other liabilities, non-current on the consolidated balance sheets at December 31, 2024. As of December 31, 2023, the CVR liability was reduced by a fair value adjustment of \$0.9 million which was recorded within selling, general and administrative expense in the consolidated statements of operations.

On May 8, 2024, the Company recognized the Royalty Fee Derivative Liability which was estimated to be \$9.2 million in connection with the Revenue Purchase and Sale Agreement (see Note 8. Financial Liabilities), which is recorded in accrued and other current liabilities on the consolidated balance sheets. To estimate the fair value, the Company uses Monte Carlo simulation models that require the use of Level 3 unobservable inputs, primarily the amount and timing of our expected future revenue, the probability of certain events, the discount rate corresponding to the risk of revenue, and to a much lesser extent the estimated volatility of these revenues. As of December 31, 2024, the estimated fair value of the Royalty Fee Derivative Liability increased to \$13.6 million, resulting in a \$4.4 million charge recorded in other income (expense), net on the consolidated statements of operations.

Financial liabilities related to long-term debt obligations are summarized in Note 8. Financial Liabilities. Other financial liabilities and financial assets measured at fair value on a recurring basis are summarized as follows:

(in thousands)	Fair Value Measurements			Total
	Level 1	Level 2	Level 3	
Financial Assets:				
Cash equivalents	\$ 125,549	\$ —	\$ —	\$ 125,549
Financial Liabilities:				
Royalty Fee Derivative Liability	\$ —	\$ —	\$ 13,620	\$ 13,620
Contingent consideration	—	—	632	632
Total	\$ —	\$ —	\$ 14,252	\$ 14,252

[Table of Contents](#)

(in thousands)	Fair Value Measurements			
	December 31, 2023			
	Level 1	Level 2	Level 3	Total
Financial Assets:				
Cash equivalents ⁽¹⁾	\$ 88,460	\$ 998	\$ —	\$ 89,458
Marketable debt securities:				
U.S. government agency securities	5,195	—	—	5,195
U.S. treasury securities	2,993	—	—	2,993
Commercial paper and corporate notes	—	6,669	—	6,669
Prepaid financial instrument in Prepaid manufacturing ⁽²⁾	—	—	625	625
Total	\$ 96,648	\$ 7,667	\$ 625	\$ 104,940
Financial Liabilities:				
Contingent consideration	\$ —	\$ —	\$ 4,472	\$ 4,472

(1) Cash equivalents consist of money market funds, U.S treasury securities, and commercial paper and corporate notes with original maturities of 90 days or less.

(2) Relates to Optional Stock Purchase Agreement.

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

(in thousands)	December 31, 2024			
	Cost	Unrealized Gain	Unrealized (Loss)	Fair Value
Money market funds	\$ 125,549	\$ —	\$ —	\$ 125,549

(in thousands)	December 31, 2023			
	Cost	Unrealized Gain	Unrealized (Loss)	Fair Value
Money market funds	\$ 79,484	\$ —	\$ —	\$ 79,484
U.S. government agency securities	5,200	—	(5)	5,195
U.S. treasury securities	11,967	2	—	11,969
Commercial paper and corporate notes	7,673	—	(6)	7,667
Total	\$ 104,324	\$ 2	\$ (11)	\$ 104,315

The Company held 9 positions that were in unrealized loss positions as of December 31, 2023. No impairment was recognized in 2024 and 2023. As of December 31, 2023, the remaining contractual maturities of available-for-sale securities were less than one year, and the average maturity of investments upon acquisition was approximately 9 months. The accrued interest receivable on available-for-sale marketable securities was immaterial at December 31, 2023.

4. Inventory

Inventory consisted of the following:

(in thousands)	December 31,	
	2024	2023
Raw materials	\$ 18,014	\$ 12,975
Work in process	83,170	82,588
Finished goods	12,686	34,537
Total	\$ 113,870	\$ 130,100

[Table of Contents](#)

During 2024, the Company recorded \$14.1 million in charges for the write-down of UDENYCA inventory that did not meet acceptance criteria. Inventory as of December 31, 2023 included \$16.4 million related to the CIMERLI ophthalmology franchise and \$17.0 million related to the YUSIMRY immunology franchise (see Note 6. Acquisition and Dispositions). During the year ended December 31, 2023, the Company recorded a \$47.0 million charge for the write-down of slow moving YUSIMRY inventory, which included the recognition of \$20.5 million in certain firm purchase commitments in cost of goods sold in the consolidated statements of operations. Of this charge, \$11.5 million was reflected in accrued and other current liabilities and \$9.0 million in other liabilities, non-current in the consolidated balance sheets as of December 31, 2023. Liabilities for firm inventory purchase commitments related to YUSIMRY were derecognized upon the YUSIMRY sale.

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, 2024 and 2023, 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,	
	2024	2023
Inventory	\$ 70,094	\$ 62,605
Inventory, non-current	43,776	67,495
Total	<u>\$ 113,870</u>	<u>\$ 130,100</u>

Prepaid manufacturing of \$11.6 million as of December 31, 2024 included prepayments of \$5.3 million to CMOs for manufacturing services of the Company's products and prepayments of \$6.4 million to various CMOs for research and development pipeline programs. Prepaid manufacturing of \$23.7 million as of December 31, 2023 includes prepayments of \$12.6 million to CMOs for manufacturing services, of which \$6.4 million related to the CIMERLI ophthalmology franchise and \$0.5 million related to the YUSIMRY immunology franchise (see Note 6. Acquisition and Dispositions), and prepayments of \$11.1 million to various CMOs for research and development pipeline programs.

5. Balance Sheet Components

Property and Equipment, Net

Property and equipment, net consisted of the following:

(in thousands)	December 31,	
	2024	2023
Machinery and equipment	\$ 13,437	\$ 13,124
Computer equipment and software	3,582	3,546
Furniture and fixtures	1,055	1,055
Leasehold improvements	5,751	5,751
Finance lease right of use assets	—	2,294
Total property and equipment	<u>23,825</u>	<u>25,770</u>
Accumulated depreciation and amortization	<u>(20,988)</u>	<u>(20,651)</u>
Property and equipment, net	<u>\$ 2,837</u>	<u>\$ 5,119</u>

Depreciation and amortization expense related to property and equipment, net was \$1.8 million, \$3.2 million and \$3.6 million in 2024, 2023 and 2022, respectively. There were no material impairments of property and equipment in 2024, 2023 and 2022.

As of December 31, 2024 and 2023, the net book value of software implementation costs related to hosting arrangements was \$2.0 million and \$3.2 million, respectively, and the amortization expense was immaterial for all periods presented.

Intangible Assets, Net

Intangible assets, net consisted of the following:

(in thousands)	December 31,	
	2024	2023
Finite-lived assets, net of accumulated amortization of \$2,719 and \$639, as of December 31, 2024 and 2023, respectively	\$ 24,787	\$ 41,871
Indefinite-lived assets - in-process research and development	28,859	28,859
Goodwill	—	943
Total Intangible assets, net	<u>\$ 53,646</u>	<u>\$ 71,673</u>

Amortization expense related to finite-lived intangible assets was \$3.4 million during the year ended December 31, 2024 and immaterial for the years ended December 31, 2023 and 2022. As of December 31, 2024, amortization expense related to finite-lived assets for each of the five succeeding fiscal years is expected to be approximately \$2.7 million. The weighted average remaining life of the finite-lived assets is 9.4 years on December 31, 2024.

In connection with the CIMERLI Sale on March 1, 2024, a finite-lived asset, net of \$2.1 million and goodwill of \$0.9 million were derecognized. In connection with the YUSIMRY Sale on June 26, 2024, a finite-lived asset with a net value of \$0.9 million was derecognized.

The exclusive license of NZV930 to Novartis Institutes, acquired as part of the Surface Acquisition, was terminated by Novartis Institutes with an effective date of October 2, 2024. As a result, the Company recognized an impairment charge of \$10.6 million for the carrying value of the Novartis Institutes out-license during the three months ended March 31, 2024, which was classified within selling, general and administrative expense in the consolidated statements of operations.

No impairment charges were recognized for goodwill or intangible assets during 2023 or 2022.

Accrued and Other Current Liabilities

Accrued and other current liabilities consisted of the following:

(in thousands)	December 31,	
	2024	2023
Accrued commercial and research and development manufacturing	\$ 12,449	\$ 23,470
Accrued co-development costs and milestone payments	12,500	26,812
Accrued royalties	1,498	42,031
Royalty fee derivative liability (Notes 3 and 8)	13,620	—
Revenue participation liability, current (Note 8)	1,148	—
Accrued other	17,382	7,628
Lease liabilities, current	1,691	2,145
Contingent consideration, current	—	3,300
Total Accrued and other current liabilities	<u>\$ 60,288</u>	<u>\$ 105,386</u>

Other Liabilities, Non-current

Other liabilities, non-current consisted of the following:

(in thousands)	December 31,	
	2024	2023
Contingent consideration, non-current	\$ 632	\$ 1,172
Deferred tax liability (Note 13)	1,102	1,102
Revenue participation liability, non-current (Note 8)	27,595	—
Other	—	10,287
Total Other liabilities, non-current	<u>\$ 29,329</u>	<u>\$ 12,561</u>

6. Acquisition and Dispositions

2024 Dispositions

UDENYCA Sale (subject to closing)

On December 2, 2024, the Company and Intas entered into the UDENYCA Purchase Agreement, pursuant to which, and upon the terms and subject to the conditions thereof, the Company has agreed to divest the UDENYCA Business to Intas. As consideration for the UDENYCA Sale, Intas has agreed to pay the Company \$483.4 million in cash, inclusive of \$118.4 million of UDENYCA product inventory, subject to downward adjustment by the amount of inventory delivered at the closing of the UDENYCA Sale less than the Inventory Target. Intas has designated Accord to purchase the physical assets, including product inventory. In addition, upon the achievement of certain contingent events by Intas, the Company is also eligible to receive two additional Earnout Payments of \$37.5 million each, provided that certain minimum UDENYCA Net Sales thresholds are met during specified periods after the closing of the UDENYCA Sale. If the UDENYCA Sale is consummated, the Company plans to use a portion of the proceeds to pay off the 2026 Convertible Notes and buy out certain royalty obligations related to UDENYCA pursuant to the Revenue Purchase and Sale Agreement.

Closing of the UDENYCA Sale is not subject to a financing condition, but is subject to closing conditions, including (i) approval of the Company's stockholders, which has occurred, (ii) the expiration or earlier termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, which has occurred, (iii) clearance from Committee on Foreign Investment in the United States or any member agency thereof acting in its capacity as a member agency, which has occurred, and (iv) certain additional closing conditions related to packaging by the Company's packaging and labeling CMOs for UDENYCA and FDA authorization of commercial supply from the Company's additional packaging and labeling CMO for UDENYCA.

The Company anticipates the transactions contemplated by the UDENYCA Purchase Agreement to close late in the first quarter or early in the second quarter of 2025. Costs of \$6.7 million related to the UDENYCA Sale were recorded in selling, general and administrative expense in the consolidated statements of operations during the year ended December 31, 2024.

YUSIMRY Sale

On June 26, 2024, the Company completed the sale of its YUSIMRY immunology franchise which comprised certain assets, including certain YUSIMRY intellectual property, contracts, YUSIMRY inventory, and all activities related to research and development of YUSIMRY. In exchange, HKF paid upfront cash consideration of \$40.0 million and assumed certain liabilities, including \$17.0 million of inventory purchase commitments. During 2024, the Company recognized a net gain on the YUSIMRY Sale of \$22.8 million, which included the cash receipts of \$40.0 million less net assets transferred to HKF or otherwise derecognized and transaction costs of \$1.0 million. At December 31, 2024, unpaid transaction costs totaled \$0.9 million. The pretax profit (loss) related to the YUSIMRY immunology franchise, which excludes any corporate overhead allocations, was \$(3.1) million, \$(59.7) million and \$(34.4) million during the years ended December 31, 2024, 2023 and 2022, respectively.

In connection with the YUSIMRY Sale, the Company and HKF entered into the YUSIMRY TSA, pursuant to which the Company is providing certain business support services on behalf of HKF including billings, collections, and the remittance of rebates, to ensure business continuity for patients and customers and were substantially completed by December 31, 2024. Under the YUSIMRY TSA, the Company is entitled to be reimbursed for its costs and has recorded income of \$0.8 million for the year ended December 31, 2024 in other income (expense), net in the consolidated statements of operations. As of December 31, 2024, assets of \$2.3 million and liabilities of \$4.3 million related to transactions entered into on behalf of HKF in accordance with the YUSIMRY TSA were presented in TSA receivables, net and TSA payables and other accrued liabilities, respectively, in the consolidated balance sheets.

CIMERLI Sale

On March 1, 2024, the Company completed the sale of its CIMERLI ophthalmology franchise through the sale of its subsidiary, Coherus Ophthalmology, to Sandoz for upfront, all-cash consideration of \$170.0 million plus an additional \$17.8 million for CIMERLI product inventory and prepaid manufacturing assets. During 2024, the Company recognized a net gain on the CIMERLI Sale of \$153.8 million, which included the cash receipts of \$187.8 million less assets transferred to Sandoz, assets derecognized, transaction costs of \$7.2 million, and other related employee transition expenses. As of December 31, 2024, unpaid commitments for retention bonuses totaled \$4.7 million. The pretax profit (loss) related to the CIMERLI ophthalmology franchise, which excludes any corporate

[Table of Contents](#)

overhead allocations, was \$2.4 million, \$16.6 million and \$(16.7) million during the years ended December 31, 2024, 2023 and 2022, respectively.

In connection with the CIMERLI Sale, the Company and Sandoz entered into the CIMERLI TSA, pursuant to which the Company is providing certain business support services on behalf of Sandoz including billings, collections, and the remittance of rebates, to ensure business continuity for patients and customers for a period not expected to extend beyond July 15, 2025. Under the CIMERLI TSA, the Company is entitled to be reimbursed for its costs and has recorded income of \$1.7 million for the year ended December 31, 2024 in other income (expense), net in the consolidated statements of operations. As of December 31, 2024, assets related to transactions entered into on behalf of Sandoz in accordance with the CIMERLI TSA of \$8.7 million were presented in TSA receivables, net and liabilities related to transactions entered into on behalf of Sandoz in accordance with the CIMERLI TSA of \$6.8 million were presented in TSA payables and other accrued liabilities in the consolidated balance sheets.

2023 Acquisition

Surface Acquisition

On September 8, 2023 (the "Acquisition Date"), in accordance with an Agreement and Plan of Merger dated June 15, 2023 (the "Merger Agreement") by and among the Company, Crimson Merger Sub I, Inc. ("Merger Sub I"), Crimson Merger Sub II, LLC ("Merger Sub II," and together with Merger Sub I, the "Merger Subs") and Surface, the Company completed the Surface Acquisition. The Surface Acquisition expanded the Company's immuno-oncology pipeline by adding important new assets, including: casdozokitug (CHS-388, formerly SRF388), an investigational, novel IL-27-targeted antibody, and CHS-114 (formerly SRF114), an investigational, CCR8-targeted antibody.

On the Acquisition Date, and in accordance with the Merger Agreement, the Company issued to the holders of all outstanding Surface common stock (subject to certain exceptions) 0.1960 shares of Coherus common stock in exchange for each share of outstanding Surface common stock and certain outstanding Surface employee equity awards. The exchange ratio was calculated pursuant to the terms of the Merger Agreement and was based on a \$5.2831 per share price of Coherus common stock and a nominal total amount of cash in lieu of fractional shares. Surface shareholders also received one CVR for each share of Surface common stock and employee equity award converted. Each CVR entitles the holder to receive quarterly contingent payments in the form of cash, stock or a combination of cash and stock at the Company's discretion during the ten-year period following September 8, 2023, for the sum of the following, less any permitted deductions in accordance with the CVR Agreement:

- 70% of all milestone- and royalty-based payments received by the Company or its affiliates under the GSK Agreement related to the program GSK4381562;
- 25% of any upfront payment received by the Company or its affiliates pursuant to potential ex-U.S. licensing agreements for CHS-114; and
- 50% of any upfront payment received by the Company or its affiliates pursuant to potential ex-U.S. licensing agreements for casdozokitug.

The Company has recorded a contingent consideration liability for the fair value of the potential payments under the CVR Agreement described above. The Company is unable to estimate a range of outcomes for potential royalty and milestone payments for CHS-114 and casdozokitug.

[Table of Contents](#)

The total consideration paid for the Surface Acquisition of \$64.6 million consisted of the following:

(in thousands, except share and per share amounts)	As of Acquisition Date
Coherus common stock issued	11,971,460
Coherus common stock share price	\$ 4.89
Fair value of components of purchase price consideration at closing:	
Equity of combined company owned by Surface equity holders	\$ 58,540
Contingent CVR liability	5,290
Equity of combined company owned by Surface former employees ⁽¹⁾	766
Fair value of total purchase consideration	<u>\$ 64,596</u>

(1) Represents 161,100 shares of Coherus common stock, net of shares withheld for taxes, issued to Surface's former employees on the Acquisition Date.

The following table below sets forth the purchase price allocation to the estimated fair value of the net assets acquired:

(in thousands)	Amounts Recognized at Acquisition Date
Assets Acquired	
Cash and cash equivalents	\$ 6,997
Investments in marketable securities	21,791
Other prepaids and other assets	5,260
In-process research and development	26,239
Out-licenses	13,530
Total assets	<u>\$ 73,817</u>
Liabilities Assumed	
Accrued and other current liabilities	\$ 7,722
Deferred tax liability	1,499
Total liabilities	<u>9,221</u>
Total net assets acquired	<u>\$ 64,596</u>

The Company believes that, even after reassessing its identification of all assets acquired and liabilities assumed, it was able to acquire Surface for a price that was completely allocable to identifiable assets acquired and liabilities assumed with no residual attributable to goodwill primarily due to Surface's need to raise additional capital to finance its operations, the challenging biotech funding environment at the time the transaction was initially announced, and the value of the acquired net assets.

The amounts allocated to identifiable intangible assets was as follows:

(in thousands)	Useful lives	Fair Value at Acquisition Date
In-process research and development - casdozokitug	n/a	\$ 25,899
In-process research and development - CHS-114	n/a	340
Out-license - GSK	15 years	2,506
Out-license - Novartis Institutes	15 years	11,024
Total identifiable intangible assets		<u>\$ 39,769</u>

The out-license intangible assets represent potential milestone and royalty-based payments to be received under two out-licensed partnership programs to advance certain next-generation cancer therapies, Novartis Institutes (NZV930) and GSK (GSK4381562). Surface shareholders received CVRs for certain percentages of these milestone and royalty-based payments, as further explained above. The exclusive license of NZV930 to Novartis Institutes was terminated by Novartis Institutes with an effective date of October 2, 2024. As a result, during the first quarter of 2024, the Company recognized a net impairment charge of \$6.8 million in selling, general and administrative expenses in the consolidated statements of operations relating to the write-off of the net carrying value of the Novartis Institutes out-license intangible asset of \$10.6 million and the final remeasurement of the CVR liability related to NZV930 of \$3.8 million to its fair value of zero.

[Table of Contents](#)*Unaudited Pro Forma Summary of Operations*

The following table shows the unaudited pro forma summary of operations for the years ended December 31, 2023 and 2022, as if the Surface Acquisition had occurred on January 1, 2022. This pro forma information does not purport to represent what the Company's actual results would have been if the acquisition had occurred as of January 1, 2022, and it is not indicative of what such results would be expected for any future period:

(in thousands)	Year Ended December 31,	
	2023	2022
Total revenues	\$ 257,244	\$ 241,042
Net loss	\$ (284,575)	\$ (369,442)

The unaudited pro forma financial information was prepared using the acquisition method of accounting and was based on the historical financial information of the Company and Surface. In order to reflect the Surface Acquisition as if it had occurred on January 1, 2022, the summary pro forma financial information includes adjustments to reflect Surface's severance expense, the early termination and related amortization expense of Surface's corporate headquarters operating lease, the loss on debt extinguishment and historical interest expense related to the cash settlement of Surface's convertible note as if it had occurred on January 1, 2022, and amortization expense on the acquired finite-lived intangible assets. The unaudited pro forma summary of operations does not reflect the income tax effects, if any, of the pro forma adjustments, given the combined entity incurred significant losses during the historical periods presented.

Acquisition-related costs of \$5.1 million were recorded in selling, general and administrative expense in the consolidated statements of operations during the year ended December 31, 2023.

7. Collaborations and Other Arrangements

In-Licensing Agreements

Junshi Biosciences

On February 1, 2021, the Company entered into the Collaboration Agreement with Junshi Biosciences for the co-development and commercialization of LOQTORZI, 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 LOQTORZI 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 became obligated to pay Junshi Biosciences up to an aggregate \$380.0 million in one-time payments for the achievement of various regulatory and sales milestones, of which we have already paid \$25.0 million, and a royalty in the low twenty percent range on net sales of LOQTORZI.

In March 2022, the Company paid \$35.0 million for the exercise of its option to license CHS-006. Thereafter, Junshi Biosciences and the Company jointly developed CHS-006 with each party responsible for the associated development costs as set forth in the Collaboration Agreement. However, on January 10, 2024, the Company announced that it delivered a notice of termination of the TIGIT Program (as defined in the Collaboration Agreement) to Junshi Biosciences pursuant to the Collaboration Agreement. The Company plans to continue to wind down work with Junshi Biosciences on the TIGIT Program pursuant to the termination. If the Company exercises its remaining option for the IL-2 cytokine, it will be obligated to pay Junshi Biosciences an additional option exercise fee of \$35.0 million and 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 LOQTORZI and the other licensed compounds and will pay for a portion of these co-development activities up to a maximum of \$25.0 million per licensed compound per year. Additionally, the Company is responsible for certain associated regulatory and technology transfer costs for LOQTORZI and other licensed compounds and will reimburse Junshi Biosciences for such costs.

On October 27, 2023, LOQTORZI was approved by the FDA in combination with cisplatin and gemcitabine for the first-line treatment of adults with metastatic or recurrent locally advanced NPC, and as monotherapy for the treatment of adults with recurrent, unresectable, or metastatic NPC with disease progression on or after platinum-containing chemotherapy. As a result, a \$25.0 million milestone payment became due to Junshi Biosciences in the first quarter of 2024 pursuant to the Collaboration Agreement. In March 2024, the Company entered into an Amendment No. 2 to the Collaboration Agreement (the "2nd Amendment") with Junshi Biosciences to revise

[Table of Contents](#)

the timing of the \$25.0 million milestone payment. Under the terms of the 2nd Amendment, the \$25.0 million milestone payment was split into two installments of \$12.5 million each, with one paid in the second quarter of 2024 and one paid in January of 2025.

The licensing transaction and the exercise of the option were accounted for as asset acquisitions under the relevant accounting rules. During the year ended December 31, 2024, the Company recognized a reduction in research and development expenses for the release of certain liabilities of \$4.8 million pursuant to the 2nd Amendment with Junshi Biosciences. Research and development expenses recognized for obligations to Junshi Biosciences were \$8.0 million and \$68.5 million (inclusive of the \$35.0 million option fee) in 2023 and 2022, respectively. In the consolidated balance sheets as of December 31, 2024 and 2023, the Company classified \$12.5 million and \$25.0 million, respectively, in accrued and other current liabilities and \$0.4 million and \$6.3 million in accounts payable, respectively, related to the co-development, regulatory and technology transfer costs related to these programs.

The accrued royalty obligation to Junshi Biosciences was \$1.5 million as of December 31, 2024 and immaterial at December 31, 2023. 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.

Apotex

On June 27, 2024, the Company entered into the Canada License Agreement with Apotex, pursuant to which, the Company granted to Apotex an exclusive license under the Company's rights to toripalimab to commercialize toripalimab within Canada. Pursuant to the Canada License Agreement, Apotex paid the Company an upfront payment of \$6.3 million United States Dollars which has been classified as net revenue in the consolidated statements of operations for the year ended December 31, 2024. In addition, Apotex agreed to pay the Company up to an aggregate of \$51.5 million Canadian Dollars in milestone payments in connection with the achievement of certain regulatory and sales milestones with respect to toripalimab in Canada. Lastly, Apotex agreed to pay the Company a low double-digit percentage of any future net sales of toripalimab in Canada that the Company will subsequently pay to Junshi Biosciences pursuant to the Collaboration Agreement.

The Canada License Agreement term continues until the tenth year after the first commercial sales of toripalimab in Canada, subject to an extension for a subsequent ten-year term at the option of Apotex. Apotex may terminate the Canada License Agreement for any reason after a specified notice period. The Canada License Agreement will terminate automatically if the rights granted to the Company by the Collaboration Agreement are terminated, if there is material breach that is not cured, if there are certain challenges to licensed patents by Apotex and in the case of certain insolvency events.

Bioeq

On November 4, 2019, the Company entered into a license agreement with Bioeq (the "Bioeq License Agreement") for the commercialization of the Bioeq Licensed Products. 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.

The Company accounted for the licensing transaction as an asset acquisition under the relevant accounting rules. The terms of the Bioeq Agreement included 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. The Company shared 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 \$38.4 million as of December 31, 2023.

On January 19, 2024 the Company entered into the CIMERLI Purchase Agreement with Sandoz. Pursuant to the CIMERLI Purchase Agreement, on March 1, 2024, the Company completed the divestiture of its CIMERLI ophthalmology franchise through the sale of its subsidiary, Coherus Ophthalmology. Refer to Note 6. Acquisition and Dispositions for additional information. Upon closing of the CIMERLI Sale, the Bioeq License Agreement was assumed by Sandoz.

Adimab Development and Option Agreement

In October 2018, Surface and Adimab entered into the A&R Adimab Agreement, which amended and restated the Original Adimab Agreement, for the discovery and optimization of proprietary antibodies as potential therapeutic product candidates. Under the A&R Adimab Agreement, the Company will select biological targets against which Adimab will use its proprietary platform technology to research and develop antibody proteins using a mutually agreed upon research plan. The A&R Adimab Agreement, among other things,

[Table of Contents](#)

provided access to additional antibodies and expanded the Company's right to evaluate and use antibodies that were modified or derived using Adimab technology for diagnostic purposes.

Adimab granted the Company the Research Option. In addition, Adimab granted the Company the Commercialization Option. Upon the exercise of a Commercialization Option, and payment of the applicable option fee to Adimab, Adimab will assign the Company the patents that cover the antibodies selected by such Commercialization Option. The Company will be required to use commercially reasonable efforts to develop, seek market approval of, and commercialize at least one antibody against the target covered by the Commercialization Option in specified markets upon the exercise of a Commercialization Option.

Under the A&R Adimab Agreement, the Company is obligated to make milestone payments and to pay specified fees upon the exercise of the Research Option or Commercialization Option. Upon exercise of a Research Option, the Company is obligated to pay a nominal research maintenance fee on each of the next four anniversaries of the exercise. Upon the exercise of each Commercialization Option, the Company will be required to pay an option exercise fee of a low seven-digit dollar amount, and the Company may be responsible for milestone payments of up to an aggregate of \$13.0 million for each licensed product that receives marketing approval. For any licensed product that is commercialized, the Company is obligated to pay Adimab tiered royalties of a low to mid single-digit percentage on worldwide net sales of such product. The Company may also partially exercise a Commercialization Option with respect to ten antibodies against a biological target by paying 65% of the option fee and later either (i) paying the balance and choosing additional antibodies for commercialization, up to the maximum number under the Commercialization Option, or (ii) foregoing the Commercialization Option entirely. For any Adimab diagnostic product that is used with or in connection with any compound or product other than a licensed antibody or licensed product, the Company is obligated to pay Adimab up to a low seven digits in regulatory milestone payments and low single-digit royalties on net sales. No additional payment is due with respect to any companion diagnostic or any diagnostic product that does not contain any licensed antibody. Any payments payable to Adimab as a result of any product candidates being developed pursuant to the GSK Agreement, will be payable to Adimab directly by GSK.

Vaccinex License Agreement

On March 23, 2021, Surface and Vaccinex entered into the Vaccinex License Agreement which provides the Company a worldwide, exclusive, sublicensable license to make, have made, use, sell, offer to sell, have sold, import, and otherwise exploit Vaccinex Licensed Products, including the antibody CHS-114 targeting CCR8. Under the Vaccinex License Agreement, the Company is obligated to use commercially reasonable efforts to develop, clinically test, achieve regulatory approval, manufacture, market and commercialize at least one Vaccinex Licensed Product.

The Company is responsible for all costs and expenses of such development, manufacturing and commercialization. Vaccinex is eligible to receive up to an aggregate of \$3.5 million based on achievement of certain clinical milestones, up to an aggregate of \$11.5 million based on achievement of certain regulatory milestones per Vaccinex Licensed Product, and low single-digit royalties on global net sales of any approved licensed products.

Out-Licensing Agreement Acquired as part of the Surface Acquisition

On September 8, 2023, at the closing of the Surface Acquisition, all the assets, liabilities, rights and obligations of Surface were assumed by the Company's direct, wholly-owned subsidiary, Surface Oncology, LLC. See further details in Note 6. Acquisition and Dispositions above.

GSK Agreement

In December 2020, Surface entered into the GSK Agreement. Pursuant to the GSK Agreement, Surface granted GSK a worldwide exclusive, sublicensable license to develop, manufacture and commercialize the Licensed Antibodies. GSK is responsible for the development, manufacturing and commercialization of the Licensed Antibodies and a joint development committee was formed to facilitate information sharing. GSK is responsible for all costs and expenses of such development, manufacturing and commercialization and is obligated to provide the Company with updates on its development, manufacturing and commercialization activities through the joint development committee. In March 2022, Surface earned a \$30.0 million milestone payment from GSK upon the dosing of the first patient in the Phase 1 trial of GSK4381562. The Company is eligible to receive up to \$60.0 million in additional clinical milestones and \$155.0 million in regulatory milestones. In addition, the Company may receive up to \$485.0 million in sales milestone payments. The Company is also eligible to receive royalties on global net sales of any approved products based on the Licensed Antibodies, ranging in percentages from high single digits to mid-teens. Due to the uncertainty of pharmaceutical development and the historical failure rates

[Table of Contents](#)

generally associated with drug development, the Company may not receive any milestone payments or any royalty payments under the GSK Agreement. The Company has not recognized license-related revenue under the GSK Agreement to date.

Unless terminated earlier, the GSK Agreement expires on a licensed product-by-licensed product and country-by-country basis on the later of ten years from the date of first commercial sale or when there is no longer a valid patent claim or regulatory exclusivity covering such licensed product in such country. Either party may terminate the GSK Agreement for an uncured material breach by the other party or upon the bankruptcy or insolvency of the other party. GSK may terminate the GSK Agreement for its convenience. The Company may terminate the GSK Agreement if GSK institutes certain actions related to the licensed patents or if GSK ceases development activities, other than for certain specified technical or safety reasons. In the event of termination, the Company would regain worldwide rights to the terminated program.

8. Financial Liabilities

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

(in thousands)	At December 31, 2024				
	Principal Amount	Unamortized Debt Discount and Debt Issuance Costs	Net Carrying Value	Estimated Fair Value	Level
Financial Liabilities:					
2029 Term Loan	\$ 38,660	\$ (1,962)	\$ 36,698	\$ 36,698	Level 2*
2026 Convertible Notes	\$ 230,000	\$ (1,771)	\$ 228,229	\$ 223,100	Level 2**

(in thousands)	At December 31, 2023				
	Principal Amount	Unamortized Debt Discount and Debt Issuance Costs	Net Carrying Value	Estimated Fair Value	Level
Financial Liabilities:					
2027 Term Loans	\$ 250,000	\$ (3,519)	\$ 246,481	\$ 246,481	Level 2*
2026 Convertible Notes	\$ 230,000	\$ (3,112)	\$ 226,888	\$ 150,155	Level 2**

* The principal amounts outstanding are subject to variable interest rates, which are based on three-month SOFR plus fixed percentages. 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.

2029 Term Loan

On May 8, 2024, the Company entered into a senior secured term loan facility of \$38.7 million that was fully funded on the 2029 Term Loan Effective Date with the Agent and the 2029 Lenders. The net proceeds of \$37.5 million, net of the original issuance discount, were used by the Company to help repay in full the existing outstanding indebtedness owed by the Company to BioPharma Credit, PLC ("BioPharma"), BPCR Limited Partnership (a "2027 Lender"), and Biopharma Credit Investments V (Master) LP (a "2027 Lender") pursuant to the 2027 Term Loans.

The 2029 Term Loan is governed by the 2029 Loan Agreement. The 2029 Term Loan will mature on May 8, 2029. The amounts borrowed under the 2029 Term Loan accrue interest equal to 8.0% per annum, plus a three-month SOFR rate. The 2029 Term Loan provides for interest-only payments on a quarterly basis until maturity. The Company may prepay the 2029 Term Loan in full or in part provided the Company (i) provides at least three (3) business days' prior written notice to the Agent, (ii) pays on the date of such prepayment (A) all outstanding principal to be prepaid plus accrued and unpaid interest, (B) a prepayment fee of (x) 10.0% of the 2029 Term Loans so prepaid if paid on or after the first anniversary of the 2029 Term Loan Effective Date and before the second anniversary of the 2029 Term Loan Effective Date; (y) 5.0% of the 2029 Term Loan so prepaid if paid after the second anniversary of the 2029 Term Loan Effective Date and on or before the third anniversary of the 2029 Term Loan Effective Date; and (z) 0% of the 2029 Term Loan so prepaid if paid after the third anniversary of the 2029 Term Loan Effective Date, (C) if paid before the first anniversary of the 2029 Term Loan Effective Date, a make-whole amount equal to the interest that would have accrued from the date of prepayment through the first anniversary of the 2029 Term Loan Effective Date, and (D) all other sums, if any, that shall become due and payable under the 2029 Loan Agreement, including

[Table of Contents](#)

interest at the default rate with respect to any past due amounts. Amounts outstanding during an event of default shall accrue interest at an additional rate of 4.0% per annum, which interest shall be payable on demand in cash.

The 2029 Term Loan is secured by a lien on substantially all of the assets of the Company, including intellectual property, subject to customary exclusions and exceptions. The 2029 Loan Agreement contains customary representations and warranties, covenants and events of default, including a financial covenant that commenced on the 2029 Term Loan Effective Date, which requires the Company to maintain certain levels of cash and cash equivalents. As of December 31, 2024, the Company was in compliance with these covenants other than to the extent that the disclosures set forth in Item 9A of this Annual Report on Form 10-K do not comply with the requirements of subclause (ii) of Section 5.2(a)(i) of the 2029 Loan Agreement for which the Company is in possession of a valid waiver, and there were no events of default under the 2029 Term Loan.

The Company incurred \$2.2 million of debt discount and issuance costs relating to the issuance of the 2029 Term Loan, which were recorded as a reduction to the carrying value of the 2029 Term Loan on the consolidated balance sheets. The debt issuance costs are being amortized and recognized as additional interest expense over the five-year contractual term of the 2029 Term Loan using the effective interest rate method.

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 following table presents the components of interest expense related to the 2029 Term Loan:

(in thousands)	Year Ended December 31, 2024
Contractual interest	\$ 3,319
Amortization of debt discount and debt issuance costs	201
Total interest expense	<u>\$ 3,520</u>

As of December 31, 2024, the total remaining unamortized debt discount and debt offering costs of \$2.0 million will be amortized using the effective interest rate over the remaining term of 4.4 years.

Assuming the fourth quarter of 2024 interest rate of 12.6%, future payments on the 2029 Term Loan are as follows:

Year ending December 31, (in thousands)	
2025 - interest only	\$ 4,940
2026 - interest only	4,940
2027 - interest only	4,940
2028 - interest only	4,954
2029 and thereafter - principal and interest	<u>40,379</u>
Total minimum payments	60,153
Less amount representing interest	<u>(21,493)</u>
2029 Term Loan, gross	38,660
Less unamortized debt discount and debt issuance costs	<u>(1,962)</u>
Net carrying amount of 2029 Term Loan	<u>\$ 36,698</u>

Revenue Purchase and Sale Agreement

On May 8, 2024, concurrent with the 2029 Term Loan, the Company entered into the Revenue Purchase and Sale Agreement with Coduet Royalty Holdings, LLC, as administrative agent, and the Purchaser Group. Under the terms of the Revenue Purchase and Sale Agreement, the Purchaser Group paid the Company \$37.5 million, subject to certain conditions at closing (the "Revenue Purchase Price"). In exchange, the Company sold to the Purchaser Group a right to receive 5.0% of U.S. net sales of UDENYCA and LOQTORZI with respect to a specified threshold applicable to UDENYCA net sales and a specified threshold applicable to LOQTORZI net sales during an applicable year and 0.5% of U.S. net sales of UDENYCA and LOQTORZI that exceeded the specified threshold during that year (the "Revenue Payment") for each calendar quarter commencing May 8, 2024. The Purchaser Group's right to receive the Revenue Payment terminates and the Company no longer has the obligation to pay Revenue Payments once the Purchaser Group receives the amount equal to 2.25 times the Revenue Purchase Price allocated to each product. The Company may also buy out the Purchaser Group's rights to receive the Revenue Payments by triggering certain conditions and paying the Purchaser Group the unpaid portion of the 2.25 multiple on the

[Table of Contents](#)

Revenue Purchase Price. The proceeds from the Revenue Purchase Price were used by the Company as part of the full repayment of the 2027 Term Loans. The Company has announced that it plans to use a portion of the proceeds of the contemplated UDENYCA Sale to buy out the right to receive royalties on net sales of UDENYCA which is expected to be \$47.7 million assuming a close late in the first quarter or early in the second quarter of 2025 in accordance with the Revenue Purchase and Sale Agreement.

The Revenue Purchase and Sale Agreement contains various representations and warranties, including with respect to organization, authorization, and certain other matters, certain covenants with respect to payment, reporting, intellectual property, in-licenses, out-licenses, and certain other actions, indemnification obligations and other provisions customary for transactions of this nature.

The Revenue Purchase and Sale Agreement contains an embedded derivative that meets the criteria to be bifurcated and accounted for as a freestanding derivative instrument subject to derivative accounting. The allocation of the Revenue Purchase Price to the embedded derivative resulted in a \$9.2 million discount on the revenue participation liability. Additionally, there was \$1.4 million in issuance costs. The Company is amortizing the discount and issuance costs to interest expense over the estimated term of the Revenue Purchase and Sale Agreement using the effective interest method. For the year ended December 31, 2024, interest expense was \$7.2 million, inclusive of the amortization of discount and issuance costs of \$1.3 million. For details on the Royalty Fee Derivative Liability, see Note 3. Fair Value Measurements.

A summary of the revenue participation liability is as follows:

(in thousands)	December 31, 2024
Revenue participation liability	\$ 37,994
Less unamortized discount and issuance costs	(9,251)
Net carrying value	\$ 28,743

Classification on the consolidated balance sheets is as follows:

(in thousands)	Balance Sheet Classification	December 31, 2024
Revenue participation liability, current	Accrued and other current liabilities	\$ 1,148
Revenue participation liability, non-current	Other liabilities, non-current	27,595
Net carrying value		\$ 28,743

2027 Term Loan

The Company entered into the Loan Agreement with BioPharma and the 2027 Lenders for a senior secured term loan facility of up to \$300.0 million, of which \$250.0 million was funded. Starting April 1, 2023, the 2027 Term Loans accrued 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%.

On February 5, 2024, the Company entered into the Consent and Amendment with the Collateral Agent and the 2027 Lenders. Pursuant to and subject to terms and conditions in the Consent and Amendment, among other things: (1) the 2027 Lenders and the Collateral Agent provided consent to consummation of the transactions contemplated by the CIMERLI Purchase Agreement between the Company and Sandoz, and released a subsidiary of the Company from its obligations and certain assets subject to the transactions contemplated thereby, (2) the 2027 Lenders and the Collateral Agent required the Company to make a partial prepayment of the principal of the loans outstanding under the 2027 Loan Agreement in the amount of \$175.0 million upon consummation of the CIMERLI Sale, subject to certain conditions and (3) the parties thereto agreed to adjust the minimum net trailing twelve month net sales covenant level to be \$125.0 million under the 2027 Loan Agreement.

As a result of the closing of the CIMERLI Sale, the Company made a partial prepayment of \$175.0 million of the total principal balance of \$250.0 million of the 2027 Term Loans on April 1, 2024, and including the prepayment premium fee, make-whole and accrued interest, the Company paid \$181.9 million. On May 8, 2024, in connection with entering into the 2029 Term Loan and the Revenue Purchase and Sale Agreement, the Company repaid in full all outstanding indebtedness and terminated all commitments under the 2027 Term Loans. The May 8, 2024 payoff amount of \$79.6 million included repayment in full of all outstanding principal, accrued interest, a 3.0% prepayment premium fee of the principal amount, a make-whole interest payment and lender fees. During the year ended December 31, 2024, the Company recorded a \$12.6 million loss on debt extinguishment in the consolidated statements of operations for the payoff of the 2027 Term Loans, which included the write-off of the remaining debt discount and debt issuance costs, the prepayment premium fee, the make-whole interest payment, and lender fees.

[Table of Contents](#)

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

(in thousands)	Year Ended December 31,		
	2024	2023	2022
Contractual interest	\$ 9,916	\$ 34,289	\$ 20,243
Amortization of debt discount and debt issuance costs	1,277	1,094	4,550
Total interest expense	\$ 11,193	\$ 35,383	\$ 24,793

1.5% Convertible Senior Subordinated Notes due April 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 Company has announced that it plans to use part of the proceeds that it receives at the closing of the Udenyca Sale to fully repay the outstanding 2026 Convertible Notes.

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, 2024, 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 equity components. 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 paid \$18.2 million to enter into privately 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. 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 the Company's common stock of \$14.82 per share on April 14, 2020, and is subject to certain adjustments under the

[Table of Contents](#)

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 in 2020. 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 sheets. 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, 2024, the holders of the 2026 Convertible Notes would have received common shares with an aggregate value of \$16.5 million based on the Company's closing stock price of \$1.38 as of December 31, 2024.

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

(in thousands)	Year Ended December 31,		
	2024	2023	2022
Stated coupon interest	\$ 3,450	\$ 3,450	\$ 3,450
Amortization of debt discount and debt issuance costs	1,341	1,313	1,286
Total interest expense	\$ 4,791	\$ 4,763	\$ 4,736

The remaining unamortized debt discount and debt offering costs related to the Company's 2026 Convertible Notes of \$1.8 million as of December 31, 2024, will be amortized using the effective interest rate over the remaining term of the 2026 Convertible Notes. The annual effective interest rate is 2.1% for the 2026 Convertible Notes.

Future payments on the 2026 Convertible Notes as of December 31, 2024 are as follows:

Year ending December 31, (in thousands)	
2025 - interest only	\$ 3,450
2026 - principal and interest	231,725
Total minimum payments	235,175
Less amount representing interest	(5,175)
2026 Convertible Notes, principal amount	230,000
Less unamortized debt discount and debt issuance costs	(1,771)
Net carrying amount of 2026 Convertible Notes	\$ 228,229

8.2% Convertible Notes due 2022

On February 29, 2016, the Company issued and sold \$100.0 million aggregate principal amount of its 8.2% Convertible Senior Notes due 2022. The 2022 Convertible Notes constituted general, senior unsubordinated obligations of the Company and were guaranteed by certain subsidiaries of the Company, bore interest at a fixed coupon rate of 8.2% per annum payable quarterly and matured on March 31, 2022. 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 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.

[Table of Contents](#)

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

(in thousands)	Year Ended December 31, 2022
Stated coupon interest	\$ 2,050
Amortization of debt discount and debt issuance costs	521
Total interest expense	<u>\$ 2,571</u>

2025 Term Loan

On January 7, 2019, the Company entered into the 2025 Term Loan with affiliates of Healthcare Royalty Partners (together, the "2025 Lender"). The 2025 Term Loan consisted of a six-year term loan facility for an aggregate principal amount of \$75.0 million (the "Borrowings"). 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.

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 January 7, 2022, 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 statements of operations for 2022. Interest expense for the year ended December 31, 2022 was immaterial.

9. 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, 2024, the Company's non-cancelable purchase commitments under the terms of its agreements are as follows:

Year ending December 31, (in thousands)	
2025	\$ 69,450
2026	16,449
2027	600
Total obligations	<u>\$ 86,499</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 generally 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. In connection with the YUSIMRY Sale, HKF assumed \$17.0 million in YUSIMRY inventory purchase commitments, of which \$17.0 million remained as of December 31, 2024. If HKF were to default on its obligations under the YUSIMRY Purchase Agreement, the Company could become liable to pay any unpaid portion of these purchase commitments.

The substantial majority of these purchase commitments are expected to transfer to the Intas Parties in conjunction with the UDENCYA Sale, if the transaction closes as anticipated.

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 it's 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. As of December 31, 2024 and 2023, the Company had an accrual of \$6.4 million related to such matters 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. 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. If the Company has any liability related to Zinc, it does not expect that it will transfer to Intas as part of the UDENYCA Sale. The Company has an accrual established as of December 31 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 9, 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.

10. Leases

Through December 31, 2023, the Company leased approximately 47,789 square feet of office space for its corporate headquarters in Redwood City, California (the "Lease Agreement"). Prior to an amendment to the Lease Agreement entered into on October 24, 2023 (the "Sixth Amendment"), the Lease Agreement was set to expire in September 2024 and contained a one-time option to extend the lease term for five years. Under the terms of the Sixth Amendment, the Company extended the lease term through September 30, 2027 and reduced the amount of office space leased to 27,532 square feet. The remaining 20,257 square feet of office space expired on December 31, 2023, according to the terms of the Sixth Amendment.

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, if any, 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 leased approximately 50 vehicles as of December 31, 2023. The vehicles leased under this arrangement were classified as finance leases. Beginning in February 2023, the Company no longer enters into these leasing arrangements and began transitioning to a reimbursement program with its employees. As of December 31, 2024, the Company has no remaining obligation under the vehicle leasing arrangement.

[Table of Contents](#)

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

(in thousands)	Balance Sheet Classification	December 31,	
		2024	2023
Assets			
Operating leases	Other assets, non-current	\$ 4,518	\$ 5,912
Finance leases	Property and equipment, net	—	1,022
Total leased assets		\$ 4,518	\$ 6,934
Liabilities			
Operating lease liabilities, current	Accrued and other current liabilities	\$ 1,691	\$ 1,424
Operating lease liabilities, non-current	Lease liabilities, non-current	3,286	4,977
Total operating lease liabilities		\$ 4,977	\$ 6,401
Finance lease liabilities, current	Accrued and other current liabilities	\$ —	\$ 721
Finance lease liabilities, non-current	Lease liabilities, non-current	—	351
Total finance lease liabilities		\$ —	\$ 1,072

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

	December 31,		
	2024	2023	2022
Weighted-Average Remaining Lease Term			
Operating leases	2.7 years	3.6 years	2.2 years
Finance leases	—	1.4 years	2.2 years
Weighted-Average Discount Rate			
Operating leases	11.9%	11.8%	8.0%
Finance leases	—	8.7%	8.4%

The components of lease expense were as follows:

(in thousands)	Year Ended December 31,		
	2024	2023	2022
Finance lease cost			
Amortization of right-of-use assets	\$ 225	\$ 1,069	\$ 1,228
Interest on lease liabilities	24	146	166
Total finance lease cost	249	1,215	1,394
Operating lease cost	2,066	2,984	3,154
Total lease cost	\$ 2,315	\$ 4,199	\$ 4,548

[Table of Contents](#)

Supplemental cash flow information related to leases was as follows:

(in thousands)	Year Ended December 31,		
	2024	2023	2022
Cash paid for amounts included in measurement of lease liabilities:			
Operating cash flows from operating leases	\$ 2,095	\$ 3,560	\$ 3,401
Operating cash flows from finance leases	\$ 24	\$ 145	\$ 155
Financing cash flows from finance leases	\$ 248	\$ 1,034	\$ 1,228
Right-of-use assets obtained in exchange for lease obligations:			
Operating leases	\$ —	\$ 2,653	\$ —
Finance leases	\$ —	\$ —	\$ 2,694

As of December 31, 2024, the maturities of the lease liabilities were as follows:

Year ending December 31, (in thousands)	Operating leases
2025	\$ 2,192
2026	2,126
2027	1,530
Total lease payments	5,848
Less imputed interest	(871)
Lease liabilities	\$ 4,977

11. Stockholders' Deficit

Public Offering

On May 16, 2023, the Company entered into an underwriting agreement (the "Underwriting Agreement") with J.P. Morgan Securities LLC and Citigroup Global Markets Inc., as representatives of the several underwriters named therein (the "Underwriters"), pursuant to which the Company issued and sold the an aggregate of 11,764,706 shares (the "Firm Shares") of our common stock, par value \$0.0001 per share, to the Underwriters (the "Public Offering"). Additionally, under the terms of the Underwriting Agreement, the Company granted the Underwriters an option, for 30 days from the date of the Underwriting Agreement, to purchase up to an additional 1,764,705 shares of common stock (the "Option Shares," and together with the Firm Shares, the "Shares"), which the Underwriters elected to exercise in full. The price to the public in the Public Offering was \$4.25 per share. The Underwriters agreed to purchase the Shares from the Company pursuant to the Underwriting Agreement at a price of \$3.995 per share.

The Offering was made pursuant to a prospectus supplement and related prospectus filed with the SEC pursuant to the Company's Registration Statement under which the Company may offer and sell up to \$150.0 million in the aggregate of its common stock, including the common stock already sold, preferred stock, debt securities, warrants and units from time to time in one or more offerings. On May 18, 2023, the Company completed the sale and issuance of an aggregate of 13,529,411 Shares, including the exercise in full of the Underwriters' option to purchase the Option Shares. The Company received net proceeds of approximately \$53.6 million, after deducting the Underwriters' discounts and commissions and offering expenses payable by the Company.

ATM Offering

On November 8, 2022, the Company filed a Registration Statement. 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, including the common stock already sold, through or to Cowen as the Company's sales agent or principal in the ATM Offering.

On May 15, 2023, pursuant to an Amendment No. 1 to Sales Agreement and in connection with the Public Offering, the Company reduced the number of shares that could be issued and sold pursuant to its ATM Offering with TD Cowen by \$86.25 million, lowering the aggregate offering price under the Sales Agreement from \$150.0 million to \$63.75 million.

On September 11, 2023, pursuant to an Amendment No. 2 to Sales Agreement, the Company increased the number of shares that could be issued and sold pursuant to its ATM Offering with TD Cowen by \$28.75 million, increasing the aggregate offering price under the Sales Agreement from \$63.75 million to \$92.5 million.

[Table of Contents](#)

The following table summarizes information regarding settlements under the ATM Offering:

(in thousands, except share and per share data)	Year Ended December 31,		
	2024	2023	2022
Number of common stock shares sold during the period	650,005	3,559,761	916,884
Weighted-average price per share	\$ 2.44	\$ 5.43	\$ 7.30
Gross proceeds	\$ 1,589	\$ 19,339	\$ 6,692
Less commissions and fees	(40)	(483)	(168)
Net proceeds after commissions and fees	\$ 1,549	\$ 18,856	\$ 6,524

As of December 31, 2024, the Company had approximately \$64.9 million of its common stock remaining available for sales under the ATM Offering.

Common Stock

On October 9, 2023, in accordance with the terms of an optional stock purchase agreement entered into with one of its CMOs on September 28, 2023 (the "Optional Stock Purchase Agreement"), the Company issued 2,225,513 shares of its common stock to one of its CMOs for a price of \$3.675 per share, with a total value of \$8.2 million in this non-cash transaction. The Optional Stock Purchase Agreement gave the Company the option, in its sole discretion, to elect to pay for certain manufacturing services provided by the CMO by either paying cash or issuing shares of our common stock in a private placement offering (the "Stock Service Fee Payment"). On October 4, 2023, the Company notified the CMO of its election of the Stock Service Fee Payment. The price per share of common stock was equal to the volume-weighted average closing trading price per share of common stock on the Nasdaq Global Market over the ten-trading day period ending on and including October 6, 2023.

12. 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 Award Plan (the "Original 2014 Plan"), which became effective upon the closing of the Company's IPO on November 6, 2014. The Original 2014 Plan was 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 with 2024 being the last calendar year with an automatic annual increase under the Original 2014 Plan. The Original 2014 Plan was amended and restated effective May 29, 2024 as the 2014 Plan with amendments that included an additional 7,000,000 shares reserved for issuance over the existing share reserve and certain other changes to the Original 2014 Plan. Additionally, the evergreen provision has been removed from the 2014 Plan such that any increase in the total number of shares of common stock that may be issued must be approved by stockholders. There were 6,010,528 shares of common stock available for future issuance as of December 31, 2024 under the 2014 Plan. All remaining shares under the Company's 2010 Equity Incentive Stock Plan (the "2010 Plan") were transferred to the Original 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 enables 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, primarily 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, 2024.

In June 2016, the Company adopted the 2016 Plan. The 2016 Plan was 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. In connection with the approval of the amendment and restatement of the Original 2014 Plan as the 2014 Plan in 2024, the Company agreed to not make any new awards under the 2016 Plan after May 29, 2024, such that all remaining shares under the 2016 Plan will remain unissued.

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 2016 Plan expire, are forfeited or canceled without the issuance of shares, the

[Table of Contents](#)

shares subject to such awards return to the 2014 Plan. In addition, shares withheld to pay for minimum statutory tax obligations with respect to full-value awards are added back to the 2014 Plan. The annual grant to eligible employees can vary depending 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 market 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.

In 2024, the Company granted an aggregate of 2,622,500 performance-based stock options ("PSOs") under the Original 2014 Plan and under the 2014 Plan to its Chief Executive Officer and certain other senior officers, which have a term of ten years. The PSOs granted under the Original 2014 Plan are comprised of 1,982,500 PSOs with performance-based vesting conditions tied to commercial, clinical and strategic milestones (the "Performance Condition PSOs"). The fair value of each Performance Condition PSO was estimated on the grant date, using the Black-Scholes model for PSOs tied to commercial, clinical and strategic milestones. Expense for the Performance Condition PSOs is recognized over the requisite service period only when the performance condition is considered probable of being achieved and is recognized over the period from the grant date through the time the milestone is expected to be achieved. The PSOs granted under the 2014 Plan comprised 640,000 PSOs with total shareholder return vesting tied to performance milestones during specified periods (the "Market Condition PSOs"). The fair value of each Market Condition PSO was estimated on the grant date using a Monte Carlo simulation model.

The following table summarizes option activity from December 31, 2023 through December 31, 2024:

	Options			
	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Terms (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2023	23,659,240	\$ 13.31		
Granted - at fair value	10,513,500	\$ 2.28		
Exercised	(174,651)	\$ 1.67		
Forfeited/Canceled	(5,292,979)	\$ 9.20		
Outstanding at December 31, 2024	<u>28,705,110</u>	\$ 10.10	6.4	\$ 889
Exercisable at December 31, 2024	<u>17,010,902</u>	\$ 14.37	4.6	\$ —

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 the options outstanding and exercisable as of December 31, 2024 is summarized by range of exercise prices 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
\$ 0.77 - \$ 2.41	6,361,791	9.5	\$ 1.74	473,666	\$ 2.35
\$ 2.59 - \$ 5.44	6,000,496	8.3	\$ 3.86	2,069,330	\$ 4.33
\$ 5.86 - \$ 12.37	5,603,496	5.3	\$ 10.28	4,386,405	\$ 10.54
\$ 12.44 - \$ 17.06	4,601,126	5.3	\$ 14.64	3,992,175	\$ 14.59
\$ 17.17 - \$ 26.58	4,691,013	3.8	\$ 18.90	4,642,138	\$ 18.91
\$ 26.62 - \$ 36.85	1,447,188	0.5	\$ 29.06	1,447,188	\$ 29.06
	<u>28,705,110</u>	6.4	\$ 10.10	<u>17,010,902</u>	\$ 14.37

[Table of Contents](#)

Additional information on options is summarized as follows:

(in thousands, except weighted-average grant-date fair value per share)	Year Ended December 31,		
	2024	2023	2022
Total intrinsic value of options exercised	\$ 110	\$ 425	\$ 914
Total grant date fair value of options vested	\$ 22,778	\$ 30,467	\$ 34,916
Weighted-average grant date fair value per share of options granted	\$ 1.49	\$ 4.19	\$ 7.04

As of December 31, 2024, total unrecognized stock-based compensation expense related to unvested stock options was \$24.6 million, which is expected to be recognized over a weighted-average period of 2.6 years.

Restricted Stock Units

The Company grants RSUs from time to time 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 the applicable grant date, provided the employee remains continuously employed with the Company. However, the RSUs granted in 2024 were issued and vested immediately to settle a portion of the 2023 annual employee performance bonuses. 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, 2023	1,726,729	\$ 11.93
RSUs granted	1,976,750	\$ 2.23
RSUs vested	(2,793,626)	\$ 5.41
RSUs canceled	(141,616)	\$ 11.50
Balances at December 31, 2024	768,237	\$ 10.79

Additional information on RSUs is summarized as follows:

(in thousands, except weighted-average grant-date fair value per share)	Year Ended December 31,		
	2024	2023	2022
Total grant date fair value of RSUs vested	\$ 15,101	\$ 18,381	\$ 13,598
Total grant date fair value of RSUs granted	\$ 4,408	\$ 11,386	\$ 22,502
Weighted-average grant-date fair value per share of RSUs granted	\$ 2.23	\$ 8.93	\$ 13.34

As of December 31, 2024, total unrecognized stock-based compensation expense related to unvested RSUs was \$2.6 million, which is expected to be recognized over a weighted-average period of 0.7 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 provided for annual increases in the number of shares available for issuance on January 1 of each year until January 1, 2024, 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 1,689,547 shares of common stock available for future issuance as of December 31, 2024. 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 six-month periods commencing on each May 16 and November 16. As of December 31, 2024, the unrecognized compensation expense associated with the ESPP was immaterial, which is expected to be recognized over a 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 statements of operations related to employees and nonemployees:

(in thousands)	Year Ended December 31,		
	2024	2023	2022
Cost of goods sold ⁽¹⁾	\$ 1,070	\$ 632	\$ 736
Research and development	8,643	14,596	18,999
Selling, general and administrative	18,089	27,882	31,002
Total stock-based compensation expense	<u>\$ 27,802</u>	<u>\$ 43,110</u>	<u>\$ 50,737</u>
Total stock-based compensation expense capitalized into inventory	<u>\$ 1,407</u>	<u>\$ 1,062</u>	<u>\$ 1,187</u>

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

Valuation Assumptions of Awards Granted to Employees

The Company estimated the fair value of each stock option and awards granted under the ESPP on the date of grant using the Black-Scholes option-pricing model. The following table illustrates the weighted-average assumptions for the Black-Scholes option-pricing model used in determining the fair value of the awards during the years ended December 31, 2024, 2023 and 2022:

	Year Ended December 31,		
	2024	2023	2022
Expected term (years)			
Stock options	5.7	6.0	6.1
ESPP	0.5	0.5	0.5
Expected volatility			
Stock options	67 %	64 %	62 %
ESPP	88 %	105 %	70 %
Risk-free interest rate			
Stock options	3.97 %	3.92 %	2.37 %
ESPP	4.94 %	5.35 %	3.77 %
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. 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 Compensation Committee of the Board approved the Company's matching of employee contributions towards their individual 401(k) Plans whereby eligible employees may elect to contribute up to the lesser of 90% of their annual compensation or the statutorily prescribed annual limit allowable under Internal Revenue Service regulations. The Company makes matching contributions of 100% of the first 4% of eligible compensation that an employee contributes to his or her 401(k) plan, up to a maximum of \$7,500 each

[Table of Contents](#)

year. The Company recorded compensation expense related to the match of \$1.5 million, \$1.8 million and \$2.1 million in 2024, 2023 and 2022, respectively.

13. Income Taxes

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

(in thousands)	Year Ended December 31,		
	2024	2023	2022
Domestic	\$ 28,507	\$ (238,272)	\$ (291,746)
Foreign	—	—	(8)
Total	<u>\$ 28,507</u>	<u>\$ (238,272)</u>	<u>\$ (291,754)</u>

For the periods presented, the income tax provision (benefit) is as follows:

(in thousands)	Year Ended December 31,		
	2024	2023	2022
Current:			
Federal	\$ —	\$ —	\$ —
State	—	—	—
Foreign	—	—	—
Subtotal	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>
Deferred:			
Federal	\$ —	\$ (380)	\$ —
State	—	—	—
Foreign	—	—	—
Subtotal	<u>\$ —</u>	<u>\$ (380)</u>	<u>\$ —</u>
Income tax provision (benefit)	<u>\$ —</u>	<u>\$ (380)</u>	<u>\$ —</u>

For the periods presented above, the income tax provision (benefit) reflects the Company's history of losses and valuation of allowances against the deferred tax assets.

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,		
	2024	2023	2022
United States federal statutory income tax rate	21.0 %	21.0 %	21.0 %
State taxes, net of federal benefit	2.8	(1.2)	1.7
Permanent items	(1.7)	—	(0.1)
Research and development credit	(23.9)	0.9	1.8
Stock-based compensation costs	31.4	(3.5)	(2.3)
Sale Transactions	1.8	—	—
Other	5.6	0.7	—
Change in valuation allowance	<u>(37.0)</u>	<u>(17.7)</u>	<u>(22.1)</u>
Effective income tax rate	<u>— %</u>	<u>0.2 %</u>	<u>— %</u>

[Table of Contents](#)

The components of the Company's net deferred tax assets (liabilities) as of December 31, 2024 and 2023 consist of the following:

(in thousands)	December 31,	
	2024	2023
Deferred tax assets:		
Net operating loss carryforwards	\$ 158,090	\$ 170,402
Research and development credits	72,031	65,225
Depreciation and amortization	28,861	37,211
Stock-based compensation	26,814	30,370
Sales related accruals	39,966	38,474
Other accruals	42,537	42,480
Capitalized research and development	50,850	46,062
Total gross deferred tax assets	419,149	430,224
Valuation allowance	(412,833)	(423,385)
Total net deferred tax assets	6,316	6,839
Deferred tax liabilities:		
Right-of-use asset	(1,004)	(1,538)
In-process research and development	(6,414)	(6,403)
Total deferred tax liabilities	(7,418)	(7,941)
Net deferred tax liabilities	\$ (1,102)	\$ (1,102)

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. As of December 31, 2024 and 2023, the Company recorded net a deferred tax liability of \$1.1 million. The net deferred tax liability relates to in-process research and development that cannot be offset against the deferred tax assets. For remaining deferred tax assets, the Company has determined that it is more likely than not that its federal and state net deferred tax assets will not be realized due to the Company's history of losses and lack of other positive evidence. As a result, the Company has recorded a valuation allowance against the remaining federal and certain state net deferred tax assets as of December 31, 2024 and 2023.

The valuation allowance decreased by \$10.6 million during the year ended December 31, 2024 and increased by \$85.6 million and \$64.4 million during the years ended December 31, 2023 and 2022, respectively.

As of December 31, 2024, the Company had net operating loss carryforwards for federal income of \$718.7 million, which will start to expire in the year 2036, and various states net operating loss carryforwards of \$124.8 million, which have various expiration dates beginning in 2031.

As of December 31, 2024, the Company had federal research and development credit carryforwards for federal income tax purposes of \$66.7 million, which will start to expire in the year 2031, and state research and development credit carryforwards of \$29.5 million, which have no expiration date.

Utilization of the net operating loss and tax credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations provided by Section 382 of the Internal Revenue Code of 1986, as amended, and similar state provisions. The annual limitation may result in the expiration of certain net operating loss and tax credit carryforwards before their utilization. Under the current 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 inception in 2011 forward remain open to examination due to the carryover of unused net operating losses and tax credits.

[Table of Contents](#)

A reconciliation of the Company's unrecognized tax benefits during 2024, 2023 and 2022 is as follows:

(in thousands)	Year Ended December 31,		
	2024	2023	2022
Balance at beginning of year	\$ 17,417	\$ 16,838	\$ 15,495
Additions based on tax positions related to current year	1,565	865	1,385
Additions (reductions) for tax positions of prior years	265	(286)	(42)
Balance at end of year	<u>\$ 19,247</u>	<u>\$ 17,417</u>	<u>\$ 16,838</u>

As of December 31, 2024, 2023 and 2022, the Company had \$19.2 million, \$17.4 million and \$16.8 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 offset by a valuation allowance. During 2024, 2023 and 2022, 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.

14. Net Income (Loss) Per Share

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

(in thousands, except share and per share data)	Year Ended December 31,		
	2024	2023	2022
Basic net income (loss) per share			
Numerator:			
Net income (loss)	<u>\$ 28,507</u>	<u>\$ (237,892)</u>	<u>\$ (291,754)</u>
Denominator:			
Weighted-average common shares outstanding	<u>114,553,537</u>	<u>94,162,637</u>	<u>77,630,020</u>
Basic net income (loss) per share	<u>\$ 0.25</u>	<u>\$ (2.53)</u>	<u>\$ (3.76)</u>
Diluted net income (loss) per share			
Numerator:			
Net income (loss)	<u>\$ 28,507</u>	<u>\$ (237,892)</u>	<u>\$ (291,754)</u>
Denominator:			
Denominator for basic net income (loss) per share	114,553,537	94,162,637	77,630,020
Add effect of potential dilutive securities:			
Stock options, including shares subject to ESPP	168,392	—	—
Restricted stock units	108,533	—	—
Denominator for diluted net income (loss) per share	<u>114,830,462</u>	<u>94,162,637</u>	<u>77,630,020</u>
Diluted net income (loss) per share	<u>\$ 0.25</u>	<u>\$ (2.53)</u>	<u>\$ (3.76)</u>

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

	Year Ended December 31,		
	2024	2023	2022
Stock options, PSOs, including shares subject to ESPP	28,535,096	24,083,222	22,214,875
Restricted stock units	895,208	2,266,387	2,399,465
Shares issuable upon conversion of 2022 Convertible Notes	—	—	1,078,632
Shares issuable upon conversion of 2026 Convertible Notes	11,942,152	11,942,152	11,942,152
Total	<u>41,372,456</u>	<u>38,291,761</u>	<u>37,635,124</u>

The amounts in the table above exclude any shares contingently issuable pursuant to the CVR Agreement because the conditions that could result in a payment becoming due were not met.

15. Subsequent Event

In connection with the December 2, 2024 UDENYCA Purchase Agreement and related UDENYCA Sale, the Company held a Special Meeting of Stockholders (the “Special Meeting”) on March 11, 2025 virtually via the Internet. At the Special Meeting, our stockholders approved the UDENYCA Sale, the UDENYCA Purchase Agreement and the other transactions and ancillary documents contemplated by the UDENYCA Purchase Agreement.

The Company expects to receive \$483.4 million in cash at closing, inclusive of \$118.4 million of UDENYCA product inventory, subject to downward adjustment by the amount of inventory delivered at the closing of the UDENYCA Sale less than the Inventory Target. In addition, the Company is also eligible to receive two additional Earnout Payments of \$37.5 million each, provided that certain minimum UDENYCA Net Sales thresholds are met during specified periods after the closing of the UDENYCA Sale. Closing of the UDENYCA Sale is subject to closing conditions, including FDA authorization of commercial supply from our additional packaging and labeling CMO for UDENYCA. The Company anticipates the closing to occur late in the first quarter or early in the second quarter of 2025.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

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.

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. 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.

Based on this evaluation, and as a result of the material weakness described below, 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 not effective at a reasonable assurance level. Notwithstanding this material weakness, management concluded the consolidated financial statements included in this report present fairly, in all material respects, our financial condition, results of operations and cash flows for the periods covered by this report and our external auditors have issued an unqualified opinion on our consolidated financial statements as of and for the year ended December 31, 2024.

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) and 15d-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 not effective as of December 31, 2024 due to the material weakness discussed below.

Material Weakness in Internal Control over Financial Reporting

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of a company's annual or interim financial statements will not be detected or prevented on a timely basis.

Management determined that there was a material weakness in the operating effectiveness of our procedures related to documentation and review of certain inventory account reconciliations. The lack of sufficient evidence of the review performed over these accounting records did not allow for the testing and validation that the relevant internal controls operated, and thus it resulted in the material weakness. The material weakness related to documentation and did not result in a misstatement with respect to our financial statements included in this Form 10-K. The effectiveness of our internal control over financial reporting as of December 31, 2024 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in its report which is included in this Item 9A of this Annual Report on Form 10-K.

Management's Remediation Measures

We are taking steps to remediate this material weakness and to strengthen our internal control over financial reporting. The remediation measures include additional training and enhancement of our documentation and retention procedures, particularly as they relate to our inventory account reconciliations. This remediation is in progress and will require validation and testing of operating effectiveness of internal controls over multiple financial reporting cycles.

Changes in Internal Control over Financial Reporting

Except for the material weakness noted above, there has been no change in the Company's internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) that occurred during the quarter ended December 31, 2024 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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, 2024, 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, because of the effect of the material weakness described below on the achievement of the objectives of the control criteria, Coherus BioSciences, Inc. (the Company) has not maintained effective internal control over financial reporting as of December 31, 2024, based on the COSO criteria.

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. The following material weakness has been identified and included in management's assessment. Management has identified a material weakness relating to the operating effectiveness of their documentation and review procedures over certain inventory account reconciliations.

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, 2024 and 2023, the related consolidated statements of operations, comprehensive income (loss), stockholders' deficit and cash flows for each of the three years in the period ended December 31, 2024, and the related notes. This material weakness was considered in determining the nature, timing and extent of audit tests applied in our audit of the 2024 consolidated financial statements, and this report does not affect our report dated March 17, 2025, which 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 17, 2025

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, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

(b) During the three months ended December 31, 2024, neither we nor any of our directors or officers adopted or terminated a “Rule 10b5-1 trading arrangement” or “non-Rule 10b5-1 trading arrangement,” as each such term is defined in Item 408(a) of Regulation S-K.

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 we 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, 2024.

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, 2024, 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, 2024, 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, 2024, 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, 2024, 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, 2024, 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
2.1††	Agreement and Plan of Merger, by and among Coherus BioSciences, Inc., Crimson Merger Sub I, Inc., Crimson Merger Sub II, LLC and Surface Oncology, Inc., dated June 15, 2023 (Form of CVR Agreement included as Exhibit A thereto).	8-K	6/16/2023	2.1	
2.2††	Purchase and Sale Agreement, by and between Coherus BioSciences, Inc. and Sandoz Inc., dated January 19, 2024	8-K	1/22/2024	2.1	
2.3††	Asset Purchase Agreement, by and between Coherus BioSciences, Inc. and Hong Kong King-Friend Industrial Company Ltd., dated as of June 26, 2024	8-K	6/27/2024	2.1	
2.4††	Asset Purchase Agreement, by and between Coherus BioSciences, Inc. and Intas Pharmaceuticals Ltd., dated December 2, 2024.	8-K	12/3/2024	2.1	
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(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)	
10.2(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)	
10.3(a)#	BioGenerics, Inc. 2010 Equity Incentive Plan, as amended.	S-1	9/25/2014	10.10(a)	
10.3(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)	
10.4(a)#	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)	
10.4(b)#	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)	

[Table of Contents](#)

Exhibit Number	Exhibit Description	Form	Incorporated by Reference		
			Date	Number	Filed Herewith
10.4(c)#	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)	
10.5#	Coherus BioSciences, Inc. 2014 Employee Stock Purchase Plan.	S-1/A	10/24/2014	10.12	
10.6#	Form of Indemnification Agreement between Coherus BioSciences, Inc. and each of its directors, officers and certain employees.	S-1/A	10/24/2014	10.13	
10.7†	Master Services Agreement, effective January 23, 2012, by and between Medpace, Inc. and BioGenerics, Inc.	S-1	9/25/2014	10.15	
10.8	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	
10.9	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	
10.10(a)#	Coherus BioSciences, Inc. 2016 Employment Commencement Incentive Plan.	10-Q	8/9/2016	10.1(a)	
10.10(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)	
10.10(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)	
10.10(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)	
10.11	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	
10.12	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	
10.13†	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	
10.14	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	
10.15	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	
10.16††	Form of Confirmation for Base Capped Call Transactions under the Indenture.	8-K	4/17/2020	10.1	
10.17	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	
10.18††	Letter Agreement, dated February 9, 2022, between Coherus BioSciences, Inc. and Shanghai Junshi Biosciences, Co., Ltd.	10-Q	5/5/2022	10.1	

[Table of Contents](#)

Exhibit Number	Exhibit Description	Form	Incorporated by Reference		
			Date	Number	Filed Herewith
10.19#	Executive Change in Control and Severance Plan, effective January 1, 2023.	10-Q	5/8/2023	10.2	
10.20	Amendment No. 1 to Sales Agreement between Coherus BioSciences, Inc. and Cowen and Company, LLC, dated May 15, 2023.	10-Q	8/2/2023	10.1	
10.21	Amendment No. 2 to Sales Agreement between Coherus BioSciences, Inc. and Cowen and Company, LLC dated September 11, 2023.	10-Q	11/6/2023	10.2	
10.22††	First Amended and Restated Development and Option Agreement between Adimab, LLC and Surface Oncology, Inc., dated October 3, 2018.	10-K	3/15/2024	10.31	
10.23††	License Agreement, dated as of December 16, 2020, by and between Surface Oncology, Inc. and GLAXOSMITHKLINE INTELLECTUAL PROPERTY (No. 4) LIMITED.	10-K	3/15/2024	10.34	
10.24††	Amendment No. 1, dated as of August 11, 2021, to License Agreement, dated as of December 16, 2020, by and between Surface Oncology, Inc. and GLAXOSMITHKLINE INTELLECTUAL PROPERTY (No. 4) LIMITED.	10-K	3/15/2024	10.35	
10.25††	Sixth Amendment, effective October 24, 2023, by and between Hudson 333 Twin Dolphin Plaza, LLC and Coherus BioSciences, Inc.	10-K	3/15/2024	10.36	
10.26††	Amendment to and Waiver, dated October 25, 2023, under the Exclusive License and Commercialization Agreement, dated February 1, 2021, by and between Coherus Biosciences, Inc. and Shanghai Junshi Biosciences, Co. Ltd.	10-K	3/15/2024	10.37	
10.27††	Exclusive Product License Agreement, dated March 23, 2021, by and between Vaccinex, Inc. and Surface Oncology, Inc.	10-K	3/15/2024	10.40	
10.28††	Amendment No. 2 to the Exclusive License and Commercialization Agreement, as amended, as of March 13, 2024, by and between Coherus BioSciences, Inc. and Shanghai Junshi Biosciences Co., Ltd.	10-Q	5/9/2024	10.2	
10.29††	Loan Agreement dated as of May 8, 2024 among Coherus BioSciences, Inc., the Guarantors, the Collateral Agent and the Lenders party thereto.	8-K/A	5/21/2024	10.1	
10.30††	Revenue Participation Right Purchase and Sale Agreement dated as of May 8, 2024 between Coherus BioSciences, Inc. and Coduet Royalty Holdings, LLC.	8-K/A	5/21/2024	10.2	
10.31#	Coherus BioSciences, Inc. Amended and Restated 2014 Equity Incentive Award Plan.	10-Q	8/8/2024	10.3	
10.32††	Omnibus Amendment to Transaction Documents dated as of June 25, 2024 among Coherus BioSciences, Inc., Coduet Royalty Holdings, LLC and Ankura Trust Company, LLC.	10-Q	8/8/2024	10.4	
10.33††	Exclusive License and Distribution Agreement dated as of June 27, 2024 between Coherus BioSciences, Inc. and Apotex, Inc.	10-Q	8/8/2024	10.5	
19.1	Coherus BioSciences, Inc. Insider Trading Compliance Policy and Procedures, effective February 27, 2023.	10-K	3/15/2024	10.38	
21.1	Subsidiaries of Coherus BioSciences, Inc.				X

[Table of Contents](#)

Exhibit Number	Exhibit Description	Form	Incorporated by Reference		
			Date	Number	Filed Herewith
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
97.1	Coherus BioSciences, Inc. Clawback Policy, effective December 1, 2023.	10-K	3/15/2024	97.1	
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 Regulation S-K, Item 601(b)(10), or schedules and attachments to this exhibit have been omitted pursuant to Regulation S-K, Item 601(a)(5). Information omitted pursuant to Regulation S-K, Item 601(b)(10) is not material and would likely cause competitive harm to the registrant if publicly disclosed.				
#	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 17, 2025

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

SIGNIFICANT SUBSIDIARIES OF COHERUS BIOSCIENCES, INC.

<u>Name of Subsidiary</u>	<u>Jurisdiction of Organization</u>
Surface Oncology, LLC	Delaware

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 Statement (Form S-8 No. 333-200593) 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,
- (3) Registration Statements (Form S-8 No. 333-203356, 333-209936, 333-216679, 333-222700, 333-229480, 333-236068, 333-251876, and 333-262134) pertaining to the Coherus BioSciences, Inc. 2014 Equity Incentive Award Plan and the Coherus BioSciences, Inc. 2014 Employee Stock Purchase Plan,
- (4) 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.,
- (5) Registration Statements (Form S-8 Nos. 333-269291 and 333-278314) pertaining to the Coherus BioSciences, Inc. 2014 Equity Incentive Award Plan, and
- (6) Registration Statement (Form S-8 No. 333-281394) pertaining to the Coherus BioSciences, Inc. Amended and Restated 2014 Equity Incentive Award Plan;

of our reports dated March 17, 2025, 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, 2024.

/s/ Ernst & Young LLP

San Mateo, California
March 17, 2025

**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 17, 2025

/s/ Dennis M. Lanfear

Dennis M. Lanfear

President and Chief 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, Bryan McMichael, 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 17, 2025

/s/ Bryan McMichael
Bryan McMichael
Chief Financial Officer

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

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officers of Coherus BioSciences, Inc. (the "Registrant") certify that the Registrant's Annual Report on Form 10-K for the year ended December 31, 2024 (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 17, 2025

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

Date: March 17, 2025

By: /s/ Bryan McMichael
Name: Bryan McMichael
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.
