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

FORM 10-Q

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

For the quarterly period ended September 30, 2023

☐ **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** **(Address of Principal Executive Office)**	**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

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 that 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 such files). Yes ☒ No ☐

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

Large accelerated filer ☐	Accelerated filer ☒
Non-accelerated filer ☐	Smaller reporting company ☐
	Emerging growth company ☐

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

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

As of October 31, 2023, 111,364,152 shares of the registrant's common stock were outstanding.

COHERUS BIOSCIENCES, INC.
FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2023
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CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements regarding future events and our future results that are subject to the safe harbors created under the Securities Act of 1933, as amended (the "Securities Act"), and the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Any statements contained herein that are not statements of historical facts contained in this Quarterly Report on Form 10-Q 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 CHS-006, casdozokitug, CHS-114 and our other product candidates in the United States and Canada;*
- *our ability and the timing in which we may be able to receive marketing authorization for the on-body injector presentation of UDENYCA® following a complete response letter for the PAS that we received on September 21, 2023 and our resubmission of the PAS to the FDA that we announced on October 5, 2023;*
- *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 realize the anticipated benefits from the acquisition (the "Surface Acquisition") of Surface Oncology, Inc. ("Surface");*
- *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 products and product candidates for us;*
- *our expectations regarding the potential market size and the size of the patient populations for our products and product candidates, if approved for commercial use;*
- *our expectations about making required future interest and principal payments as they become due in connection with our debt obligations;*
- *our financial performance, including, but not limited to, projected future performance of our gross margins, 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;*

- *the scope of protection we are able to establish and maintain for intellectual property rights covering our products and product candidates;*
- *our ability to finalize the Definitive Agreements or close on the transactions contemplated by them;*
- *our expectations regarding the scope or enforceability of third-party intellectual property rights, or the applicability of such rights to our products and product candidates;*
- *the cost, timing and outcomes of litigation involving our products and product candidates;*
- *our reliance on third-party contract research organizations to conduct clinical trials of our product candidates;*
- *the benefits of the use of our products and product candidates;*
- *the rate and degree of market acceptance of our current or any future products and product candidates;*
- *our ability to compete with companies currently producing competitor products, including Neulasta, Humira and Lucentis and other biosimilar products made by other companies;*
- *developments and projections relating to our competitors, our market opportunity and our industry; and*
- *the potential impact of COVID-19 and other viral pandemics and the continuation of the war in Ukraine and the war between Israel and Hamas 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 II, Item 1A Risk Factors and discussed elsewhere in this Quarterly Report on Form 10-Q. 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. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures, or investments we may make or enter into, except for the acquisition of Surface to the extent described herein.

This Quarterly Report on Form 10-Q 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. FINANCIAL INFORMATION

ITEM 1. Unaudited Condensed Consolidated Financial Statements

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

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 80,259	$ 63,547
Investments in marketable securities	50,818	128,134
Trade receivables, net	216,511	109,964
Inventory	66,783	38,791
Prepaid manufacturing	13,772	17,880
Other prepaids and current assets	16,222	22,918
Total current assets	444,365	381,234
Property and equipment, net	6,069	8,754
Inventory, non-current	79,002	76,260
Goodwill and intangible assets, net	46,524	5,931
Other assets, non-current	7,823	8,668
Total assets	$ 583,783	$ 480,847
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 37,092	$ 11,526
Accrued rebates, fees and reserves	117,369	54,461
Accrued compensation	18,084	22,610
Accrued and other current liabilities	67,114	50,097
Total current liabilities	239,659	138,694
Term loans	246,217	245,483
Convertible notes	226,557	225,575
Lease liabilities, non-current	1,436	5,046
Other liabilities, non-current	3,513	3,467
Total liabilities	717,382	618,265
Commitments and contingencies (Note 9)		
Stockholders' deficit:		
Common stock ($0.0001 par value; shares authorized: 300,000,000; shares issued and outstanding: 109,113,046 and 78,851,516 at September 30, 2023 and December 31, 2022, respectively)	11	8
Additional paid-in capital	1,366,502	1,204,431
Accumulated other comprehensive loss	(265)	(249)
Accumulated deficit	(1,499,847)	(1,341,608)
Total stockholders' deficit	(133,599)	(137,418)
Total liabilities and stockholders' deficit	$ 583,783	$ 480,847

See accompanying notes.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Net revenue	$ 74,568	$ 45,424	$ 165,720	$ 165,690
Costs and expenses:				
Cost of goods sold	32,703	35,234	74,425	55,881
Research and development	25,647	45,808	83,068	170,336
Selling, general and administrative	48,224	44,831	142,521	144,860
Total costs and expenses	106,574	125,873	300,014	371,077
Loss from operations	(32,006)	(80,449)	(134,294)	(205,387)
Interest expense	(10,268)	(7,540)	(29,923)	(23,089)
Loss on debt extinguishment	—	—	—	(6,222)
Other income (expense), net	2,253	1,339	5,598	1,814
Loss before income taxes	(40,021)	(86,650)	(158,619)	(232,884)
Income tax provision (benefit)	(380)	—	(380)	—
Net loss	$ (39,641)	$ (86,650)	$ (158,239)	$ (232,884)
Basic and diluted net loss per share	$ (0.41)	$ (1.11)	$ (1.79)	$ (3.00)
Weighted-average number of shares used in computing basic and diluted net loss per share	97,738,509	77,746,895	88,277,936	77,520,244

See accompanying notes.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Net loss	$ (39,641)	$ (86,650)	$ (158,239)	$ (232,884)
Other comprehensive income (loss):				
Unrealized gain (loss) on available-for-sale securities, net of tax	32	—	(15)	—
Foreign currency translation adjustments, net of tax	—	—	(1)	—
Comprehensive loss	$ (39,609)	$ (86,650)	$ (158,255)	$ (232,884)

See accompanying notes.

Coherus BioSciences, Inc.
Condensed Consolidated Statements of Stockholders' Deficit
(in thousands, except share and per share data)
(unaudited)

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Loss	Deficit	Deficit
Balances at December 31, 2022	78,851,516	$ 8	$ 1,204,431	$ (249)	$ (1,341,608)	$ (137,418)
Net loss	—	—	—	—	(75,729)	(75,729)
Issuance of common stock upon exercise of stock options	24,107	—	103	—	—	103
Issuance of common stock upon vesting of restricted stock units ("RSUs")	771,167	—	—	—	—	—
Issuance of common stock under ATM Offering, net of issuance costs	1,131,450	—	7,059	—	—	7,059
Taxes paid related to net share settlement of RSUs	(289,944)	—	(2,781)	—	—	(2,781)
Stock-based compensation expense	—	—	12,288	—	—	12,288
Other comprehensive loss, net of tax	—	—	—	(29)	—	(29)
Balances at March 31, 2023	80,488,296	8	1,221,100	(278)	(1,417,337)	(196,507)
Net loss	—	—	—	—	(42,869)	(42,869)
Issuance of common stock upon exercise of stock options	8,182	—	14	—	—	14
Issuance of common stock upon vesting of RSUs	142,982	—	—	—	—	—
Issuance of common stock under Public Offering, net of issuance costs	13,529,411	1	53,624	—	—	53,625
Offering costs associated with ATM offering	—	—	(74)	—	—	(74)
Taxes paid related to net share settlement of RSUs	(48,529)	—	(305)	—	—	(305)
Issuance of common stock under the employee stock purchase plan ("ESPP")	321,672	—	1,337	—	—	1,337
Stock-based compensation expense	—	—	10,034	—	—	10,034
Other comprehensive loss, net of tax	—	—	—	(19)	—	(19)
Balances at June 30, 2023	94,442,014	9	1,285,730	(297)	(1,460,206)	(174,764)
Net loss	—	—	—	—	(39,641)	(39,641)
Issuance of common stock upon exercise of stock options	27,977	—	53	—	—	53
Issuance of common stock upon vesting of RSUs	72,918	—	—	—	—	—
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	2,428,311	1	11,436	—	—	11,437
Taxes paid related to net share settlement of RSUs	(25,141)	—	(115)	—	—	(115)
Stock-based compensation expense	—	—	10,152	—	—	10,152
Other comprehensive gain, net of tax	—	—	—	32	—	32
Balances at September 30, 2023	109,113,046	$ 11	$ 1,366,502	$ (265)	$ (1,499,847)	$ (133,599)

(1) See Note 6 for further discussion.

Coherus BioSciences, Inc.
Condensed Consolidated Statements of Stockholders' Equity (Deficit)
(in thousands, except share and per share data)
(unaudited)

	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	—	—	—	—	(96,084)	(96,084)
Issuance of common stock upon exercise of stock options	102,632	—	544	—	—	544
Issuance of common stock upon vesting of RSUs	491,087	—	—	—	—	—
Taxes paid related to net share settlement of RSUs	(185,644)	—	(2,658)	—	—	(2,658)
Stock-based compensation expense	—	—	13,037	—	—	13,037
Other comprehensive loss, net of tax	—	—	—	(2)	—	(2)
Balances at March 31, 2022	77,338,171	7	1,158,766	(272)	(1,145,938)	12,563
Net loss	—	—	—	—	(50,150)	(50,150)
Issuance of common stock upon exercise of stock options	4,499	—	8	—	—	8
Issuance of common stock upon vesting of RSUs	173,867	—	—	—	—	—
Taxes paid related to net share settlement of RSUs	(58,771)	—	(642)	—	—	(642)
Issuance of common stock under the ESPP	244,983	—	1,655	—	—	1,655
Stock-based compensation expense	—	—	13,935	—	—	13,935
Other comprehensive gain, net of tax	—	—	—	2	—	2
Balances at June 30, 2022	77,702,749	7	1,173,722	(270)	(1,196,088)	(22,629)
Net loss	—	—	—	—	(86,650)	(86,650)
Issuance of common stock upon exercise of stock options	6,557	—	79	—	—	79
Issuance of common stock upon vesting of RSUs	93,606	—	—	—	—	—
Taxes paid related to net share settlement of RSUs	(32,319)	—	(321)	—	—	(321)
Stock-based compensation expense	—	—	12,388	—	—	12,388
Balances at September 30, 2022	77,770,593	$ 7	$ 1,185,868	$ (270)	$ (1,282,738)	$ (97,133)

See accompanying notes.

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

	Nine Months Ended September 30,	
	2023	2022
Operating activities		
Net loss	$ (158,239)	$ (232,884)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,728	2,649
Stock-based compensation expense	32,312	39,011
Inventory write-offs, net	4,369	26,000
Non-cash accretion of discount on marketable securities	(2,835)	—
Non-cash interest expense from amortization of debt discount & issuance costs	1,812	5,631
Non-cash operating lease expense	2,016	1,854
Option payment to Shanghai Junshi Biosciences Co., Ltd. ("Junshi Biosciences")	—	35,000
Loss on debt extinguishment	—	6,222
Other non-cash adjustments, net	(915)	(10)
Changes in operating assets and liabilities:		
Trade receivables, net	(106,626)	31,849
Inventory	(34,941)	(37,556)
Prepaid manufacturing	4,108	(6,967)
Other prepaid, current and non-current assets	10,702	(12,509)
Accounts payable	24,545	(6,149)
Accrued rebates, fees and reserves	60,602	(25,006)
Accrued compensation	(8,810)	(623)
Accrued and other current and non-current liabilities	7,225	32,317
Net cash used in operating activities	(161,947)	(141,171)
Investing activities		
Purchases of property and equipment	(252)	(1,952)
Proceeds from disposal of property and equipment	769	—
Purchases of investments in marketable securities	(19,507)	—
Proceeds from maturities of investments in marketable securities	108,148	—
Proceeds from sale of investments in marketable securities	13,282	—
Cash and cash equivalents acquired from Surface Acquisition	6,997	—
Option payment to Junshi Biosciences	—	(35,000)
Net cash provided by (used in) investing activities	109,437	(36,952)
Financing activities		
Proceeds from 2027 Term Loans, net of debt discount & issuance costs	—	240,679
Proceeds from issuance of common stock under ATM Offering, net of issuance costs	18,198	—
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	170	631
Proceeds from purchase under the employee stock purchase plan	1,337	1,655
Taxes paid related to net share settlement	(3,261)	(3,621)
Repayment of 2022 Convertible Notes and premiums	—	(109,000)
Repayment of 2025 Term Loan, premiums and exit fees	—	(81,750)
Other financing activities	(835)	(861)
Net cash provided by financing activities	69,234	47,733
Net increase (decrease) in cash, cash equivalents and restricted cash	16,724	(130,390)
Cash, cash equivalents and restricted cash at beginning of period	63,987	417,635
Cash, cash equivalents and restricted cash at end of period	$ 80,711	$ 287,245

See accompanying notes.

Coherus BioSciences, Inc.
Notes to Condensed Consolidated Financial Statements
(unaudited)

1. Organization and Summary of Significant Accounting Policies

Organization

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. Coherus' strategy is to build a leading immuno-oncology franchise funded with cash generated from net sales of its diversified portfolio of United States Food and Drug Administration ("FDA")-approved therapeutics. The Company's headquarters and laboratories are located in Redwood City, California and in Camarillo, California, respectively. The Company sells UDENYCA® (pegfilgrastim-cbqv), a biosimilar to Neulasta, a long-acting granulocyte-colony stimulating factor, in the United States. On August 2, 2022, the FDA approved CIMERLI® (ranibizumab-eqrn), a biosimilar to Lucentis, and commercial launch commenced in October 2022 in the United States. The Company launched YUSIMRY™ (adalimumab-aqvh), a biosimilar to Humira (adalimumab), in the United States in July 2023. On October 27, 2023, the Company announced that the FDA approved LOQTORZI™ (toripalimab-tpzi) 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 the Company developed in collaboration with Shanghai Junshi Biosciences Co., Ltd. ("Junshi Biosciences"). The Company expects to launch LOQTORZI in the U.S. in the first quarter of 2024.

The Company's product pipeline comprises the following four product candidates: CHS-006, an antibody targeting TIGIT being developed in collaboration with Junshi Biosciences; CHS-1000, an antibody targeting ILT4; casdozokitug (CHS-388, formerly SRF388), an antibody targeting interleukin 27 ("IL-27"); and CHS-114 (formerly SRF114), a highly specific afucosylated immunoglobulin isotype G1 ("IgG1") antibody targeting CCR8. In addition to the Company's internally developed portfolio of product candidates, the Company has two product candidates, NZV930 and GSK4381562, which are exclusively licensed to Novartis Institutes for Biomedical Research, Inc. ("Novartis Institutes") and GlaxoSmithKline Intellectual Property No. 4 Limited ("GSK"), respectively. On January 9, 2023, the Company announced that it entered into a binding term sheet (the "Term Sheet") with Klinge Biopharma GmbH ("Klinge Biopharma") for the exclusive commercialization rights to FYB203, a biosimilar candidate to Eylea® (aflibercept), in the United States. The Company and Klinge Biopharma continue to conduct due diligence and discuss terms of the transaction. The material terms of the transaction with Klinge Biopharma will be included in a subsequent filing by the Company when definitive agreements are executed.

Basis of Consolidation

The accompanying unaudited condensed consolidated financial statements include the accounts of Coherus and its wholly-owned subsidiaries. All intercompany transactions and balances have been eliminated upon consolidation. The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with United States generally accepted accounting principles ("U.S. GAAP") for interim financial information and in accordance with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X of the Securities Act of 1933, as amended (the "Securities Act"). Accordingly, they do not include all of the information and notes required by U.S. GAAP for complete financial statements. These unaudited condensed consolidated financial statements reflect all adjustments, including normal recurring accruals, that the Company believes are necessary to fairly state the financial position and the results of the Company's operations and cash flows for interim periods in accordance with U.S. GAAP. Interim-period results are not necessarily indicative of results of operations or cash flows for a full year or any subsequent interim period.

The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the Company's audited financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2022 (the "2022 Form 10-K") filed with the SEC.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make judgements, estimates and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses, and related disclosures. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances. These estimates form the basis for making judgments about the carrying values of assets and liabilities when these values are not readily apparent from other sources. Estimates are assessed each period and updated to reflect current information. Accounting estimates and judgements are inherently uncertain and therefore actual results could differ from these estimates.

Cash, Cash Equivalents and Restricted Cash

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

(in thousands)	**January 1,**	
At beginning of period:	**2023**	**2022**
Cash and cash equivalents	$ 63,547	$ 417,195
Restricted cash	440	440
Total cash, cash equivalents and restricted cash	$ 63,987	$ 417,635

	September 30,	
At end of period:	**2023**	**2022**
Cash and cash equivalents	$ 80,259	$ 286,805
Restricted cash	452	440
Total cash, cash equivalents and restricted cash	$ 80,711	$ 287,245

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

Trade Receivables

Trade receivables are recorded net of allowances for chargebacks, cash discounts for prompt payment and credit losses. The Company estimates an allowance for expected credit losses by considering factors such as historical experience, credit quality, the age of the accounts receivable balances, and current economic conditions that may affect a customer's ability to pay. The corresponding expense for the credit loss allowance is reflected in selling, general and administrative expenses. The credit loss allowance was immaterial as of September 30, 2023 and December 31, 2022.

Derivative Instruments

In January 2023, the Company commenced using derivative contracts (foreign exchange option contracts) for the purpose of economically hedging exposure to changes in currency fluctuations between the U.S. Dollar and the Euro. The Company recognizes all derivatives at fair value on the condensed consolidated balance sheets, and corresponding gains and losses are recognized in other income (expense), net in the condensed consolidated statements of operations. The estimated fair value of derivative financial instruments represents the amount required to enter into similar

contracts with similar remaining maturities based on quoted market prices. During the periods presented, the Company did not apply hedge accounting to these instruments (see Note 10).

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, 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 condensed consolidated statement of operations. The estimations of fair values 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)

Intangible Assets

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.

Definite-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 is recorded as a component of cost of goods sold in the consolidated statements of operations, and amortization expense from out-licenses is recorded in cost of goods sold. The estimated life for capitalized milestone payments is ten years and fifteen years for acquired out-licenses.

Contingent Consideration

Contingent consideration relates to the potential payments to holders of Contingent Value Rights (“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 condensed consolidated statement 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.

Stock-Based Compensation

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

Recent Accounting Pronouncements

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

2. Revenue

The Company launched YUSIMRY in the United States in July 2023 and initiated sales of CIMERLI in October 2022. All net product revenue was generated in the United States, and the Company's net revenue was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	**2023**	**2022**	**2023**	**2022**
Products				
UDENYCA	$ 32,967	$ 45,325	$ 90,875	$ 165,512
CIMERLI	40,037	—	72,939	—
YUSIMRY	1,360	—	1,360	—
Total net product revenue	74,364	45,325	165,174	165,512
Other	204	99	546	178
Total net revenue	$ 74,568	$ 45,424	$ 165,720	$ 165,690

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
McKesson Corporation	44 %	37 %	38 %	37 %
AmeriSource-Bergen Corporation	41 %	45 %	45 %	45 %
Cardinal Health, Inc.	13 %	17 %	15 %	17 %

Product Sales Discounts and Allowances

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

	Nine Months Ended September 30, 2023			
(in thousands)	Chargebacks and Discounts for Prompt Payment	Rebates	Other Fees, Co-pay Assistance and Returns	Total
Balances at December 31, 2022	$ 42,677	$ 38,713	$ 19,113	$ 100,503
Provision related to sales made in:				
Current period	387,238	83,009	69,362	539,609
Prior period - increase (decrease)	(1,375)	1,540	4,469	4,634
Payments and customer credits issued	(379,076)	(42,097)	(55,681)	(476,854)
Balances at September 30, 2023	$ 49,464	$ 81,165	$ 37,263	$ 167,892

	Nine Months Ended September 30, 2022			
(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	321,056	50,939	54,967	426,962
Prior period - increase (decrease)	(2,055)	(5,064)	(181)	(7,300)
Payments and customer credits issued	(320,022)	(64,869)	(61,829)	(446,720)
Balances at September 30, 2022	$ 28,644	$ 35,010	$ 19,011	$ 82,665

The total provision related to sales made in the prior period was $1.1 million and $(1.4) million for the three months ended September 30, 2023 and 2022, respectively. 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 unaudited condensed consolidated balance sheets.

3. Fair Value Measurements

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

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

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

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. Realized gains and losses, if any, on available-for-sale securities are included in other income (expense), net, in the condensed consolidated statements of operations based on the specific identification method.

In connection with the Surface Acquisition on September 8, 2023 (see Note 6), the Company acquired money market funds and marketable securities and recorded a contingent consideration liability related to the CVRs issued in connection with the acquisition. The fair value of the CVR liability was 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 liability will be met. There was no change in the CVR liability from September 8, 2023 to September 30, 2023. The CVR liabilities were recorded in accrued and other current liabilities and other liabilities, non-current on the condensed consolidated balance sheets.

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

	Fair Value Measurements September 30, 2023			
(in thousands)	**Level 1**	**Level 2**	**Level 3**	**Total**
Financial Assets:				
Money market funds	$ 62,389	$ —	$ —	$ 62,389
Marketable debt securities:				
U.S. government agency securities	18,111	—	—	18,111
U.S. treasury securities	24,986	—	—	24,986
Commercial paper and corporate notes	—	7,721	—	7,721
Total	$ 105,486	$ 7,721	$ —	$ 113,207
Financial Liabilities:				
Contingent consideration	$ —	$ —	$ 5,392	$ 5,392

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

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

	September 30, 2023			
(in thousands)	Cost	Unrealized Gain	Unrealized (Loss)	Fair Value
Money market funds	$ 62,389	$ —	$ —	$ 62,389
U.S. government agency securities	18,134	—	(23)	18,111
U.S. treasury securities	24,988	1	(3)	24,986
Commercial paper and corporate notes	7,742	—	(21)	7,721
Total	$ 113,253	$ 1	$ (47)	$ 113,207

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

The Company held 14 positions that were in unrealized loss positions as of September 30, 2023, and aggregated gross unrealized losses on available-for-sale debt securities were not material. No impairment was recognized in the three and nine months ended September 30, 2023. As of September 30, 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 ten months. The accrued interest receivable on available-for-sale marketable securities was immaterial at September 30, 2023 and December 31, 2022.

There were no investments in marketable securities during the nine months ended September 30, 2022; thus, no unrealized gain (loss) was recognized during such period.

4. Inventory

Inventory consisted of the following:

(in thousands)	September 30, 2023	December 31, 2022
Raw materials	$ 11,326	$ 10,262
Work in process	106,608	86,712
Finished goods	27,851	18,077
Total	$ 145,785	$ 115,051

Inventory is stated at the lower of cost or estimated net realizable value with cost determined under the first-in first-out method. The determination of excess or obsolete inventory requires judgment including consideration of many factors, such as estimates of future product demand, current and future market conditions, product expiration information, and potential product obsolescence, among others. During the third quarter of 2022, the Company recorded a $26.0 million write-down of inventory in cost of goods sold in the condensed consolidated statement of operations. The write-down was due to the competitive environment and lower demand for UDENYCA resulting in certain inventory becoming at risk of expiration.

The Company began capitalizing YUSIMRY inventory in the second quarter of 2022 and had $ 41.1 million and $23.7 million of such inventory as of September 30, 2023 and December 31, 2022, respectively. Inventory expected to be sold

more than twelve months from the balance sheet date is classified as inventory, non-current on the condensed consolidated balance sheets. As of September 30, 2023 and December 31, 2022, 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)	September 30, 2023	December 31, 2022
Inventory	$ 66,783	$ 38,791
Inventory, non-current	79,002	76,260
Total	$ 145,785	$ 115,051

Prepaid manufacturing of $13.8 million as of September 30, 2023 includes prepayments of $ 12.4 million to contract manufacturing organizations ("CMOs") for manufacturing services for the Company's products, which the Company expects to be converted into inventory within the next twelve months; and prepayments of $1.4 million to various CMOs for research and development pipeline programs. Prepaid manufacturing of $17.9 million as of December 31, 2022 included prepayments of $13.0 million to CMOs for manufacturing services of the Company's products and prepayments of $4.9 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)	September 30, 2023	December 31, 2022
Machinery and equipment	$ 13,141	$ 12,944
Computer equipment and software	3,232	3,183
Furniture and fixtures	1,258	1,258
Leasehold improvements	6,234	6,198
Finance lease right of use assets	2,663	4,632
Construction in progress	407	696
Total property and equipment	26,935	28,911
Accumulated depreciation and amortization	(20,866)	(20,157)
Property and equipment, net	$ 6,069	$ 8,754

Depreciation and amortization expense related to property and equipment, net was $ 0.8 million and $2.5 million for the three and nine months ended September 30, 2023, respectively, and $0.9 million and $2.6 million for the three and nine months ended September 30, 2022, respectively.

As of September 30, 2023 and December 31, 2022, the net book value of software implementation costs related to hosting arrangements was $3.2 million and $3.5 million, respectively, and the amortization expense was immaterial for all periods presented.

Goodwill and Intangible Assets, Net

Goodwill and intangible assets, net consisted of the following:

(in thousands)	September 30, 2023	December 31, 2022
Goodwill	$ 943	$ 943
Indefinite-lived assets - IPR&D	28,859	2,620
Finite-lived assets, net	16,722	2,368
Total Goodwill and intangible assets, net	$ 46,524	$ 5,931

Amortization expense and accumulated amortization related to finite-lived intangible assets was immaterial in all periods presented. Amortization expense for each of the five succeeding fiscal years will be approximately $1.3 million.

Accrued and Other Current Liabilities

Accrued and other current liabilities consisted of the following:

(in thousands)	September 30, 2023	December 31, 2022
Accrued commercial and research and development manufacturing	$ 17,057	$ 21,774
Accrued co-development costs payable to Junshi Biosciences	1,293	8,356
Accrued royalties	30,557	5,015
Accrued other	9,698	10,634
Lease liabilities, current	4,469	4,318
Contingent consideration, current	4,040	—
Total Accrued and other current liabilities	$ 67,114	$ 50,097

Other Liabilities, Non-current

Other liabilities, non-current consisted of the following:

(in thousands)	September 30, 2023	December 31, 2022
Contingent consideration, non-current	$ 1,352	$ 102
Deferred tax liability	1,102	—
Other	1,059	3,365
Total Other liabilities, non-current	$ 3,513	$ 3,467

6. 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., a direct, wholly owned subsidiary of the Company (“Merger Sub I”), Crimson Merger Sub II, LLC, a direct, wholly owned subsidiary of the Company (“Merger Sub II,” and together with Merger Sub I, the “Merger Subs”), and Surface, the Company completed the Surface Acquisition. Surface is a clinical-stage immuno-oncology (“I-O”) company focused on using its specialized knowledge of the biological pathways critical to the immunosuppressive tumor microenvironment for the development of next-generation cancer therapies. The Surface Acquisition expanded the Company’s I-O pipeline with the following: casdozokitug (CHS-388, formerly SRF388), an investigational, novel IL-27-targeted antibody currently being evaluated in

a Phase 2 clinical trial in HCC, and CHS-114 (formerly SRF114), an investigational, CCR8-targeted antibody currently in a Phase 1/2 study as a monotherapy in patients with advanced solid tumors.

On the Acquisition Date, and in accordance with the Merger Agreement, the Company issued to the holders of all outstanding Surface common stock (other than treasury shares, any shares of Surface common stock held directly by the Company or the Merger Subs immediately prior to the Acquisition Date and shares of Surface common stock issued and outstanding immediately prior to the Acquisition Date and held by any holder properly demanding appraisal for such shares in accordance with Section 262 of the Delaware General Corporation Law) 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 10-year period following September 8, 2023, for the sum of the following, less any permitted deductions (in accordance with 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")):

- 70% of all milestone- and royalty-based payments actually received by the Company or its affiliates from GSK under a license agreement with GSK, dated December 16, 2020, which was subsequently amended in August 2021 (as amended, the "GSK Agreement") related to the existing program (GSK4381562);
- 70% of all milestone- and royalty-based payments actually received by the Company or its affiliates from Novartis Institutes under the collaboration agreement between Surface and Novartis Institutes dated January 9, 2016 which was subsequently amended in May 2016, July 2017, September 2017, and October 2018 (as amended, the "Novartis Agreement") related to the existing program (NZV930);
- 25% of any upfront payment actually received by the Company or its affiliates pursuant to potential ex-U.S. licensing agreements for CHS-114; and
- 50% of any upfront payment actually 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 upfront payments for CHS-114 and casdozokitug.

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

(in thousands, except 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	$	64,596

(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 Company has accounted for the Surface Acquisition as a business combination which requires, among other things, that the assets acquired and liabilities assumed generally be recognized at their fair value on the Acquisition Date. Fair value estimates are based on management's 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. The judgments used to determine the estimated fair value assigned to each class of assets acquired and liabilities assumed, as well as asset lives, can materially impact the Company's results of operations. The purchase price allocation for the Surface Acquisition is preliminary and subject to revisions as additional information about fair value of assets and liabilities becomes available. This is primarily related to the Company's deferred tax liabilities assumed in connection with the Surface Acquisition, as the 2023 short period tax returns have not yet been filed. Additional information that existed as of the Acquisition Date, but is unknown to the Company, may become known during the remainder of the measurement period, not to exceed 12 months from 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	$ 73,817
Liabilities Assumed	
Accrued and other current liabilities	$ 7,722
Deferred tax liability	1,499
Total liabilities	9,221
Total net assets acquired	$ 64,596

The Company believes 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 amount allocated to identifiable intangible assets has been attributed to the following assets:

(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		$ 39,769

Surface had two out-licensed partnership programs, with Novartis Institutes (NZV930) and GSK (GSK4381562), to advance certain next-generation cancer therapies. The out-license intangible assets represent potential milestone and royalty-based payments to be received in the future. Surface shareholders received CVRs for certain percentages of these milestone and royalty-based payments on existing programs with Novartis Institutes (NZV930) and GSK (GSK4381562), as further explained above.

Following the Acquisition Date, the operating results of Surface have been included in the condensed consolidated financial statements. For the period September 9, 2023 through September 30, 2023, there was no revenue attributable

to Surface and operating losses attributable to Surface for such period were $ 1.4 million, excluding acquisition-related costs.

Unaudited Pro Forma Summary of Operations

The following table shows the unaudited pro forma summary of operations for the three and nine months ended September 30, 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:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2023	2022	2023	2022
Total revenues	$ 74,568	$ 45,424	$ 165,720	$ 195,690
Net loss	$ (49,984)	$ (108,472)	$ (204,922)	$ (291,341)

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 condensed combined financial information does not reflect the income tax effects of the pro forma adjustments, as management believes income tax adjustments to not be meaningful given the combined entity incurred significant losses during the historical periods presented.

Acquisition-related costs of $2.6 million and $4.5 million were recorded in selling, general and administrative expense in the condensed consolidated statement of operations during the three and nine months ended September 30, 2023, respectively.

7. Collaborations and Other Arrangements

In-Licensing Agreements

Junshi Biosciences

On February 1, 2021, the Company entered into an Exclusive License and Commercialization Agreement (the "Collaboration Agreement") with Junshi Biosciences for the co-development and commercialization of 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 will have the right to conduct all commercial activities of LOQTORZI in the United States and Canada. The Company will be obligated to pay Junshi Biosciences a 20% royalty on net sales of LOQTORZI and up to an aggregate $380.0 million in one-time payments for the achievement of various regulatory and sales milestones.

In March 2022, the Company paid $ 35.0 million for the exercise of its option to license CHS-006. Junshi Biosciences and the Company are jointly developing CHS-006 with each party responsible for the associated development costs as set forth in the Collaboration Agreement. If the Company exercises its remaining option for the IL-2 cytokine, it will be

obligated to pay an additional option exercise fee of $ 35.0 million. Additionally, for each exercised option, the Company will be obligated to pay Junshi Biosciences an 18% royalty on net sales, up to $ 85.0 million for the achievement of certain regulatory approvals, and up to $170.0 million for the attainment of certain sales thresholds. Under the Collaboration Agreement, the Company retains the right to collaborate in the development of LOQTORZI and the other licensed compounds, including CHS-006, and will pay for a portion of these co-development activities up to a maximum of $25.0 million per licensed compound per year. Beginning in 2023, the scope of the development plan for LOQTORZI in the United States was reduced based on changes approved by the Company and Junshi Biosciences. 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.

The licensing transaction and the exercise of the option were accounted for as asset acquisitions under the relevant accounting rules. Research and development expenses recognized for obligations to Junshi Biosciences were $3.1 million and $7.7 million for the three and nine months ended September 30, 2023, respectively. Research and development expenses were $7.6 million for the three months ended September 30, 2022 and $ 67.6 million in the nine months ended September 30, 2022, inclusive of the $35.0 million option fee incurred in the first quarter of 2022. In the condensed consolidated balance sheets as of September 30, 2023, the Company has classified $1.3 million in accrued and other current liabilities and $9.5 million in accounts payable related to the co-development, regulatory and technology transfer costs related to these programs.

As of September 30, 2023, the Company did not have any outstanding milestone or royalty payment obligations to Junshi Biosciences. The additional milestone payments and royalties are contingent upon future events and, therefore, will be recorded when it is probable that a milestone will be achieved or when royalties are due.

Bioeq

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

Bioeq will manufacture and supply the Bioeq Licensed Products to the Company in accordance with terms and conditions specified in the Bioeq License Agreement and a manufacturing and supply agreement between the Company and Bioeq dated September 29, 2022 (the “Bioeq Manufacturing Agreement”). The Bioeq Manufacturing Agreement will remain in force until the first to occur of the following: (1) the termination of the Bioeq License Agreement; (2) the exercise of a right to termination by the Company or Bioeq for a material breach of the other party that is not cured in accordance with the Bioeq Manufacturing Agreement; and (3) the exercise of a right to termination by Bioeq if invoices are not paid in full in accordance with the Bioeq Manufacturing Agreement.

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

The Company accounted for the licensing transaction as an asset acquisition under the relevant accounting rules. The Company paid Bioeq an upfront and a milestone payment aggregating to €10 million ($11.1 million), which was recorded as research and development expense in the Company's consolidated statement of operations in 2019. The terms of the Bioeq License Agreement include an aggregate of up to €12.5 million in additional milestone payments in connection with the achievement of certain development and regulatory milestones with respect to the Bioeq Licensed Products in the United States including a €2.5 million milestone related to the FDA approval of the CIMERLI Section 351(k) BLA that was paid in the fourth quarter of 2022. This was recorded as an intangible asset and is being amortized over ten years. The Company shares a percentage of gross profits on sales of Bioeq Licensed Products in the United States with Bioeq in the low- to mid-fifty percent range. Royalties due to Bioeq were $27.8 million and $2.9 million as of September 30, 2023 and December 31, 2022, respectively. The remaining milestone payments and royalties are contingent upon future events and, therefore, will be recorded when it becomes probable that a milestone will be achieved.

Adimab Development and Option Agreement

In October 2018, Surface 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, 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, extended the discovery term of the Original Adimab Agreement, 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.

Upon the Company's selection of a target, the Company and Adimab will initiate a research plan and the discovery term begins. During the discovery term, Adimab will grant the Company a non-exclusive, non-sublicensable license under its technology with respect to the target, to research, design and preclinically develop and use antibodies that were modified or derived using Adimab technology, solely to evaluate such antibodies, perform the Company's responsibilities under the research plan, and use such antibodies for certain diagnostic purposes. The Company also will grant to Adimab a non-exclusive, nontransferable license with respect to the target under the Company's technology that covers or relates to such target, solely to perform its responsibilities under the research plan during the discovery period. The Company is required to pay Adimab at an agreed upon rate for its full-time employees during the discovery period while Adimab performs research on each target under the applicable research plan.

Adimab granted the Company 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 the Company against a specific biological target for a specified period of time (the "Research Option"). In addition, Adimab granted the Company 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 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. During the discovery term, the Company may be obligated to pay Adimab up to $0.3 million for technical milestones achieved against each biological target. 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.

The A&R Adimab Agreement will remain in effect until (a) the earlier of (i) the expiration of the Research and Commercialization Options (if they expire without exercise) and (ii) 12 months from the effective date without the Company providing materials that pass Adimab's quality control; or (b) if a Research Option is exercised but the Commercialization Option is not, then upon the expiration of the last to expire research license term; or (c) upon commercialization of a product, until the end of the royalty term, which will vary on a product-by-product and country-by-country basis, ending on the later of (y) the expiration of the last valid claim covering the licensed product in such country as the product is manufactured or sold, or (z) ten years after the first commercial sale of the licensed product in such country.

Either party may terminate the A&R Adimab Agreement for material breach if such breach remains uncured for a specified period of time, however, if a Research Option or Commercialization Option has been exercised and the breach only applies to the applicable target of such Research Option or Commercialization Option, then the termination right will only apply to such target. The Company may also terminate the A&R Adimab Agreement for any reason with prior notice to Adimab. If Adimab is bankrupt, the Company will be entitled to a complete duplicate of, or complete access to, all rights and licenses granted under or pursuant to the A&R Adimab Agreement.

Out-Licensing Agreements 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. Surface Acquisition above.

Novartis Institutes

In January 2016, Surface entered into the Novartis Agreement. Pursuant to the Novartis Agreement, Surface granted Novartis Institutes a worldwide exclusive license to research, develop, manufacture and commercialize antibodies that target cluster of differentiation 73 ("CD73"). Under the Novartis Agreement, the Company is currently entitled to potential development milestones of $325.0 million and sales milestones of $200.0 million, as well as tiered royalties on annual net sales by Novartis Institutes ranging from high single-digit to mid-teens percentages upon the successful commercialization of NZV930. Due to the uncertainty of pharmaceutical development and the historical failure rates generally associated with drug development, the Company may not receive any milestone payments or any royalty payments under the Novartis Agreement. The Company did not recognize any revenue relating to the Novartis Agreement during the three months ended September 30, 2023.

Unless terminated earlier, the Novartis Agreement will continue in effect until neither the Company nor Novartis Institutes is researching, developing, manufacturing or commercializing NZV930. Novartis Institutes may terminate the Novartis Agreement for any or no reason upon prior notice to the Company within a specified time period. Either party

may terminate the Novartis Agreement in full if an undisputed material breach is not cured within a certain period of time or upon notice of insolvency of the other party. To the extent Novartis Institutes terminates for convenience, or the Company terminates for Novartis Institutes' uncured material breach, Novartis Institutes will grant the Company, on mutually agreeable financial terms, an exclusive, worldwide, irrevocable, perpetual and royalty-bearing license with respect to intellectual property controlled by Novartis Institutes that is reasonably necessary to research, develop, manufacture or commercialize NZV930.

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 antibodies that target CD112R, also known as 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 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 generally associated with drug development, the Company may not receive any milestone payments or any royalty payments under the GSK Agreement. The Company did not recognize license-related revenue under the GSK Agreement during the three months ended September 30, 2023.

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.

Other

On January 9, 2023, the Company announced that it entered into the Term Sheet with Klinge Biopharma for the exclusive commercialization rights to FYB203, a biosimilar candidate to Eylea® (aflibercept), in the United States. The Company and Klinge Biopharma continue to conduct due diligence and discuss terms of the transaction. The material terms of the transaction with Klinge Biopharma will be included in a subsequent filing by the Company when definitive agreements are executed.

8. Debt Obligations

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

	At September 30, 2023				
(in thousands)	Principal Amount	Unamortized Debt Discount and Debt Issuance Costs	Net Carrying Value	Estimated Fair Value	Level
Financial Liabilities:					
2027 Term Loans	$ 250,000	$ (3,783)	$ 246,217	$ 246,217	Level 2*
2026 Convertible Notes	$ 230,000	$ (3,443)	$ 226,557	$ 139,007	Level 2**

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

* The principal amounts outstanding are subject to variable interest rates, which are based on three-month SOFR starting April 1, 2023 plus fixed percentages. Through March 31, 2023, the variable component was based on the three-month LIBOR. 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.

2027 Term Loans

The Company entered into a loan agreement in January 2022 (as amended to date, the "Loan Agreement") with BioPharma Credit, PLC, (as the "Collateral Agent"), BPCR Limited Partnership (as a "Lender"), and Biopharma Credit Investments V (Master) LP, acting by its general partner, BioPharma Credit Investments V GP LLC (as a "Lender") that provides for a senior secured term loan facility of up to $300.0 million to be funded in four committed tranches: (i) a Tranche A Loan in an aggregate principal amount of $100.0 million (the "Tranche A Loan") that was funded on January 5, 2022 (the "Tranche A Closing Date"); (ii) a Tranche B Loan in an aggregate principal amount of $100.0 million (the "Tranche B Loan") that was funded on March 31, 2022; (iii) a Tranche C Loan in an aggregate principal amount of $50.0 million (the "Tranche C Loan") that was not funded; and (iv) a Tranche D Loan in an aggregate principal amount of $50.0 million (the "Tranche D Loan" and, together with the Tranche A Loan, the Tranche B Loan, and the Tranche C Loan, the "2027 Term Loans") that was funded on September 14, 2022. The Company has the right to request an uncommitted additional facility amount of up to $100.0 million that is subject to new terms and conditions.

The 2027 Term Loans mature on either (i) the fifth anniversary of the Tranche A Closing Date; or (ii) October 15, 2025, if the outstanding aggregate principal amount of the 2026 Convertible Notes is greater than $50.0 million on October 1, 2025. The 2027 Term Loans accrued interest from inception through March 31, 2023 at 8.25% plus three-month LIBOR per annum with a LIBOR floor of 1.0%; and starting April 1, 2023, accrue interest at 8.25% plus the sum (the "Adjusted Term SOFR") of three-month SOFR and 0.26161% per annum, with a floor on Adjusted Term SOFR of 1.0%. The interest rate for the third quarter of 2023 was 13.76%. Interest is payable quarterly in arrears on March 31, June 30, September 30 and December 31 of each year. Repayment of outstanding principal of the 2027 Term Loans will be made in five equal quarterly payments of principal commencing March 31, 2026.

The Company adopted the prospective method to account for future cash payments. Under the prospective method, the effective interest rate is not constant, and any change in the expected cash flows is recognized prospectively as an adjustment to the effective yield.

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

Pursuant to the Loan Agreement, and subject to certain restrictions, proceeds of the 2027 Term Loans were used to fund the Company's general corporate and working capital requirements except for the following: in January 2022, proceeds of the Tranche A Loan were used to repay in full all amounts outstanding under the Company's $75.0 million aggregate principal credit agreement with affiliates of Healthcare Royalty Partners (the "2025 Term Loan"), as well as all associated costs and expenses pursuant to which a payoff amount of $81.9 million was outstanding; in March 2022, proceeds of the Tranche B Loan were drawn in connection with the full repayment of all amounts outstanding under the Company's $100.0 million aggregate principal amount 8.2% Convertible Senior Notes (the "2022 Convertible Notes"), as well as all associated costs and expenses pursuant to which a payoff amount of $111.1 million was outstanding.

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

As of September 30, 2023, the Company was in full compliance with these covenants, and there were no events of default under the 2027 Term Loans.

In connection with the closing of Tranche A, the Company incurred $7.8 million in debt discounts and issuance costs of which $6.8 million related to all the tranches of the 2027 Term Loans and was thus allocated pro rata between the tranches. The unamortized debt discount and issuance costs allocated to funded tranches are presented as deductions to the 2027 Term Loan balance and are amortized into interest expense using the effective interest method. The $2.3 million allocated to Tranche B was fully amortized over the commitment period prior to funding and recognized as interest expense in the first quarter of 2022. The associated debt discounts and issuance costs of unfunded tranches were deferred as assets and amortized into interest expense using the straight-line method over the commitment period of the respective tranches. At the closing dates of Tranche B on March 31, 2022 and Tranche D on September 14, 2022, the Company incurred an additional $1.0 million and $0.5 million, respectively, in debt issuance costs. As of September 30, 2023, the total remaining unamortized debt discount and debt offering costs related to Tranches A, B and D of $3.8 million will be amortized using the effective interest rate over the remaining term of 3.3 years.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2023	2022	2023	2022
Contractual interest	$ 8,790	$ 5,665	$ 25,404	$ 12,577
Amortization of debt discount and debt issuance costs	255	622	830	4,122
Total interest expense	$ 9,045	$ 6,287	$ 26,234	$ 16,699

Assuming the third quarter of 2023 interest rate of 13.76%, future payments on the 2027 Term Loans as of September 30, 2023 are as follows:

Year ending December 31, (in thousands)	
Remainder of 2023 - interest only	$ 8,790
2024 - interest only	34,970
2025 - interest only	34,873
2026 - principal and interest	224,345
2027 - principal and interest	50,095
Total minimum payments	353,073
Less amount representing interest	(103,073)
2027 Term Loans, gross	250,000
Less unamortized debt discount and debt issuance costs	(3,783)
Net carrying amount of 2027 Term Loans	$ 246,217

1.5% Convertible Senior Subordinated Notes due 2026

In April 2020, the Company issued and sold $ 230.0 million aggregate principal amount of its 1.5% Convertible Senior Subordinated notes due 2026 (the “2026 Convertible Notes”) in a private offering to qualified institutional buyers pursuant to Rule 144A under the Securities Act. The net proceeds from the offering were $ 222.2 million after deducting initial purchasers’ fees and offering expenses. The 2026 Convertible Notes are general unsecured obligations and will be subordinated to the Company’s designated senior indebtedness (as defined in the indenture for the 2026 Convertible Notes) and structurally subordinated to all existing and future indebtedness and other liabilities, including trade payables . The 2026 Convertible Notes accrue interest at a rate of 1.5% per annum, payable semi-annually in arrears on April 15 and October 15 of each year, 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. Since inception, the conversion price has been 51.9224 shares of common stock per $ 1,000 principal amount of the 2026 Convertible Notes, which represents a conversion price of approximately $19.26 per share of common stock. The initial conversion price represents a premium of approximately 30.0% over the last reported sale of $ 14.82 per share of the Company’s common stock on the Nasdaq Global Market on April 14, 2020, the date the 2026 Convertible Notes were issued. The conversion rate and conversion price will be subject to customary adjustments upon the occurrence of certain events. If a “make-whole fundamental change” (as defined in the indenture for the 2026 Convertible Notes) occurs, the Company will, in certain circumstances, increase the conversion rate for a specified period of time for noteholders who convert their 2026 Convertible Notes in connection with that make-whole fundamental change. The 2026 Convertible Notes are not redeemable at the Company’s election before maturity. If a “fundamental change” (as defined in the indenture for the 2026 Convertible Notes) occurs, then, subject to a limited exception, noteholders may require the Company to repurchase their 2026 Convertible Notes for cash. The repurchase price will be equal to the principal amount of the 2026

Convertible Notes to be repurchased, plus accrued and unpaid interest, if any, to, but excluding, the applicable repurchase date.

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

As of September 30, 2023, the Company was in full compliance with these covenants and there were no events of default under the 2026 Convertible Notes.

The Company evaluated the features embedded in the 2026 Convertible Notes under the relevant accounting rules and concluded that the embedded features do not meet the requirements for bifurcation, and therefore do not need to be separately accounted for as an equity component. The proceeds received from the issuance of the convertible debt were recorded as a liability on the condensed 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 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; thus, they are recorded as a reduction to additional paid-in capital on the condensed consolidated balance sheets. The capped calls will not be subsequently re-measured as long as the conditions for equity classification continue to be met.

The Company incurred $0.9 million of debt issuance costs relating to the issuance of the 2026 Convertible Notes, which were recorded as a reduction to the notes on the condensed 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 September 30, 2023, the holders of the 2026 Convertible Notes would have received common shares with an aggregate value of $44.7 million based on the Company's closing stock price of $3.74 as of September 29, 2023.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	**2023**	**2022**	**2023**	**2022**
Stated coupon interest	$ 863	$ 863	$ 2,588	$ 2,588
Amortization of debt discount and debt issuance costs	329	322	982	962
Total interest expense	$ 1,192	$ 1,185	$ 3,570	$ 3,550

The remaining unamortized debt discount and debt offering costs related to the 2026 Convertible Notes of $ 3.4 million as of September 30, 2023 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 September 30, 2023 are as follows:

Year ending December 31, (in thousands)	
Remainder of 2023 - interest only	$ 1,725
2024 - interest only	3,450
2025 - interest only	3,450
2026	231,725
Total minimum payments	240,350
Less amount representing interest	(10,350)
2026 Convertible Notes, principal amount	230,000
Less unamortized debt discount and debt issuance costs	(3,443)
Net carrying amount of 2026 Convertible Notes	$ 226,557

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, bore interest at a fixed coupon rate of 8.2% per annum payable quarterly in arrears and matured on March 31, 2022. In March 2022, the Company fully repaid the 2022 Convertible Notes, and a s 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% premium of the outstanding principal amount and accrued and unpaid interest. For the nine months ended September 30, 2022, interest expense on the 2022 Convertible Notes was $2.6 million, which included $2.1 million of stated coupon interest and $ 0.5 million amortization of debt discount and debt issuance costs.

2025 Term Loan

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

Pursuant to the terms of the 2025 Term Loan, the Company was required to begin paying principal on the Borrowings in equal quarterly installments beginning on the third anniversary of the 2025 Term Loan Closing Date, with the outstanding balance to be repaid on January 7, 2025, the maturity date. In January 2022, pursuant to the Company entering into the 2027 Term Loans, the Company voluntarily prepaid all amounts outstanding under the 2025 Term Loan. The payoff amount of $81.9 million included principal repayment in full, accrued interest, a 5.0% prepayment premium fee of the Borrowings principal amount, and an exit fee of 4.0% of the Borrowings principal amount. The prepayment premium fee and unamortized exit fee, debt discount and debt issuance costs, net from the payoff of the 2025 Term Loan totaled $6.2 million and was recorded in loss on debt extinguishment in the condensed consolidated statement of operations for the nine months ended September 30, 2022. For the nine months ended September 30, 2022, interest expense on the 2025 Term Loan was $0.2 million which represented stated coupon interest.

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 September 30, 2023, the Company's non-cancelable purchase commitments under the terms of its agreements are as follows:

Year ending December 31, (in thousands)		
2023*	$	15,117
2024		54,929
2025		11,050
2026		839
Total obligations	$	81,935

* Includes a reduction compared to December 31, 2022 resulting from a contract change to lower the number of UDENYCA batches to be produced at a specific CMO.

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.

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 is 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 September 30, 2023 and December 31, 2022, the Company had an accrual of $6.4 million and $4.7 million, respectively, related to such matters that was included in accrued rebates, fees and reserves on the condensed consolidated balance sheets.

In late April of 2022, the Company received a demand letter from Zinc Health Services, LLC ("Zinc") asserting that Zinc was entitled to approximately $14.0 million from the Company for claims related to certain sales of UDENYCA from October 2020 through December 2021. The Company is continuing to evaluate the claims in the letter. No legal

proceeding has been filed in connection with the claims in the letter and based on currently available information the final resolution of the matter is uncertain. The Company intends to defend any legal proceeding that may be filed. The Company's accrual as of September 30, 2023 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. Derivatives

The Company is exposed to foreign currency exchange rate risk related to its international purchases. In the first quarter of 2023, the Company started utilizing euro currency contracts to manage euro currency risk in purchasing inventory and future settlement of euro denominated assets and liabilities. The volume of the Company's foreign currency contract activity is limited by the amount of transaction exposure in each foreign currency and the Company's election whether to hedge the transactions. There are no derivative instruments entered into for speculative or trading purposes.

The Company did not elect hedge accounting for any of its currency contracts. All outstanding contracts are with the same counterparty. Changes in the net fair value of contracts are recorded in other income (expense), net in the condensed consolidated statements of operations.

Since the Company's derivatives all matured and settled by September 30, 2023, there were no derivative assets or derivative liabilities as of September 30, 2023.

The pre-tax gain (loss) of foreign currency contracts not designated as hedging instruments were recorded on the condensed consolidated statements of operations as follows:

(in thousands)	Statement of Operations Classification	Three Months Ended September 30, 2023	Nine Months Ended September 30, 2023
Currency contracts	Other income (expense), net	$ 82	$ —

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 (collectively, the "Underwriters"), pursuant to which the Company issued and sold an aggregate of 11,764,706 shares (the "Firm Shares") of its 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 shelf registration statement on Form S-3 that was declared effective on November 17, 2022 (the

"Registration Statement") under which the Company may offer and sell up to $ 150.0 million in the aggregate of its common stock, preferred stock, debt securities, warrants and units from time to time in one or more offerings.

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 the Registration Statement. Also on November 8, 2022, the Company entered into a sales agreement ("Sales Agreement") with Cowen and Company, LLC ("TD Cowen"), pursuant to which the Company may issue and sell from time to time up to $150.0 million of its common stock through or to TD Cowen as the Company's sales agent or principal in an at-the-market offering ("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 amount 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 amount 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.

The following table summarizes information regarding settlements under the ATM Offering for the three and nine months ended September 30, 2023:

(in thousands, except share and per share data)	Three Months Ended September 30, 2023	Nine Months Ended September 30, 2023
Number of common stock shares sold during the period	2,428,311	3,559,761
Weighted-average price per share	$ 4.92	$ 5.43
Gross proceeds	$ 11,938	$ 19,339
Less commissions and fees	(298)	(483)
Net proceeds after commissions and fees	$ 11,640	$ 18,856

As of September 30, 2023, the Company had approximately $ 66.5 million of its common stock remaining available for sales under the ATM Offering.

12. Stock-Based Compensation

The following table summarizes the classification of stock-based compensation expense in the Company's condensed consolidated statements of operations related to options and restricted stock units granted to employees and nonemployees:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2023	2022	2023	2022
Cost of goods sold [1]	$ 174	$ 184	$ 535	$ 555
Research and development	2,929	5,173	11,760	14,707
Selling, general and administrative	6,850	6,925	20,017	23,749
Stock-based compensation expense	$ 9,953	$ 12,282	$ 32,312	$ 39,011
Stock-based compensation expense capitalized into inventory	$ 373	$ 290	$ 697	$ 904

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

The stock-based compensation for the nine months ended September 30, 2023 includes restructuring charges described in Note 14 of $1.1 million in research and development expense and a net forfeiture credit of $ 0.1 million in selling, general and administrative expense. For the three months ended September 30, 2023, there were no restructuring charges included in stock-based compensation.

The stock-based compensation expense recorded in connection with the Surface Acquisition that was not included in the consideration transferred was immaterial.

13. Net Loss Per Share

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Stock options, including shares subject to ESPP	24,558,893	22,535,371	24,003,706	22,267,304
Restricted stock units	2,141,403	2,305,743	2,354,166	2,401,188
Shares issuable upon conversion of 2022 Convertible Notes	—	—	—	1,442,127
Shares issuable upon conversion of 2026 Convertible Notes	11,942,152	11,942,152	11,942,152	11,942,152
Total	38,642,448	36,783,266	38,300,024	38,052,771

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.

14. 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. There were no additional restructuring charges in the third quarter of 2023, as the reduction in force was completed during the second quarter of 2023.

For the nine months ended September 30, 2023, the condensed consolidated statement of operations includes $ 3.6 million in research and development expense and $1.3 million in selling, general and administrative expense related to the reduction in force.

15. Subsequent Events

Common Stock

On October 9, 2023, in accordance with the terms of an Optional Stock Purchase Agreement entered with a CMO on September 28, 2023 (the “Optional Stock Purchase Agreement”), the Company issued 2,225,513 shares of its common stock to the CMO for a price of $3.675 per share, representing an aggregate value of $ 8.2 million. 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 its 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.

Sixth Amendment to Lease

The Company has been a party to an existing Office Lease (as amended, the “Lease”) with Hudson 333 Twin Dolphin Plaza, LLC (the “Landlord”), under which the Company leases approximately 47,789 square feet of office space located at 333 Twin Dolphin Drive, Redwood City, California for the Company’s principal executive offices with an expiration date of September 30, 2024. On October 24, 2023, the Company entered into the Sixth Amendment (the “Amendment”) to the Lease with the Landlord. Under the Amendment, the Company has extended the term of the Lease through September 30, 2027 for only approximately 27,532 square feet of office space (the “Remaining Premises”). For the other 20,257 square feet of office space (the “Reduction Space”), the Amendment provides that the term of the lease shall expire for the Reduction Space on December 31, 2023. After December 31, 2023, the leased premises shall consist only of the Remaining Premises.

Except for the early expiration described above for the Reduction Space, the term of the Lease is extended through September 30, 2027.

The Amendment provides for monthly base rent on the Remaining Premises of approximately $ 0.2 million per month from January 1, 2024 through September 30, 2024. The Amendment also provides for certain limited rent abatements on the Remaining Premises prior to September 30, 2024. The Amendment provides for annual base rent on

the Remaining Premises from October 1, 2024 through September 30, 2027 starting at approximately $ 1.8 million per year and increases up to approximately $1.9 million per year.

The Landlord has agreed that the Company shall not be required to remove (or pay for the removal) of certain tenant improvements existing in the Reduction Space. The Company is obligated to pay the Landlord certain costs, taxes and operating expenses related to the Remaining Premises pursuant to the Lease.

Approval of LOQTORZI

On October 27, 2023, the FDA approved LOQTORZI 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. The approval was based on results of the JUPITER-02 Phase 3 study and the POLARIS-02 Phase 2 study and is irrespective of a patient's PD-L1 status. LOQTORZI is a next-generation, programmed death receptor-1 (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. The Company plans and projects payment of the $ 25.0 million milestone due to Junshi Biosciences pursuant to the Collaboration Agreement dated as of February 1, 2021 to occur in March 2024.

ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The interim financial statements included in this Quarterly Report on Form 10-Q and this Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2022, and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, contained in the 2022 Form 10-K. In addition to historical information, this discussion and analysis contains forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act. These forward-looking statements are subject to risks and uncertainties, including those discussed in the section titled "Risk Factors," set forth in Part II – Other Information, Item 1A below and elsewhere in this report, that could cause actual results to differ materially from historical results or anticipated results.

Overview

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

Our commercial portfolio includes three FDA-approved biosimilar products. Our first product, UDENYCA, a biosimilar to Neulasta, a long-acting granulocyte-colony stimulating factor ("G-CSF"), was launched commercially in the United States in January 2019. The FDA approved the prior approval supplement ("PAS") for an autoinjector ("AI") presentation of UDENYCA on March 3, 2023, and on May 22, 2023 we announced the availability of UDENYCA AI for commercial sale. The FDA issued a complete response letter ("CRL") for the PAS for our third pegfilgrastim presentation, the UDENYCA® on-body injector ("OBI"), on September 21, 2023, solely due to the FDA's ongoing review of inspection findings at a third-party filler. On October 5, 2023, we announced that we had resubmitted the PAS for UDENYCA OBI following the resolution of the FDA's inspectional findings at the third-party filler. We anticipate the FDA to complete its review of the resubmitted PAS for UDENYCA OBI in the fourth quarter of 2023 or the early part of 2024. Our second product, CIMERLI (ranibizumab-eqrn), was approved by the FDA in August 2022 as a biosimilar product interchangeable with Lucentis (ranibizumab injection) 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. We launched CIMERLI commercially in the United States in October 2022. We launched YUSIMRY (adalimumab-aqvh), a biosimilar to Humira (adalimumab), in the United States in July 2023.

In addition to three FDA-approved biosimilar products, our commercial portfolio also includes LOQTORZI. On October 27, 2023, we announced that the FDA approved LOQTORZI 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 expect to launch LOQTORZI in the U.S. in the first quarter of 2024.

We also have a pipeline of earlier stage clinical and preclinical immuno-oncology programs. On September 8, 2023, we acquired Surface and took ownership of its assets, including its portfolio of product candidates. The lead clinical stage product candidate from the Surface Acquisition is casdozokitug (CHS-388, formerly SRF388), an investigational 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, one of the subunits of IL-27, EBI3, is highly expressed during pregnancy and its expression is correlated with maternal-fetal tolerance. Due to its immunosuppressive 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 and fast track designation from the FDA for the treatment of hepatocellular carcinoma (“HCC”) in November 2020. Casdozokitug is currently in two on-going clinical studies, a Phase 1/2 study in patients with advanced solid tumors (clinicaltrials.gov identifier# NCT04374877) and a Phase 2 study in HCC (clinicaltrials.gov identifier# NCT05359861). Our second clinical-stage product candidate from the Surface Acquisition, 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”). CHS-114 is designed to cause depletion of intra-tumoral Treg cells, important regulators of immune suppression and tolerance, through antibody-dependent cellular cytotoxicity (“ADCC”), or antibody-dependent cellular phagocytosis (“ADCP”), or both, that has shown anti-tumor activity in preclinical models. We are enrolling patients with advanced solid tumors in North America in a clinical trial evaluating safety and pharmacokinetics of CHS-114 (clinicaltrials.gov identifier# NCT05635643). In addition to our internally developed portfolio of product candidates that we obtained in the Surface Acquisition, we have two product candidates, NZV930 and GSK4381562, which are exclusively licensed to Novartis Institutes and GSK, respectively. We will pay 70% of all milestone- and royalty-based payments that we or our affiliates actually receive from the product candidates licensed to Novartis Institutes and GSK during the ten-year period following the entry into the CVR Agreement to the holders of CVRs. We are also developing CHS-006, an investigational recombinant humanized IgG4κ monoclonal antibody designed to act specifically against human TIGIT in collaboration with Junshi Biosciences. We are enrolling patients with advanced solid tumors in North America in a clinical trial evaluating safety and pharmacokinetics of LOQTORZI in combination with CHS-006 (clinicaltrials.gov identifier# NCT05757492). We are also pursuing an early-stage development candidate that is in investigational new drug application-enabling studies, CHS-1000, an antibody targeting human ILT4, designed to improve anti-PD-1 clinical benefit by transforming an unfavorable TME to a more favorable TME.

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

We primarily operate in the United States and partner with companies that operate in other countries. We have no material direct exposure to the war between Russia and Ukraine or the war between Israel and Hamas; however, we are monitoring any broader economic impact from these conflicts, including, without limitation, heightened risk of cyberattacks, increased prices of fuel and other commodities, and potential impacts to our partners’ supply chains.

Business Update

Surface Acquisition

On September 8, 2023, in accordance with the Merger Agreement, we completed the acquisition of Surface, a clinical-stage I-O company focused on using its specialized knowledge of the biological pathways critical to the immunosuppressive tumor microenvironment for the development of next-generation cancer therapies. The Surface Acquisition expanded our I-O pipeline with the following: casdozokitug (CHS-388, formerly SRF388), an investigational, novel IL-27-targeted antibody currently being evaluated in a Phase 2 clinical trial in HCC, and CHS-114 (formerly SRF114), an investigational, CCR8-targeted antibody currently in a Phase 1/2 study as a monotherapy in patients with advanced solid tumors.

On September 8, 2023, we issued to the holders of all outstanding Surface common stock (other than treasury shares, any shares of Surface common stock held directly by us or the Merger Subs immediately prior to the Acquisition Date and shares of Surface common stock issued and outstanding immediately prior to the Acquisition Date and held by any holder properly demanding appraisal for such shares in accordance with Section 262 of the Delaware General Corporation Law) 0.1960 shares of our 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 our 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 our discretion during the 10-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 actually received by us or our affiliates under the GSK Agreement related to the existing program (GSK4381562);
- 70% of all milestone- and royalty-based payments actually received by us or our affiliates under the Novartis Agreement related to the existing program (NZV930);
- 25% of any upfront payment actually received by us or our affiliates pursuant to potential ex-U.S. licensing agreements for CHS-114; and
- 50% of any upfront payment actually received by us or our affiliates pursuant to potential ex-U.S. licensing agreements for casdozokitug.

We expensed $2.6 million and $4.5 million of acquisition-related costs during the three and nine months ended September 30, 2023, respectively.

Other Updates

On October 27, 2023, we announced that the FDA approved LOQTORZI 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 expect to launch LOQTORZI in the U.S. in the first quarter of 2024.

During the nine months ended September 30, 2023, we donated approximately 36,000 units of UDENYCA in the pre-filled syringe (“PFS”) presentation to the nonprofit organization Direct Relief to benefit cancer patients in low- and middle-income countries requiring increased access for vulnerable patients. The carrying value of this inventory was written down to zero in the third quarter of 2022, thus there was no charge associated with the donation.

On October 9, 2023, in accordance with the terms of an Optional Stock Purchase Agreement entered with a CMO on September 28, 2023, we issued 2,225,513 shares of our common stock to the CMO for a price of $3.675 per share, representing an aggregate value of $8.2 million. The Optional Stock Purchase Agreement gave us the option in our sole discretion to elect to pay for certain manufacturing services provided by the CMO by either paying cash or electing for the Stock Service Fee Payment. On October 4, 2023, we notified the CMO of our 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.

On November 8, 2022, we filed the Registration Statement, which was declared effective on November 17, 2022. Under the Registration Statement, we may offer and sell up to $150.0 million in the aggregate of our common stock, preferred stock, debt securities, warrants and units from time to time in one or more offerings. Also on November 8, 2022, we entered into the Sales Agreement pursuant to which we may issue and sell from time to time up to $150.0 million of our common stock in the ATM Offering. On May 15, 2023, pursuant to an Amendment No. 1 to Sales Agreement, we reduced the amount of shares that could be issued and sold pursuant to its ATM Offering 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, we increased the amount 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. For the ATM Offering program to date as of September 30, 2023, we sold 4,476,645 shares of common stock at a weighted-average price per share of $5.81 for gross proceeds of $26.0 million pursuant to the ATM Offering and received net proceeds of $25.4 million, net of $0.6 million of commissions and fees of which 2,428,311 shares of common stock were sold during the quarter ended September 30, 2023 at a weighted-average price per share of $4.92 for gross proceeds of $11.9 million pursuant to the ATM Offering and received net proceeds of $11.6 million, net of $0.3 million of commissions and fees.

Products and Product Candidates

Our portfolio includes the following products and product candidates:

Oncology

- UDENYCA, a biosimilar to Neulasta, a long-acting G-CSF, was launched commercially in the United States in January 2019. The FDA approved the PAS for an AI presentation of UDENYCA on March 3, 2023, and on May 22, 2023 we announced the availability of UDENYCA AI for commercial sale. The FDA issued a CRL for the PAS for our third pegfilgrastim presentation, UDENYCA OBI, on September 21, 2023, solely due to the FDA's ongoing review of inspection findings at a third-party filler. On October 5, 2023, we announced that we had resubmitted the PAS for UDENYCA OBI following the resolution of the FDA's inspection findings at the third-party filler. We anticipate the FDA to complete its review of the resubmitted PAS for UDENYCA OBI in the fourth quarter of 2023 or the early part of 2024.

- 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 the FDA approved LOQTORZI 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 expect to launch LOQTORZI in the U.S. in the first quarter of 2024.

- 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 and fast track designation from the FDA for the treatment of HCC in November 2020. Casdozokitug is currently in two on-going clinical studies a Phase 1/2 study in advanced solid tumors (clinicaltrials.gov identifier# NCT04374877) and a Phase 2 study in HCC (clinicaltrials.gov identifier# NCT05359861).

- 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, and/or ADCP. 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 in North America in a clinical trial evaluating safety and pharmacokinetics of CHS-114 (clinicaltrials.gov identifier# NCT05635643).

- CHS-006 is an investigational recombinant humanized IgG4κ monoclonal antibody designed to act specifically against human TIGIT that we are developing in collaboration with Junshi Biosciences. A number of third-party preclinical and clinical studies have demonstrated that activation of the TIGIT pathway may be a crucial underlying mechanism for tumor immune evasion and resistance to PD-1 blockade therapy in some tumor types. In preclinical studies the combination of TIGIT and PD-1/PD-L1 antibodies showed a synergistic potential to enhance antitumor response, and thus we hypothesize that combination treatment in cancer patients may overcome anti-PD-1 resistance and possibly broaden the cancer patient population that can benefit from immunotherapy.

  A dose escalation, dose expansion clinical trial (clinicaltrials.gov identifier# NCT05061628) evaluating the safety, tolerability and pharmacokinetic properties of CHS-006 as monotherapy and in combination with PD-1 inhibitor LOQTORZI in patients with advanced solid tumors is ongoing in China. We are enrolling patients with advanced solid tumors in North America in a clinical trial evaluating safety and pharmacokinetics of LOQTORZI in combination with CHS-006 (clinicaltrials.gov identifier# NCT05757492).

- We are pursuing an early-stage development candidate, CHS-1000, an antibody targeting human ILT4, designed to improve anti-PD-1 clinical benefit by transforming an unfavorable TME to a more favorable TME. We plan to submit an investigational new drug application (“IND”) to the FDA in 2024 for CHS-1000.

- In addition to our internally developed portfolio of product candidates that we obtained in the Surface Acquisition, we also own NZV930 and GSK4381562, which are exclusively licensed to Novartis Institutes and GSK, respectively. NZV930 is an antibody designed to inhibit CD73, which is a critical enzyme involved in the production of extracellular adenosine, a key metabolite with strong immunosuppressive properties within the TME. NZV930 aims to reduce the production of immunosuppressive adenosine within the TME. GSK4381562 is an antibody targeting CD112R, also known as PVRIG, an inhibitory protein expressed on natural killer (“NK”) and T cells. GSK4381562 blocks the interaction of CD112R with CD112, its binding partner that is expressed on tumor cells. GSK4381562 can promote the activation of both NK and T cells, with potential to elicit a strong anti-tumor response and promote immunological memory. We will pay 70% of all milestone- and royalty-based payments that we or our affiliates actually receive from the product candidates

licensed to Novartis Institutes and GSK during the ten-year period following the entry into the CVR Agreement to the holders of CVRs.

Ophthalmology

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

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

Immunology

- YUSIMRY, a biosimilar of Humira (adalimumab), is a monoclonal antibody that can bind to tumor necrosis factor ("TNF"). YUSIMRY provides certain therapeutic benefits for treatment of patients with certain inflammatory diseases characterized by increased production of TNF in the body, including rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, psoriasis and ulcerative colitis. In December 2021, the FDA approved YUSIMRY, which we launched in the United States in July 2023. The list price of YUSIMRY at launch represented an approximately 85% discount to the list price of Humira. YUSIMRY is now available for sale nationwide through retail, mail order, and specialty pharmacy channels.

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 next-generation engineered IL-2 cytokine, and certain negotiation rights to two undisclosed preclinical immuno-oncology drug candidates. We will have the right to conduct all commercial activities of LOQTORZI in the United States and Canada. We will be obligated to pay Junshi Biosciences a 20% royalty on net sales of LOQTORZI and up to an aggregate $380.0 million in one-time payments for the achievement of various regulatory and sales milestones.

In March 2022, we paid $35.0 million for the exercise of our option to license CHS-006. We and Junshi Biosciences are jointly developing CHS-006 with each party responsible for the associated development costs as set forth in the Collaboration Agreement. If we exercise our remaining option for the IL-2 cytokine, we will be obligated to pay an additional option exercise fee of $35.0 million. Additionally, for each exercised option, we will be obligated to pay Junshi Biosciences an 18% royalty on net sales, up to $85.0 million for the achievement of certain regulatory approvals, and up to $170.0 million for attainment of certain sales thresholds. Under the Collaboration Agreement, we retain the right to collaborate in the development of LOQTORZI and the other licensed compounds, including CHS-006, and will pay for a portion of these co-development activities up to a maximum of $25.0 million per licensed compound per year. Beginning in 2023, the scope of the development plan for LOQTORZI in the United States has been reduced based on changes approved by us and Junshi Biosciences. 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 September 30, 2023, we did not have any outstanding milestone or royalty payment obligations to Junshi Biosciences. The additional milestone payments, option fee for the IL-2 cytokine and royalties are contingent upon future events and, therefore, will be recorded if and when it becomes probable that a milestone will be achieved, or when an option fee or royalties are incurred.

In connection with the Collaboration Agreement, we entered into a Stock Purchase Agreement with Junshi Biosciences agreeing, subject to customary conditions, to acquire certain equity interests in us. Pursuant to the Stock Purchase Agreement, on April 16, 2021, we issued 2,491,988 unregistered shares of our common stock to Junshi Biosciences, at a price per share of $20.06, for an aggregate amount of approximately $50.0 million in cash. Under the terms of the Stock Purchase Agreement, Junshi Biosciences was not permitted to sell, transfer, make any short sale of, or grant any option for the sale of the common stock for the two-year period following its effective date.

Out-Licensing Agreements Acquired as part of Surface Acquisition

Novartis

Pursuant to the Novartis Agreement, Surface granted Novartis Institutes a worldwide exclusive license to research, develop, manufacture and commercialize antibodies that target CD73. Under the Novartis Agreement, we are currently entitled to potential development milestones of $325.0 million and sales milestones of $200.0 million, as well as tiered royalties on annual net sales by Novartis Institutes ranging from high single-digit to mid-teens percentages upon the successful commercialization of NZV930. 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 Novartis Agreement. We did not recognize any revenue relating to the Novartis Agreement during the three months ended September 30, 2023.

GSK Agreement

Pursuant to the GSK Agreement, Surface granted GSK a worldwide exclusive, sublicensable license to develop, manufacture and commercialize antibodies that target the antibody GSK4381562, targeting CD112R, also known as PVRIG. 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 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 did not recognize license-related revenue under the GSK Agreement during the three months ended September 30, 2023.

COVID-19 Update

As a result of the COVID-19 pandemic, we experienced and may, as a result of future outbreaks, experience disruptions that could severely impact our business, clinical trials and preclinical studies. See “Risk Factors – Risks Related to COVID-19.”

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 October 2022. Our total net revenues were $74.6 million and $45.4 million during the three months ended September 30, 2023 and 2022 , respectively, and $165.7 million and $165.7 million during the nine months ended September 30, 2023 and 2022, respectively.

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 Inc. and Amgen USA Inc. (collectively “Amgen”). As a result, cost of goods sold reflects a mid-single digit royalty on net product revenue, which began July 1, 2019 and continues for five years from then. Additionally, we share a percentage of gross profits on sales of Bioeq Licensed Products in the United States with Bioeq in the low- to mid-fifty percent range, and pursuant to the Genentech Agreement we incur a royalty that is a low single-digit percentage of net sales of CIMERLI that must be paid through the end of 2023.

Research and Development Expense

Research and development expense represents costs incurred to conduct research, such as the discovery and development of our product candidates. We recognize all research and development costs as they are incurred. We currently track research and development costs incurred on a product candidate basis only for external research and development expenses. Our external research and development expense consists primarily of:

- expense incurred under agreements with collaborators, consultants, third-party contract research organizations (“CROs”), and investigative sites where a substantial portion of our preclinical studies and all of our clinical trials are conducted;
- costs of acquiring originator comparator materials and manufacturing preclinical study and clinical trial supplies and other materials from CMOs, and related costs associated with release and stability testing;
- costs associated with manufacturing process development activities, analytical activities and pre-launch inventory manufactured prior to regulatory approval being obtained or deemed to be probable; and
- upfront and certain milestone payments related to licensing and collaboration agreements.

Internal costs are associated with activities performed by our research and development organization and generally benefit multiple programs. These costs are not separately allocated by product candidate. Unallocated, internal research and development costs consist primarily of:

- personnel-related expense, which includes salaries, benefits and stock-based compensation; and
- facilities and other allocated expense, which include direct and allocated expense for rent and maintenance of facilities, depreciation and amortization of leasehold improvements and equipment, laboratory and

other supplies.

The largest component of our total operating expense has historically been our investment in research and development activities, including the licensing and collaboration costs, clinical development and manufacturing process development of our product candidates.

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

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, acquisition-related costs, and costs associated with establishing commercial capabilities in support of the commercialization of UDENYCA, CIMERLI, YUSIMRY and LOQTORZI. Personnel costs consist of salaries, benefits and stock-based compensation.

Interest Expense

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

Loss on Debt Extinguishment

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

Other Income (Expense), Net

Other income (expense), net consists primarily of interest earned on our cash 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 disposal of long-lived assets, and the change in fair value of our foreign currency contracts that we use to manage our exposure to foreign currency exchange rate risk.

Income Tax Provision (Benefit)

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.

Results of Operations

Comparison of Three and Nine Months Ended September 30, 2023 and 2022

Revenue

	Three Months Ended September 30,			Nine Months Ended September 30,		
(in thousands)	**2023**	**2022**	**Change**	**2023**	**2022**	**Change**
Net revenue	$ 74,568	$ 45,424	$ 29,144	$ 165,720	$ 165,690	$ 30

The increase in net revenue for the three months ended September 30, 2023 compared to the three months ended September 30, 2022 was primarily due to our launches of CIMERLI in October 2022 and YUSIMRY in July 2023, which contributed $40.0 million and $1.4 million of net revenue, respectively. This was partially offset by lower UDENYCA net revenue primarily from a decline in the average net selling price per unit resulting from competition and reduced market access. Although net revenue was flat in the nine months ended September 30, 2023, the composition of our net revenue changed. Our launches of CIMERLI in October 2022 and YUSIMRY in July 2023 contributed $72.9 million and $1.4 million of net revenue in the nine months ended September 30, 2023 and 2022, respectively, offset by a $74.6 million decline in UDENYCA net revenue primarily related to the decline in the average net selling price per unit. Our net revenue and market penetration may continue to be adversely impacted by pricing trends and competitive dynamics in the overall pegfilgrastim market. In addition, the COVID-19 pandemic has negatively impacted the pre-filled syringe pegfilgrastim market due to preferences to administer medication at home.

We expect our net revenue in 2023 to be higher than in 2022, as a result of the continued growth in sales of CIMERLI and the continued market share growth of UDENYCA.

Cost of Goods Sold

	Three Months Ended September 30,			Nine Months Ended September 30,		
(in thousands)	**2023**	**2022**	**Change**	**2023**	**2022**	**Change**
Cost of goods sold	$ 32,703	$ 35,234	$ (2,531)	$ 74,425	$ 55,881	$ 18,544
Gross margin	56 %	22 %		55 %	66 %	

The decrease in cost of goods sold for the three months ended September 30, 2023 compared to the same period in the prior year was primarily due to the $26.0 million write-down in the third quarter of 2022 of inventory at risk of expiration and due to the sale in the third quarter of 2023 of certain of those UDENYCA units having a total original cost of $2.4 million but no carrying value following the write-off, partially offset by a $17.0 million increase in royalty costs and $8.4 million increase in product costs driven primarily by CIMERLI sales and the mix of products sold.

The increase in cost of goods sold for the nine months ended September 30, 2023 compared to the same period in the prior year was due to a $28.1 million increase in royalty costs and $13.1 million increase in product costs both driven primarily by CIMERLI sales and the mix of products sold, $3.0 million in contract modification fees with one of our manufacturers for reducing the number of UDENYCA batches to be produced, and $2.3 million in write-offs, net of recoveries for inventory that was damaged during processing. These unfavorable factors were offset by the $26.0 million write-down in the third quarter of 2022 of inventory at risk of expiration and due to the sale in the third quarter of 2023 of certain of those UDENYCA units having no carrying value following the write-off and a total original cost of $2.4 million.

In addition, gross margins in the three and nine months ended September 30, 2023 were unfavorably impacted due to product mix resulting from increased volumes of CIMERLI sold following the product specific Q-Code implementation in April 2023, the launch of UDENYCA AI in May 2023, and the launch of YUSIMRY in July 2023.

We expect our gross margin for the full year 2023 to be lower than the full year 2022 primarily due to royalties incurred on CIMERLI sales, sales of YUSIMRY in a very competitive market, and continued declines in net realized prices of UDENYCA due to market pressures.

Research and Development Expense

	Three Months Ended September 30,			Nine Months Ended September 30,		
(in thousands)	**2023**	**2022**	**Change**	**2023**	**2022**	**Change**
Research and development	$ 25,647	$ 45,808	$ (20,161)	$ 83,068	$ 170,336	$ (87,268)

The decrease in research and development expense in the three months ended September 30, 2023 was primarily due to the following:

- a decrease of $9.0 million in YUSIMRY costs primarily due to certain manufacturing costs for YUSIMRY being capitalized since mid-2022, as well as completion of key studies in the second half of 2022;
- a decrease of $6.4 million in costs to develop additional presentations of UDENYCA;
- a decrease of $5.2 million in personnel and stock-based compensation expense primarily due to fewer employees;
- a decrease of $1.5 million in facilities, supplies and materials and other infrastructure related expenses to support our research and development programs; and
- a decrease of $1.4 million in co-development costs for LOQTORZI and CHS-006 resulting from reducing the scope of the development plan for LOQTORZI in the United States beginning in 2023.

The decrease was partially offset by an increase of $2.4 million for development of CHS-1000.

The decrease in research and development expense in the nine months ended September 30, 2023 was primarily due to the following:

- the first quarter of 2022 including an upfront payment of $35.0 million to exercise our option to license CHS-006, a TIGIT-targeted antibody, in the United States and Canada;
- a decrease of $20.1 million in co-development costs for LOQTORZI and CHS-006 resulting from reducing the scope of the development plan for LOQTORZI in the United States beginning in 2023;
- a decrease of $17.1 million in YUSIMRY costs primarily due to certain manufacturing costs for YUSIMRY being capitalized since mid-2022, as well as completion of key studies in the second half of 2022;
- a decrease of $11.7 million in costs to develop additional presentations of UDENYCA;
- a decrease of $5.3 million in personnel and stock-based compensation expense primarily due to fewer employees; and
- a decrease of $2.4 million in facilities, supplies and materials and other infrastructure related expenses to support our research and development programs.

The decrease was partially offset by an increase of $4.3 million for development of CHS-1000.

Excluding the potential impact of any acquisitions or business development transactions that have not been consummated, we expect our research and development expense for the full year 2023 to be lower than the full year 2022 due to the reduced scope of the development plan for LOQTORZI in the United States based on changes approved by us and Junshi Biosciences.

Selling, General and Administrative Expense

	Three Months Ended September 30,			Nine Months Ended September 30,		
(in thousands)	**2023**	**2022**	**Change**	**2023**	**2022**	**Change**
Selling, general and administrative	$ 48,224	$ 44,831	$ 3,393	$ 142,521	$ 144,860	$ (2,339)

The increase in selling, general and administrative expense in the three months ended September 30, 2023 was primarily due to an increase in professional services of $4.7 million driven by the Surface Acquisition and third-party processing fees from multiple products being commercialized, partially offset by a $1.9 million reduction in employee and consultant costs due to a lower average headcount.

The decrease in selling, general and administrative expense in the nine months ended September 30, 2023 was primarily due to a lower average headcount, including reductions of $5.3 million in employee and consultant costs and $3.7 million in stock-based compensation. These decreases were partially offset by increases of $3.8 million in professional services driven by the Surface Acquisition and third-party processing fees , $1.6 million in facilities, supplies and materials to support the commercial infrastructure for our products, and $1.2 million in travel-related costs.

Excluding the potential impact of any acquisitions or business development transactions that have not been consummated, we expect our selling, general and administrative expense for the full year 2023 to be lower than the full year 2022 primarily as a result of decreased commercial costs and our reduction in force that occurred in the first quarter of 2023.

Interest Expense

	Three Months Ended September 30,			Nine Months Ended September 30,		
(in thousands)	**2023**	**2022**	**Change**	**2023**	**2022**	**Change**
Interest expense	$ 10,268	$ 7,540	$ 2,728	$ 29,923	$ 23,089	$ 6,834

The increase in interest expense in the three months ended September 30, 2023 was primarily due to a higher average outstanding debt balance and higher average interest rate.

The increase in interest expense in the nine months ended September 30, 2023 was primarily due to a higher average outstanding debt balance and higher average interest rate. This was partially offset by $3.6 million of interest expense in the first nine months of 2022 related to the 2027 Term Loans discount and debt issuance costs that were allocated to unfunded tranches and subsequently amortized over the respective commitment periods for tranches, including $2.3 million allocated to Tranche B that was fully amortized in the first quarter of 2022.

Our 2027 Term Loans have a variable interest rate component that resets at the beginning of every quarter, and the total interest rates ranged from 9.25% in the first quarter of 2022 to 12.00% in the fourth quarter of 2022. The interest rate on the 2027 Term Loans increased to 13.76% for the third quarter of 2023 and will be 13.91% for the fourth quarter of 2023. As a result of the higher interest rate and higher average outstanding debt balance, we expect interest expense to be higher for the full year 2023 compared to the full year 2022.

Loss on Debt Extinguishment

(in thousands)	Nine Months Ended September 30, 2023	2022	Change
Loss on debt extinguishment	$ —	$ 6,222	$ (6,222)

The $6.2 million loss on debt extinguishment recorded in the first nine months of 2022 resulted from voluntarily prepaying all amounts outstanding under the 2025 Term Loan in January 2022.

Other Income (Expense), Net

(in thousands)	Three Months Ended September 30, 2023	2022	Change	Nine Months Ended September 30, 2023	2022	Change
Other income (expense), net	$ 2,253	$ 1,339	$ 914	$ 5,598	$ 1,814	$ 3,784

Other income (expense), net in the three months and nine months ended September 30, 2023 changed favorably compared to the same period in the prior year primarily due to investing in our marketable securities during the fourth quarter of 2022. This resulted in interest income and non-cash accretion of discount on our marketable securities held during the three and nine months ended September 30, 2023 compared to not holding investments in marketable securities during the same periods in the prior year.

Income Tax Provision (Benefit)

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. The Company recognized $0.4 million of income tax benefit for the three and nine months ended September 30, 2023. No income tax provision or benefit was recognized for the three and nine months ended September 30, 2022.

Liquidity and Capital Resources

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

(in thousands)	September 30, 2023	December 31, 2022
Financial assets		
Total Cash, cash equivalents and marketable securities	$ 131,077	$ 191,681
Debt obligations:		
2027 Term Loans	$ 246,217	$ 245,483
2026 Convertible Notes	226,557	225,575
Total debt obligations	$ 472,774	$ 471,058

Although we were profitable in 2020 and 2019, due to our research and development expenditures and decline in revenue beginning in 2021, we have generated significant operating losses in all other years since our inception, including in 2021, 2022 and the three and nine months ended September 30, 2023. We have funded our operations primarily through sales of our common stock, issuance and incurrence of convertible and term debt and sales of our products.

On September 8, 2023, we obtained $28.8 million of cash, cash equivalents and marketable securities as part of the Surface Acquisition.

On May 16, 2023, we entered into the Underwriting Agreement with the Underwriters, pursuant to which we sold an aggregate of 11,764,706 Firm Shares to the Underwriters. Additionally, under the terms of the Underwriting Agreement, we granted the Underwriters an option, for 30 days from the date of the Underwriting Agreement, to purchase up to an additional 1,764,705 Option 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 us pursuant to the Underwriting Agreement at a price of $3.995 per share.

On May 18, 2023, we completed the sale and issuance of an aggregate of 13,529,411 Shares in the Public Offering, including the exercise in full of the Underwriters' option to purchase the Option Shares. We received net proceeds of approximately $53.6 million, after deducting the Underwriters' discounts and commissions and offering expenses payable by us.

On November 8, 2022, we entered into the Sales Agreement related to the ATM Offering pursuant to which we may issue and sell from time to time up to $150.0 million of our common stock. On May 15, 2023, pursuant to an Amendment No. 1 to Sales Agreement and in connection with the Public Offering, we reduced the amount 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 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 amount 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. During the three months ended September 30, 2023, 2,428,311 shares were sold pursuant to the ATM Offering. For the ATM Offering program to date as of September 30, 2023, we sold 4,476,645 shares of common stock at a weighted-average price per share of $5.81 for gross proceeds of $26.0 million and received net proceeds of $25.4 million, net of $0.6 million of commissions and fees. During the nine months ended September 30, 2023, we sold 3,559,761 shares of common stock at a weighted-average price per share of $5.43 for gross proceeds of $19.3 million pursuant to the ATM Offering and received net proceeds of $18.9 million, net of $0.5 million of commissions and fees. As of September 30, 2023, we had approximately $66.5 million of our common stock remaining available for sales under the ATM Offering. The ability to elect to sell shares of our common stock in the ATM Offering from time to time adds to our financial flexibility.

As of September 30, 2023, we had an accumulated deficit of $1.5 billion and cash, cash equivalents, and marketable securities of $131.1 million. We believe that our available cash, cash equivalents, marketable securities, cash collected from product sales, ATM Offering and Public Offering proceeds received to date will be sufficient to fund our planned expenditures and meet our obligations for at least the twelve months following our financial statement issuance date.

We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Further, our operating plan may change, and we may need additional funds to meet operational needs and capital requirements for product development and commercialization sooner than planned. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates and the extent to which we may enter into additional agreements with third parties to participate in their development and commercialization, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated research and development activities, and on-going and future licensing and collaboration obligations. We may need to raise additional funds in the future; however, there can be no assurance that such efforts will be successful or that, if they are successful, the terms and conditions of such financing will be favorable. Our future funding requirements will depend on many factors, including the following:

- cash proceeds from product sales;
- the costs of manufacturing, distributing and marketing our products;
- the cost of manufacturing clinical supplies and any products that we may develop;

- the terms and timing of any other collaborative, licensing and other arrangements that we have established or may establish;
- the timing, receipt and amount of sales, profit sharing or royalties, if any, from any product candidates that are approved in the future;
- the number and characteristics of product candidates that we pursue;
- the scope, rate of progress, results and cost of our clinical trials, preclinical testing and other related activities;
- the costs of acquiring originator comparator materials and manufacturing preclinical study and clinical trial supplies and other materials from CMOs and related costs associated with release and stability testing;
- the cost, timing and outcomes of regulatory approvals;
- the cost of preparing, filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the extent to which we acquire or invest in businesses, products or technologies;
- the impact of general economic conditions on our business, including but not limited to increased interest rates and high inflation; and
- the costs of the impact from the COVID-19 pandemic and future outbreaks.

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

Financing arrangements

2027 Term Loans

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

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

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

Pursuant to the 2027 Term Loans agreement, and subject to certain restrictions, proceeds of the 2027 Term Loans were used to fund our general corporate and working capital requirements except for the following: in January 2022, proceeds of the Tranche A Loan were used to voluntarily repay in full all amounts outstanding under the 2025 Term Loan,

as well as all associated costs and expenses; and proceeds of the Tranche B Loan were drawn in connection with the full repayment of our 2022 Convertible Notes due in March 2022.

As of September 30, 2023, we were in full compliance with these covenants, and there were no events of default under the 2027 Term Loans.

2026 Convertible Notes

As of September 30, 2023, the carrying amount of our $230.0 million aggregate principal amount convertible senior subordinated notes due 2026 was $226.6 million. The 2026 Convertible Notes accrue interest at a rate of 1.5% per annum, payable semi-annually in arrears on April 15 and October 15 of each year, and will mature on April 15, 2026, unless earlier repurchased or converted at the option of holders. Since inception, the conversion price has been 51.9224 shares of common stock per $1,000 principal amount of the 2026 Convertible Notes, which represents a conversion price of approximately $19.26 per share of common stock. The initial conversion price represents a premium of approximately 30.0% over the last reported sale of $14.82 per share of our common stock on the Nasdaq Global Market on April 14, 2020, the date the 2026 Convertible Notes were issued. The conversion rate and conversion price will be subject to customary adjustments upon the occurrence of certain events. The 2026 Convertible Notes are not redeemable at our election before maturity. If the 2026 Convertible Notes were converted on September 29, 2023, the holders of the 2026 Convertible Notes would have received common shares with an aggregate value of $44.7 million based on our closing stock price of $3.74.

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

Contingent Milestones

We have obligations to make future payments to third parties that become due and payable upon the achievement of certain development, regulatory and commercial milestones (such as clinical trial achievements, the filing of a BLA, approval by the FDA or product launch). These milestone payments and other similar fees are contingent upon future events and therefore are only recorded when it becomes probable that a milestone will be achieved or other applicable criteria will be met. Because the achievement of these milestones had not reached the threshold for recognition as of September 30, 2023, such contingencies were not recorded in our financial statements.

The following presents a summary of our active partnerships and collaborations that have contingent regulatory and sales milestones as of September 30, 2023:

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

(1) Excludes any amounts due according to the Term Sheet with Klinge Biopharma. The Company and Klinge Biopharma continue to conduct due diligence and discuss terms of the transaction. The material terms of the transaction with Klinge Biopharma will be included in a subsequent filing by the Company when definitive agreements are executed.

(2) On October 27, 2023, we announced that the FDA approved LOQTORZI 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 expect to launch LOQTORZI in the U.S. in the first quarter of 2024. We plan and project payment of the $25.0 million milestone payment that became due because of the recent FDA approval of LOQTORZI to occur in March 2024.

(3) Upon initiation of the first qualifying clinical trial that contains the optioned TIGIT molecule, we will be required to pay Junshi Biosciences a milestone payment of $20.0 million.

(4) Relates to a milestone contingent upon the launch readiness of a PFS product, if achieved during 2023.

Contingent Value Rights

We have recorded a contingent consideration liability for the fair value of the potential payments under 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 can be in the form of cash, stock or a combination of cash and stock. As of September 30, 2023, no payments are due to CVR holders. For further details, see Note 6. Surface Acquisition in the Notes to Condensed Consolidated Financial Statements contained in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Other 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 September 30, 2023 were $81.9 million, as outlined in Note 9. Commitments and Contingencies in the Notes to Condensed Consolidated Financial Statements contained in Part I, Item 1 of this Quarterly Report on Form 10-Q.

There have been no significant changes to our leases during the nine months ended September 30, 2023, as compared to the discussion in the 2022 Form 10-K, except for the Amendment entered into on October 24, 2023 for our principal executive offices as outlined in Note 15. Subsequent Events in the Notes to Condensed Consolidated Financial Statements contained in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Summary Statement of Cash Flows

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

	Nine Months Ended September 30,	
(in thousands)	**2023**	**2022**
Net cash used in operating activities	$ (161,947)	$ (141,171)
Net cash provided by (used in) investing activities	109,437	(36,952)
Net cash provided by financing activities	69,234	47,733
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 16,724	$ (130,390)

Net cash used in operating activities

Cash used in operating activities of $161.9 million for the nine months ended September 30, 2023 was primarily due to the net loss of $158.2 million adjusted for non-cash items including stock-based compensation expense of $32.3 million and other non-cash adjustments of $7.2 million, partially offset by the changes in our operating assets and liabilities of $43.2 million.

Cash used in operating activities of $141.2 million for the nine months ended September 30, 2022 was primarily

due to the net loss of $232.9 million adjusted for the classification of the cash option payment to Junshi Biosciences of $35.0 million to investing activities, non-cash items including stock-based compensation expense of $39.0 million, write-down for inventory at risk of expiration of $26.0 million, loss on debt extinguishment of $6.2 million and other non-cash adjustments of $10.1 million, partially offset by the changes in our operating assets and liabilities of $24.6 million.

Net cash provided by (used in) investing activities

Cash provided by investing activities of $109.4 million for the nine months ended September 30, 2023 was primarily due to proceeds from maturities of investments in marketable securities of $108.1 million, proceeds from sale of investments in marketable securities of $13.3 million, and $7.0 million of cash acquired from the Surface Acquisition, partially offset by purchases of investments in marketable securities of $19.5 million.

Cash used in investing activities of $37.0 million for the nine months ended September 30, 2022 was primarily due to the option fee payment of $35.0 million to license CHS-006 from Junshi Biosciences and purchases of property and equipment of $2.0 million.

Net cash provided by financing activities

Cash provided by financing activities of $69.2 million for the nine months ended September 30, 2023 was primarily due to proceeds of $53.6 million from the Public Offering, net of issuance costs, $18.2 million proceeds from the ATM Offering, net of issuance costs, and $1.3 million proceeds from purchase under the ESPP. These were partially offset by $3.3 million in tax payments related to net share settlement.

Cash provided by financing activities of $47.7 million for the nine months ended September 30, 2022 was primarily due to proceeds of $240.7 million under the 2027 Term Loans, net of debt discount and issuance costs and $1.7 million proceeds from purchase under the ESPP. These were partially offset by fully repaying $109.0 million on the 2022 Convertible Notes and $81.8 million on the 2025 Term Loan (excluding interest which is accounted for as an operating activity), and $3.6 million in tax payments related to net share settlement of RSUs.

Critical Accounting Estimates

The preparation of our condensed consolidated financial statements in accordance with 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 condensed consolidated financial statements, as well as the reported revenue generated and expense incurred during the reporting periods. 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.

Other than as relates to the Surface Acquisition which was accounted for as a business combination and is described below, there have been no significant changes to our critical accounting estimates during the nine months ended September 30, 2023, as compared to the critical accounting estimates described in our 2022 Form 10-K. We believe that the critical accounting estimates discussed in the 2022 Form 10-K are meaningful to understanding our historical and future performance, as these estimates relate to the more significant areas involving management's judgments and assumptions.

Business Combination Accounting and Valuation of Acquired Assets

We completed the Surface Acquisition on September 8, 2023, which was accounted for as a business combination. We account for acquisitions of entities that include inputs and processes and have the ability to create outputs as

business combinations. Judgment was required in assessing whether the acquired processes or activities, along with their inputs, met 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, 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 condensed consolidated statement 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.

Recent Accounting Pronouncements

For a description of the impact of recent accounting pronouncements, see Note 1. Organization and Summary of Significant Accounting Policies in the Notes to Condensed Consolidated Financial Statements contained in Part I, Item 1 of this Quarterly Report on Form 10-Q.

ITEM 3. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risk related to changes in interest rates. As of September 30, 2023, we had cash and cash equivalents and marketable securities of $131.1 million, primarily invested in U.S. treasuries and government agency securities, commercial paper, corporate bonds and money market funds. Our primary exposure to market risk is interest rate sensitivity. Our marketable securities are subject to interest rate risk and could fall in value if market interest rates increase. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, we believe that our exposure to interest rate risk on these investments is not significant and a 1% movement in market interest rates would not have a material impact to our financial results. We do not enter into investments for trading or speculative purposes.

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

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

We are exposed to interest rate risk with respect to variable rate debt. As of September 30, 2023, we had $250.0 million principal outstanding on our 2027 Term Loans that starting April 1, 2023, accrue interest at 8.25% plus the Adjusted Term SOFR, with a floor on Adjusted Term SOFR of 1.0%. We currently do not hedge our variable interest rate

debt. The interest rate for our variable rate debt during the quarter ended September 30, 2023 was 13.76%, and the interest rate during the fourth quarter of 2023 will be 13.91%. A hypothetical 100 basis point increase in the interest rate on our variable rate debt could result in up to a $2.5 million increase in the annual interest expense as of September 30, 2023.

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

Substantially all of our sales are denominated in U.S. dollars. We have exposure to the exchange rate between the U.S. Dollar and the Euro because we make purchases of CIMERLI inventory from and pay royalties to our partner Bioeq that are denominated in Euros. Accordingly, fluctuations in the exchange rate between the U.S. Dollar and the Euro may impact our condensed consolidated statements of operations. For information on our economic hedges of foreign currency exchange rate risk, see Note 10. Derivatives in the Notes to Condensed Consolidated Financial Statements contained in Part I, Item 1 of this Quarterly Report on Form 10-Q.

ITEM 4. Controls and Procedures

Evaluation of Effectiveness of Disclosure Controls and Procedures

We carried out an evaluation, under the supervision of our President and 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 Quarterly Report on Form 10-Q. Based on that evaluation, our President and Chief Executive Officer and our Chief Financial Officer have concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures were, in design and operation, effective at the reasonable assurance level.

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 SEC's rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer, principal financial officer and principal accounting officer, as appropriate, to allow for timely decisions regarding required disclosure.

We intend to review and evaluate the design and effectiveness of our disclosure controls and procedures on an ongoing basis and to correct any material deficiencies that we may discover. Our goal is to ensure that our management has timely access to material information that could affect our business. While we believe the present design of our disclosure controls and procedures is effective to achieve our goal, future events affecting our business may cause us to modify our disclosure controls and procedures. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Changes in Internal Control Over Financial Reporting .

There were no changes in our internal control over financial reporting that occurred during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints, and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

PART II – OTHER INFORMATION

ITEM 1. Legal Proceedings

The information called for by this Item is incorporated herein by reference to the information set forth in Note 9. Commitments and Contingencies in the Notes to Condensed Consolidated Financial Statements contained in Part I, Item 1 of this Quarterly Report on Form 10-Q.

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 Quarterly Report on Form 10-Q, 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 three products that have been approved and marketed, with multiple products either approved and not yet marketed or not approved and still in development.
- We may be unable to realize the anticipated benefits of the Surface Acquisition.
- The applicability of clinical data generated outside the United States, particularly from a single country such as China, is subject to FDA concurrence for its suitability in supporting product approvals in the United States. If the FDA or comparable regulatory agencies do not accept data from such trials, our development plans will be delayed and diminished, which could materially harm our business.
- The commercial success of our existing products or any future products will depend upon the degree of market acceptance and adoption by prescribing physicians, healthcare providers and the patients to whom our medicines are prescribed. Additionally, obtaining placement on national and/or local clinical guidelines/pathways, as well as coverage on third-party payor formularies, can impact our short and long-term financial performance.
- As we have in-licensed development and/or commercial rights to LOQTORZI and CHS-006, we rely on prior and ongoing preclinical, clinical, regulatory and manufacturing expertise of our collaborators in order to advance these product candidates through regulatory approvals in the United States and other licensed territories.
- Our products and our product candidates, even if approved, will remain subject to regulatory scrutiny.
- Disruptions at the FDA and other government agencies caused by funding shortages, government shut-downs or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel,

and conduct foreign inspections of manufacturing facilities, or otherwise prevent new or modified products from being developed, or approved or commercialized in a timely manner or at all, which could negatively impact our business.

- Our biosimilar products or our biosimilar product candidates, if approved, will face significant competition from the reference products and from other biosimilar products or pharmaceuticals approved for the same indication as the originator products. 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.

- The future commercial success of our product LOQTORZI and our product candidates CHS-006, casdozokitug and CHS-114 and any other immuno-oncology product candidates, if approved, will depend on our ability to successfully transition our company's clinical, commercial, manufacturing, regulatory, marketing and general historical focus on biosimilars to a new strategy to build a leading immuno-oncology franchise funded with cash generated by our commercial biosimilar business.

- If an improved version of an originator product, such as Neulasta, Humira or Lucentis, is developed or if the market for the originator product significantly declines, sales or potential sales of our biosimilar product candidates may suffer.

- Healthcare reform measures, including the Inflation Reduction Act of 2022 (the "IRA"), may increase the difficulty and cost for us to obtain marketing approval for and commercialize our products, affect the prices we may set, and have a material adverse effect on our business and results of operations.

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

- We rely on third parties to conduct our nonclinical and clinical studies and perform other tasks for us. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

- We are subject to a multitude of manufacturing risks. Any adverse developments affecting the manufacturing operations of our biosimilar product candidates could substantially increase our costs and limit supply for our product candidates.

- The continuation of the war between Russia and Ukraine and the war between Israel and Hamas 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 Quarterly Report on Form 10-Q. 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 three products that have been approved and marketed, with multiple products either approved and not yet marketed or not approved and still in development.

With the exception of generating net income of $132.2 million and $89.8 million in 2020 and 2019, respectively, we incurred net losses in each year from our inception in September 2010 through December 31, 2022, including net losses of $291.8 million and $287.1 million in 2022 and 2021, respectively. We also incurred a net loss of $158.2 million in the nine months ended September 30, 2023. It is uncertain that we will be profitable in future periods as research and development is expensive and risky. The amount of our future net losses or any future net income will depend, in part, on the amount of our future expenditures offset by the amount of future product sales, including sales of our current products or any other products that may receive regulatory approval. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk.

For example, as of September 30, 2023, we had an accumulated deficit of $1.5 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. Launching this product and advancing our product candidates through clinical development will be expensive and could result in us continuing to experience future net losses.

For YUSIMRY and CIMERLI, which are launched products, and if we obtain regulatory approval to market any other biosimilar product candidate, our future revenue will depend upon the size of any markets in which our product candidates may receive approval and our ability to achieve sufficient market acceptance, pricing, reimbursement from third-party payers, and adequate market share for our product candidates which include all product candidates for which we obtained commercial rights, in those markets. However, even if additional product candidates in addition to our current products gain regulatory approval and are commercialized, we may not remain profitable.

Our expenses will increase substantially if and as we:

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

- establish a sales, marketing and distribution infrastructure to commercialize any of our product candidates for which we may obtain marketing approval;
- make upfront, milestone, royalty or other payments under any license agreements;
- continue our nonclinical and clinical development of our product candidates;
- initiate additional nonclinical, clinical or other studies for our product candidates;
- expand the scope of our current clinical studies for our product candidates;
- advance our programs into more expensive clinical studies;
- change or add contract manufacturers, clinical research service providers, testing laboratories, device suppliers, legal service providers or other vendors or suppliers;
- seek regulatory and marketing approvals for our product candidates that successfully complete clinical studies;
- seek to identify, assess, acquire and/or develop other product candidates or products that may be complementary to our products;
- seek to create, maintain, protect and expand our intellectual property portfolio;
- engage legal counsel and technical experts to help us evaluate and avoid infringing any valid and enforceable intellectual property rights of third parties;
- engage in litigation, including patent litigation, and Inter Partes Review ("IPR") proceedings with originator companies or others that may hold patents;
- seek to attract and retain skilled personnel;
- create additional infrastructure to support our operations as a public company and our product development and planned future commercialization efforts; and
- experience any delays or encounter issues with any of the above, including but not limited to failed studies, conflicting results, safety issues, manufacturing delays, litigation or regulatory challenges that may require longer follow-up of existing studies, additional major studies or additional supportive studies or analyses in order to pursue marketing approval.

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

We continue to be dependent on the ability to raise funds. This additional funding may not be available on acceptable terms or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development and commercialization efforts or other operations.

As of September 30, 2023, our cash, cash equivalents and marketable securities were $131.1 million. We expect that our existing cash and cash equivalents, investments and cash collected from our product sales will be sufficient to fund our current operations for the foreseeable future. We have financed our operations primarily through the sale of equity securities, convertible notes, credit facilities, license agreements and through recent product sales of our products.

However, our operating or investing plans may change as a result of many factors that may currently be unknown

to us, and we may need to seek additional funds sooner than planned. Our future funding requirements will depend on many factors, including but not limited to:

- our ability to continue to successfully commercialize our products;
- the scope, rate of progress, results and cost of any clinical studies, nonclinical testing and other related activities;
- the cost of manufacturing clinical drug supplies and establishing commercial supplies, of our product candidates and any products that we may develop;
- the number and characteristics of product candidates that we pursue;
- the cost, timing and outcomes of regulatory approvals;
- the cost and timing of establishing sales, marketing and distribution capabilities;
- our ability to successfully integrate the business of Surface following consummation of the Surface Acquisition;
- the terms and timing of any licensing or other arrangements to acquire intellectual property rights that we may establish, including any milestone and royalty payments thereunder;
- the timing of conversion in common shares or repayment in cash of our convertible debt, or the timing of repayment in cash, whether due or not, of our long-term debt; and
- the cost, timing and outcomes of any litigation that we may file against third parties or that may be filed against us by third parties.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders, and the issuance of additional securities, whether equity or debt, by us or the possibility of such issuance may cause the market price of our shares to decline. The sale of additional equity or convertible securities, such as the sales in the Public Offering or sales from time to time through our ATM Offering, may dilute the share ownership of our existing stockholders. The incurrence of indebtedness could result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as those contained in the Loan Agreement we entered into in January 2022 with the Collateral Agent and the Lenders that provides for a senior secured term loan facility of up to $300.0 million, including limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. For more information on our restrictive covenants please read the Loan Agreement, the First Amendment to Loan Agreement and the Second Amendment and Waiver to Loan Agreement filed as exhibits to our public filings. We could also be required to seek funds through arrangements with collaborative partners or otherwise at an earlier stage or for a lower price than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or for specific strategic considerations.

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

We may fail to realize the anticipated benefits of the Surface Acquisition.

On September 8, 2023, we completed the Surface Acquisition. Our future success will depend, in part, upon our ability to manage our expanded business, including challenges related to the management and monitoring of new operations and products and associated increased costs and complexity associated with the acquisition of Surface. It is possible that the integration of Surface's business could result in the loss of key employees; the disruption of our ongoing business or the ongoing business of Surface; or inconsistencies in standards, controls, procedures or policies, in each case, that could adversely affect our ability to achieve the anticipated benefits of the acquisition. Integration efforts between the two companies may also divert management's attention from our core business and other opportunities that could have been beneficial to our stockholders. An inability to realize the full extent of, or any of, the anticipated benefits of the acquisition, as well as any delays encountered in the integration process, could have an adverse effect on our business and results of operations, which may affect the value of the shares of our common stock. If we are unable to achieve these objectives, the anticipated benefits of the acquisition may not be realized fully or at all or may take longer or cost more to realize than expected. In particular, the acquisition may not be accretive to our stock value in the near or long term.

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

To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change" (generally defined as a greater than 50 percentage point change (by value) in its equity ownership by shareholders who own, directly or indirectly, 5% or more of our common stock, or are otherwise treated as "5% shareholders" over a rolling three-year period), such corporation's ability to use its pre-change net operating loss carryforwards ("NOLs") and other pre-change tax attributes (such as research tax credits) to offset its post-change income or taxes may be limited. We have experienced ownership changes in the past and may experience ownership changes in the future (some of which changes are outside our control). As a result, if we earn net taxable income, our ability to use our pre-change NOLs to offset such taxable income may be subject to limitations. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, we may be unable to use a material portion of our NOLs and other tax attributes, which could adversely affect our future cash flows.

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

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

Certain clinical trials supporting our regulatory strategies were conducted outside the United States in foreign countries such as China, and we or our collaborators in the future may choose to conduct one or more clinical trials or a portion of such clinical trials for our product candidates outside the United States. The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the United States population and United States medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to good clinical practice ("GCP") regulations; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, the FDA will not accept the data as support for an application

for marketing approval unless the study is well-designed and well-conducted in accordance with GCP requirements and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in current or future product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction.

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

We are a biopharmaceutical company with a limited operating history in an emerging regulatory environment of biosimilar and immuno-oncology products. Although we have received upfront payments, milestone and other contingent payments and/or funding for development from some of our collaboration and license agreements, our only approved products include UDENYCA, YUSIMRY, LOQTORZI and CIMERLI which are approved for commercialization in the United States, and we have no products approved in any other territories.

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

- CHS-006;
- additional presentations of UDENYCA;
- CHS-1000;
- casdozokitug; and
- CHS-114

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

- our ability to continue to successfully commercialize UDENYCA product presentations, CIMERLI and LOQTORZI;
- our ability to successfully commercialize YUSIMRY in a very competitive adalimumab market;
- competing against numerous current and future pegfilgrastim, ranibizumab and adalimumab products with significant market share;
- healthcare providers, payers, and patients adopting our products and product candidates once approved and launched;
- our ability to procure and commercialize our in-licensed biosimilar candidates;
- obtaining additional regulatory and marketing approvals for product candidates for which we complete clinical studies;
- obtaining adequate third-party coverage and reimbursements for our products;
- obtaining market acceptance of our products and product candidates as viable treatment options;
- completing nonclinical and clinical development of our product candidates;

- developing and testing of our product formulations;
- attracting, hiring and retaining qualified personnel;
- developing a sustainable and scalable manufacturing process for our products and any approved product candidates and establishing and maintaining supply and manufacturing relationships with third parties that can conduct the process and provide adequate (in amount and quality) products to support clinical development and the market demand for our products and product candidates, if approved;
- addressing any competing technological and market developments;
- identifying, assessing and developing (or acquiring/in-licensing on favorable terms) new product candidates;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how; and
- defending against any litigation including patent or trade secret infringement lawsuits, that may be filed against us, or achieving successful outcomes of IPR petitions that we have filed, or may in the future file, against third parties.

Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs to commercialize any such product. Our expenses could increase beyond our expectations if we are required by the FDA, the European Medical Agency (the "EMA"), other regulatory agencies, domestic or foreign, or by any unfavorable outcomes in intellectual property litigation filed against us, to change our manufacturing processes or assays or to perform clinical, nonclinical or other types of studies in addition to those that we currently anticipate. In cases where we are successful in obtaining additional regulatory approvals to market one or more of our product candidates, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the number of biosimilar or immuno-oncology competitors in such markets, the accepted price for the product, the ability to get reimbursement at any price, the nature and degree of competition from originators and other biosimilar or immuno-oncology companies (including competition from large pharmaceutical companies entering the biosimilar market or possessing large established positions in the immuno-oncology market that may be able to gain advantages in the sale of biosimilar or immuno-oncology products based on brand recognition and/or existing relationships with customers and payers) and whether we own (or have partnered with companies owning) the commercial rights for that territory. If the market for our products and product candidates (or our share of that market) is not as significant as we expect, the price of our products is not what we project, the indication approved by regulatory authorities is narrower than we expect or the reasonably accepted population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. If we are unable to successfully complete development and obtain additional regulatory approval for our products, our business may suffer.

The commercial success of our existing products or any future products will depend upon the degree of market acceptance and adoption by prescribing physicians, healthcare providers and the patients to whom our medicines are prescribed. Additionally, obtaining placement on national and/or local clinical guidelines/pathways, as well as coverage on third-party payor formularies, can impact our short and long-term financial performance.

Even with the requisite approvals from the FDA and comparable foreign regulatory authorities, the commercial success of our products or product candidates, if approved, will depend in part on the medical community, patients and third-party payers accepting our products and product candidates as medically useful, cost-effective and safe. Any product that we bring to the market may not gain market acceptance by physicians, patients, third-party payers and others in the medical community. The degree of market acceptance of our recently launched product, CIMERLI, or any of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the safety and efficacy of the product, as demonstrated in clinical studies, and potential advantages over competing treatments;
- the prevalence and severity of any side effects and any limitations or warnings contained in a product's approved labeling;
- the clinical indications for which approval is granted;
- for our immuno-oncology product candidates, our ability to compete in a competitive immuno-oncology market that may differ from the biosimilar market;
- inclusion, in either parity or better position, on commonly accepted clinical guidelines or pathways that influence prescribing patterns and/or affect reimbursement;
- for our biosimilar product candidates, the possibility that a competitor may achieve interchangeability and we may not;
- relative convenience, ease of administration and any real or perceived benefit from administration at home as opposed to in the clinic;
- policies and practices governing the naming of biosimilar product candidates;
- prevalence of the disease or condition for which the product is approved;
- the cost of treatment, particularly in relation to competing treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support and timing of market introduction of competitive products;
- the extent to which the product is approved for inclusion on formularies of hospitals, integrated delivery networks and managed care organizations;
- publicity concerning our products or competing products and treatments;
- the extent to which third-party payers (including government and national/regional commercial plans) provide adequate third-party coverage and reimbursement for our products and product candidates, if approved;
- the price at which we sell our products;
- the potential impact of the IRA on the pharmaceutical industry and the market for biosimilars;
- the actions taken by current and future competitors to delay, restrict or block customer usage of the product; and
- our ability to maintain compliance with regulatory requirements.

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

The future commercial success of our product LOQTORZI and our product candidates CHS-006, casdozokitug and CHS-114 and any other immuno-oncology product candidates, if approved, will depend on our ability to successfully transition our company's clinical, commercial, manufacturing, regulatory, marketing and general historical focus on biosimilars to a new strategy to build a leading immuno-oncology franchise funded with cash generated by our commercial biosimilar business. We may have little or no success making this strategic transition if there is difficulty hiring and retaining employees with expertise in both biosimilar and immuno-oncology products, managing our licensing relationship with our partner for LOQTORZI and CHS-006, regulatory differences between biosimilars and immuno-oncology products and other factors.

Our acquisition of LOQTORZI, CHS-006, casdozokitug and CHS-114 represented a significant strategic shift for our company from a historical focus on biosimilars to a new strategy to build a leading immuno-oncology franchise funded with cash generated by our commercial biosimilar business. Pivoting in this manner requires hiring and retaining new employees with expertise across multiple therapeutic areas, particularly immuno-oncology, in a highly competitive global market for talent. In addition, our strategic transition requires us to rely heavily on our licensing relationship with Junshi Biosciences, our partner for LOQTORZI. A bilateral relationship involves significant risks, including those discussed below in the Risk Factor titled "we are dependent on Junshi Biosciences, Bioeq, and Orox) for the commercialization of our product candidates in certain markets and we intend to seek additional commercialization partners for major markets, and the failure to commercialize in those markets could have a material adverse effect on our business and operating results." We have managed in a highly complex regulatory environment for biosimilars in the past where approval from the FDA primarily requires a demonstration that our product shows biosimilarity with the reference product. However, with our strategic shift to operating in both the biosimilar and immuno-oncological spaces, we must still maintain regulatory expertise within the biosimilar area while also building capabilities in the immuno-oncology market. FDA regulation of immuno-oncology product candidates like LOQTORZI is different than for biosimilars because we must demonstrate the safety, purity and efficacy of the product candidate to the satisfaction of the FDA rather than relying on the safety and efficacy data of the reference product and demonstrate biosimilarity. This process of generating acceptable safety and efficacy data from clinical trials represents a relatively new approach for our company, so it involves more execution risk for us than for biosimilars where we have many years of experience advancing product candidates. If we fail to successfully manage the transition of our focus on biosimilars to our new strategy to build a leading immuno-oncology franchise funded with cash generated by our commercial biosimilar business it will materially and adversely affect our financial results.

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

Pricing, coverage and reimbursement of our products, or any of our product candidates, if approved, may not be adequate to support our commercial infrastructure. The prices required to successfully compete may not continue to be sufficient to recover our development and manufacturing costs, and as a result, we may not be profitable in the future. Accordingly, the availability and adequacy of coverage and reimbursement by governmental and commercial payers are essential to enable provider/patient access to our products and our patient support services must be sufficiently scaled to meet the needs of patients receiving our products. Sales will depend substantially, both domestically and abroad, on the extent to which the costs of our products will be paid for by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations or reimbursed by government authorities, private health insurers and other third-party payers. If coverage and reimbursement are not available, or are available only to limited levels, or become unavailable, we may not be able to successfully commercialize our products or any of our product candidates, if approved. Even if coverage is provided, the approved reimbursement amount may not be adequate to allow us to establish or maintain pricing sufficient to realize a return on our investment.

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, U.S. Centers for Medicare & Medicaid Services ("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. A product specific Q-Code was also assigned to CIMERLI effective April 2023. 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-Codes assigned by CMS for UDENYCA and CIMERLI, 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 Medicare, then the cost of the relevant product may be absorbed by healthcare providers or charged to patients. If this is the case, our expectations of the pricing we expect to achieve for such product and the related potential revenue, may be significantly diminished.

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

Increasing efforts by governmental and third-party payers in the United States and abroad to control healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our products or any of our product candidates. While cost containment practices generally benefit biosimilars, severe cost containment practices may adversely affect our product sales. Furthermore, the impact of the IRA on our business and the pharmaceutical industry generally is currently unknown. We expect to experience pricing pressures in connection with the sale of our products and any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes.

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

Our products and our product candidates, even If approved, will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies and submission of safety, efficacy and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA, and comparable foreign regulatory authority, requirements, including ensuring that quality control and manufacturing procedures conform to

current Good Manufacturing Practices ("cGMP") regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any NDA, original BLA submitted under Section 351(a) of the Public Health Service Act ("PHSA"), Section 351(k) BLA or MAA. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

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

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

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

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

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

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States, China or other foreign countries.

Disruptions at the FDA and other government agencies caused by funding shortages, government shut-downs or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, and conduct foreign inspections of manufacturing facilities, or otherwise prevent new or modified products from being developed, or approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, 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 and/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. Even though the FDA has since resumed standard inspection operations of domestic facilities where feasible, the FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates as it adapts to the evolving COVID-19 pandemic, and any resurgence of the virus or emergence of new variants may lead to further inspectional delays. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if they are put in place again in regions such as China, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, including in China where we partner with Junshi Biosciences for LOQTORZI, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Risks Related to Competitive Activity

Our biosimilar products or our biosimilar product candidates, if approved, will face significant competition from the reference products and from other biosimilar products or pharmaceuticals approved for the same indication as the originator products. 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.

LOQTORZI is entering a competitive market in the United States where a number of anti-PD-1 or PD-L1 antibody drugs have been approved by the FDA including the following marketed products from several competitors: Keytruda® (pembrolizumab) from Merck & Company, Inc. (“Merck”), Opdivo® (nivolumab) from Bristol-Myers Squibb Company

(“BMS”), Tecentriq® (atezolizumab) from Genentech, Imfinzi® (durvalumab) from AstraZeneca plc (“AstraZeneca”), Bavencio® (avelumab) from EMD Serono Inc. and Pfizer Inc. (“Pfizer”), and Libtayo® (cemiplimab-rwlc) from Regeneron Pharmaceuticals, Inc. (“Regeneron”) and Sanofi S.A. (“Sanofi”), and Jemperli (dostarlimab-gxly) from GlaxoSmithKline plc (“GlaxoSmithKline”). In addition to 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 BeiGene, Ltd. (in collaboration with Novartis International AG (“Novartis”)). We believe there is potentially a high unmet need for LOQTORZI for treatment for NPC based on the current FDA-approved treatment alternatives and the lack of any approved immunotherapies.

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

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

CIMERLI faces competition in the United States from F. Hoffman-La Roche Ltd. (“Roche”)/Genentech (the manufacturer of Lucentis, Vabysmo and Susvimo™) and Biogen Inc. (“Biogen”) with collaborator Samsung Bioepis Co., Ltd. (“Samsung Bioepis”), who have each disclosed the development of a Lucentis biosimilar candidate.

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

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

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

- settling, or refusing to settle, patent lawsuits with biosimilar companies, resulting in such patents remaining an obstacle for biosimilar approval;
- submitting Citizen Petitions to request the FDA Commissioner to take administrative action with respect to prospective and submitted biosimilar applications;
- appealing denials of Citizen Petitions in United States federal district courts and seeking injunctive relief to reverse approval of biosimilar applications;
- restricting access to reference brand products for equivalence and biosimilarity testing that interferes with timely biosimilar development plans;
- attempting to influence potential market share by conducting medical education with physicians, payers, regulators and patients claiming that biosimilar products are too complex for biosimilar approval or are too dissimilar from originator products to be trusted as safe and effective alternatives;
- implementing payer market access tactics that benefit their brands at the expense of biosimilars;

- seeking state law restrictions on the substitution of biosimilar products at the pharmacy without the intervention of a physician or through other restrictive means such as excessive recordkeeping requirements or patient and physician notification;
- seeking federal or state regulatory restrictions on the use of the same non-proprietary name as the reference brand product for a biosimilar or interchangeable biologic;
- seeking changes to the United States Pharmacopeia, an industry recognized compilation of drug and biologic standards;
- obtaining new patents covering existing products or processes, which could extend patent exclusivity for a number of years or otherwise delay the launch of biosimilars; and
- influencing legislatures so that they attach special patent extension amendments to unrelated federal legislation.

Our products and our product candidates, if approved, could face price competition from other products or biosimilars of the same reference products for the same indication. This price competition could exceed our capacity to respond, detrimentally affecting our market share and revenue as well as adversely affecting the overall financial health and attractiveness of the market for the biosimilar.

Competitors in the biosimilar market have the ability to compete on price through PBMs, payers and their third-party administrators, IDNs and hospitals who exert downward pricing pressure on our product offerings. It is possible our biosimilar competitors' compliance with price discounting demands in exchange for market share or volume requirements could exceed our capacity to respond in kind and reduce market prices beyond our expectations. There could be similar price competition in the immuno-oncology market that could adversely affect our results in the future. Such practices may limit our ability to increase market share and may also impact profitability.

We face intense competition and rapid technological change and the possibility that our competitors may develop therapies that are similar, more advanced, less costly, easier to administer or more effective than ours, which may adversely affect our financial condition and our ability to successfully commercialize our product candidates.

Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and more experienced marketing and manufacturing organizations. Additional mergers and acquisitions in the pharmaceutical industry may result in even more resources being concentrated in our competitors. As a result, these companies may obtain regulatory approval more rapidly than we are able to and may be more effective in selling and marketing their products. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis, products that are more effective or less costly than any product candidate that we may develop; they may also obtain patent protection that could block our products; and they may obtain regulatory approval, product commercialization and market penetration earlier than we do. Our competitors may have products that are easier to administer than our products, which could adversely affect our results, such as due to the observed trend that a large number of patients demonstrate a preference to administer medication at home due to COVID-19 or other factors. Biosimilar or immuno-oncology product candidates developed by our competitors may render our potential product candidates uneconomical, less desirable or obsolete, and we may not be successful in marketing our product candidates against competitors.

If other competitors to LOQTORZI, casdozokitug, CHS-114 and CHS-006 are approved and successfully commercialized before LOQTORZI, casdozokitug, CHS-114 and CHS-006, our business would suffer.

There are a number of companies that currently commercialize PD-1/PD-L1 blocking antibodies or antibodies targeting TIGIT or are developing such compounds for commercialization in the United States. If other competitors to LOQTORZI, casdozokitug, CHS-114 and CHS-006 are successfully commercialized before LOQTORZI, casdozokitug, CHS-

114 and CHS-006, we may never achieve meaningful market share for these products, our revenue would be reduced and, as a result, our business, prospects and financial condition could suffer.

If an improved version of an originator product, such as Neulasta, Humira or Lucentis, is developed or if the market for the originator product significantly declines, sales or potential sales of our biosimilar products and product candidates may suffer.

Originator companies may develop improved versions of a reference product as part of a life cycle extension strategy and may obtain regulatory approval of the improved version under a new or supplemental BLA submitted to the applicable regulatory authority. Should the originator company succeed in obtaining an approval of an improved biologic product, it may capture a significant share of the collective reference product market in the applicable jurisdiction and significantly reduce the market for the reference product and thereby the potential size of the market for our biosimilar products and product candidates. In addition, the improved product may be protected by additional patent rights that may subject our follow-on biosimilar to claims of infringement.

Biologic reference products may also face competition as technological advances are made that may offer patients a more convenient form of administration or increased efficacy or as new products are introduced. External developments can also result in changing preferences for convenient forms of administration of products that may impact our business. As new products are approved that compete with the reference product to our biosimilar product candidates, sales of the reference originator product may be adversely impacted or rendered obsolete. If the market for the reference product is impacted, we may lose significant market share or experience limited market potential for our approved biosimilar products or product candidates, and the value of our product pipeline could be negatively impacted. As a result of the above factors, our business, prospects and financial condition could suffer.

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

Our development of novel biologic product candidates, such as casdozokitug, CHS-114 and CHS-006, 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 and any of our future product candidates approved under an original BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to Congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, could be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products will depend on a number of marketplace and regulatory factors that are still developing.

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

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

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

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

We will need to expand and effectively manage our managerial, scientific, operational, financial, commercial and other resources in order to successfully pursue our product development and commercialization efforts. Our success also depends on our continued ability to attract, retain and motivate highly qualified management and technical personnel. We may not be able to attract or retain qualified management and scientific and product development personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses, particularly those located in the San Francisco Bay Area. We also use equity compensation as a part of a comprehensive compensation package for our personnel. 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 11. Stock-Based Compensation and Employee Benefits to our financial statements included in our Annual Report for the Fiscal Year ended December 31, 2022. If we are not able to attract, retain and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

We may need to expand our organization, particularly due to employee turnover and the transition of our strategy from a biosimilars business to a company using cash flows from our commercial biosimilars portfolio to fund our immuno-oncology pipeline, and we may experience difficulties in managing this turnover and ongoing transition, which could disrupt our operations.

As of September 30, 2023, we had 299 full-time and part-time employees. As our development and commercialization plans and strategies develop and evolve from time to time and as we experience turnover, we may need to hire additional people in the future. Further, as we develop and build our immuno-oncology platform, such work could further divert internal resources. Our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these hiring activities. We may not be able to effectively manage the transition in our operations, which may result in weaknesses in our infrastructure, operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of our current and potential future product candidates. If our management is unable to effectively manage our turnover and transition of our strategy, our expenses may increase more than expected, our ability to generate and/or grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

Risks Related to Reliance on Third Parties

We rely on third parties to conduct our nonclinical and clinical studies and perform other tasks for us. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory

requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third-party clinical research organizations ("CROs") to monitor and manage data for our ongoing nonclinical and clinical programs. We rely on these parties for execution of our nonclinical and clinical studies and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs and other vendors are required to comply with cGMP, GCP, and 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 CRO or any other participating parties violate federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

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

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

We rely on third parties, and in some cases a single third party, to manufacture nonclinical, clinical and commercial drug supplies of our product candidates and to store critical components of our product candidates for us. Our business could be harmed if those third parties fail to provide us with sufficient quantities of product candidates or fail to do so at acceptable quality levels or prices.

We do not currently have the infrastructure or capability internally to manufacture supplies of our product candidates for use in our nonclinical and clinical studies, and we lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale. We rely on third-party manufacturers to manufacture and supply us with our product candidates for our preclinical and clinical studies as well as to establish commercial supplies of our product candidates. Successfully transferring complicated manufacturing techniques to contract manufacturing organizations and scaling up these techniques for commercial quantities is time consuming and we may

not be able to achieve such transfer or do so in a timely manner. Moreover, the availability of contract manufacturing services for protein-based therapeutics is highly variable and there are periods of relatively abundant capacity alternating with periods in which there is little available capacity. If our need for contract manufacturing services increases during a period of industry-wide production capacity shortage, we may not be able to produce our product candidates on a timely basis or on commercially viable terms. Although we will plan accordingly and generally do not begin a clinical study unless we believe we have a sufficient supply of a product candidate to complete such study, any significant delay or discontinuation in the supply of a product candidate for an ongoing clinical study due to the need to replace a third-party manufacturer could considerably delay completion of our clinical studies, product testing and potential regulatory approval of our product candidates, which could harm our business and results of operations.

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

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

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

We have exclusive licenses from Junshi Biosciences to develop and commercialize LOQTORZI and CHS-006 in the United States and Canada. We have an exclusive license from Bioeq to commercialize CIMERLI in the United States. Our licensors are responsible for supplying us with drug substance and final drug products.

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

Our licenses with Junshi Biosciences, Bioeq, Orox, or other future license or collaboration agreements, may not result in positive outcomes. Factors that may affect the success of our licenses and collaborations include, but are not limited to, the following:

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

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

Risks Related to Manufacturing and Supply Chain

We are subject to a multitude of manufacturing risks and the risks of inaccurately forecasting sales of our products. Any adverse developments affecting the manufacturing operations of our product candidates could substantially increase our costs and limit supply for our product candidates.

The process of manufacturing our product candidates is complex, highly regulated and subject to several risks, including but not limited to:

- product loss due to contamination, equipment failure or improper installation or operation of equipment or vendor or operator error;
- equipment failures, labor shortages, natural disasters, power failures and numerous other factors associated with the manufacturing facilities in which our product candidates are produced, and potentially exacerbated by climate change; and
- disruption of supply chains for critical and specialized raw materials, delays in regulatory inspections of manufacturing and testing facilities, and reduced manufacturing capacities created by global events such as the COVID-19 pandemic and the ongoing conflict in Ukraine.

We have experienced reduced production yields, product defects and other supply disruptions. For example, we have experienced failures with respect to the manufacturing of certain lots of each of our product candidates resulting in delays prior to our taking corrective action. Additionally, if microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.

Any adverse developments affecting manufacturing operations for our product candidates, including due to sudden or long-term changes in weather patterns, may result in shipment delays, inventory shortages, lot failures, withdrawals or recalls or other interruptions in the supply of our product candidates. We may also have to take inventory write-offs and incur other charges and expenses for products that are manufactured in reliance on a forecast that proves to be inaccurate because we do not sell as many units as forecasted. For example, during the third quarter of 2022, we

recorded a $26.0 million write-down of inventory that was at risk of expiration. Although we believe that the assumptions that we use in estimating inventory write-downs are reasonable, additional write-downs of inventory may be required in the future if actual market conditions are less favorable than our projections, which could materially and adversely impact our financial results. In addition to such write-offs, we may also have to incur charges and expenses related to firm purchase commitments or for product candidates that fail to meet specifications, undertake costly remediation efforts or seek costlier manufacturing alternatives.

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

For our products and our product candidates, we currently engage a distinct vendor or service provider for each of the principal activities supporting our manufacture and development of these products, such as manufacture of the biological substance present in each of the products, manufacture of the final filled and finished presentation of these products, as well as laboratory testing, formulation development and clinical testing of these products. For example, in September 2022 we entered into the Bioeq Manufacturing Agreement for our supply of CIMERLI. Because we currently have engaged a limited number of back-up suppliers or vendors for these single-sourced services, and although we believe that there are alternate sources that could fulfill these activities, we cannot assure you that identifying and establishing relationships with alternate suppliers and vendors would not result in significant delay in the development of our product candidates. Additional delays or cost increases could occur due to the direct or indirect effects of the COVID-19 pandemic and the ongoing conflict in Ukraine. Additionally, we may not be able to enter into arrangements with alternative service providers on commercially reasonable terms or at all. A delay in the development of our product candidates, or having to enter into a new agreement with a different third party on less favorable terms than we have with our current suppliers, could have a material adverse impact on our business.

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

All entities involved in the preparation of therapeutics for clinical studies or commercial sale, including our existing contract manufacturers for our product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in clinical studies must be manufactured in accordance with cGMP. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of contaminants or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We, our collaboration partners, or our contract manufacturers must supply all necessary documentation in support of a Section 351(k) BLA, original BLA, NDA or MAA on a timely basis and must adhere to GLP and cGMP regulations enforced by the FDA and other regulatory agencies through their facilities inspection program. Some of our contract manufacturers may have never produced a commercially approved pharmaceutical product and therefore have not obtained the requisite regulatory authority approvals to do so. The facilities and quality systems of some or all of our collaboration partners and third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates or any of our other potential products. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. Although we oversee the contract manufacturers, we cannot control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements. If these facilities do not pass a pre-approval plant inspection, regulatory approval of the products may not be granted or may be substantially delayed until any violations are corrected to the satisfaction of the regulatory authority, if ever.

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

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

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

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

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

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

The inherent variability in protein structure from one production lot to another is a fundamental consideration with respect to establishing biosimilarity to an originator product to support regulatory approval requirements. For example, the glycosylation of the protein, meaning the manner in which sugar molecules are attached to the protein backbone of a therapeutic protein when it is produced in a living cell, is critical to therapeutic efficacy, half-life, efficacy and even safety of the therapeutic and is therefore a key consideration for biosimilarity. Defining and understanding the variability of an originator molecule in order to match its glycosylation profile requires significant skill in cell biology, protein purification and analytical protein chemistry. Furthermore, manufacturing proteins with reliable and consistent glycosylation profiles at scale is challenging and highly dependent on the skill of the cell biologist and process scientist.

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

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

Risks Related to Adverse Events

Our products or our product candidates may cause undesirable side effects or have other properties that could, as applicable, delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following marketing approval, if granted.

As with most pharmaceutical products, use of our products or our product candidates could be associated with side effects or adverse events, which can vary in severity (from minor reactions to death) and frequency (infrequent or prevalent). Side effects or adverse events associated with the use of our product candidates may be observed at any time, including in clinical trials or when a product is commercialized. Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical studies and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. Results of our studies could reveal a high and unacceptable severity and prevalence of side effects such as toxicity or other safety issues and could require us or our collaboration partners to perform additional studies or halt development or sale of these product candidates or expose us to product liability lawsuits, which will harm our business. In such an event, we may be required by regulatory agencies to conduct additional animal or human studies regarding the safety and efficacy of our product candidates, which we have not planned or anticipated or our studies could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny or withdraw approval of our product candidates for any or all targeted indications. There can be no assurance that we will resolve any issues related to any product-related adverse events to the satisfaction of the FDA or any other regulatory agency in a timely manner, if ever, which could harm our business, prospects and financial condition.

Additionally, product quality characteristics have been shown to be sensitive to changes in process conditions, manufacturing techniques, equipment or sites and other such related considerations, hence any manufacturing process changes we implement prior to or after regulatory approval could impact product safety and efficacy.

Drug-related side effects could affect patient recruitment for clinical trials, the ability of enrolled patients to complete our studies or result in potential product liability claims. We currently carry product liability insurance and we are required to maintain product liability insurance pursuant to certain of our license agreements. We believe our product liability insurance coverage is sufficient in light of our current clinical programs; however, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. A successful product liability claim or series of claims brought against us could adversely affect our results of operations and business. In addition, regardless of merit or eventual outcome, product liability claims may result in impairment of our business reputation, withdrawal of clinical study participants, costs due to related litigation, distraction of management's attention from our primary business, initiation of investigations by regulators, substantial monetary awards to patients or other claimants, the inability to commercialize our product candidates and decreased demand for our product candidates, if approved for commercial sale.

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

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label;
- we may be required to create a REMS plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers and/or other

elements to assure safe use;

- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects.

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

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

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

Risks Related to Intellectual Property

If we infringe or are alleged to infringe intellectual property rights of third parties, our business could be harmed. Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.

Our commercial success depends in large part on avoiding infringement of the patents and proprietary rights of third parties. There have been many lawsuits and other proceedings involving patent and other intellectual property rights in the pharmaceutical industry, including patent infringement lawsuits, interferences, oppositions and reexamination proceedings before the USPTO and corresponding foreign patent offices. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. As the pharmaceutical industry expands and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

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

Third parties may assert that we are employing their proprietary technology without authorization. We are aware of third-party patents or patent applications with claims, for example, to compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. While we have conducted freedom to operate analyses with respect to our products and our product candidates, including our in-licensed biosimilar candidates, as well as our pipeline candidates, we cannot guarantee that any of our analyses are complete and thorough, nor can we be sure that we have identified each patent and pending application in the United States and abroad that is relevant or necessary to the commercialization of our product candidates. Moreover, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents covering our product candidates. With respect to products we are evaluating for inclusion in our future product pipeline, our freedom to operate analyses, including our research on the timing of potentially relevant patent expirations, are ongoing.

There may also be patent applications that have been filed but not published and if such applications issue as patents, they could be asserted against us. For example, in most cases, a patent filed today would not become known to industry participants for at least 18 months given patent rules applicable in most jurisdictions, which do not require publication of patent applications until 18 months after filing. Moreover, some United States patents may issue without any prior publication in cases where the patent applicant does not also make a foreign filing. We may also face claims from non-practicing entities that have no relevant product revenue and against whom our own patent portfolio may have no deterrent effect. In addition, coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our product candidates, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid and/or unenforceable, and we may not be able to do this. Proving that a patent is invalid or unenforceable is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Also in proceedings before courts in Europe, the burden of proving invalidity of the patent usually rests on the party alleging invalidity. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on us. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

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

On May 10, 2017, Amgen Inc. and Amgen Manufacturing Inc. filed an action against us in the United States District Court for the District of Delaware alleging infringement of one or more claims of Amgen's US patent 8,273,707 (the "'707 patent") under 35 U.S.C. § 271. The complaint seeks injunctive relief, monetary damages and attorney fees. On December 7, 2017, the United States Magistrate Judge issued under seal a Report and Recommendation to the District

Court recommending that the District Court grant, with prejudice, our pending motion to dismiss Amgen's complaint for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6). On March 26, 2018, Judge Stark of the District Court adopted the United States Magistrate Judge's Report and Recommendation to grant our motion pursuant to Federal Rule of Civil Procedure 12(b)(6) to dismiss with prejudice the patent infringement complaint alleging infringement of the '707 patent on the grounds that such complaint failed to state a claim upon which relief may be granted. In May 2018, Amgen filed a Notice of Appeal in the United States Court of Appeals for the Federal Circuit. We and Amgen filed briefs in this matter and oral argument was held on May 8, 2019. On July 29, 2019, the Federal Circuit issued a precedential opinion affirming the District Court's judgment in our favor. The Federal Circuit held that the doctrine of prosecution history estoppel barred Amgen from succeeding on its infringement claim and affirmed the District Court's dismissal. In a Joint Status Report, dated September 20, 2019, Amgen stated that it does not intend to further appeal the Federal Circuit's decision. On October 11, 2019, we filed a Motion for Attorneys' Fees with the District Court. Amgen filed its Answering Brief in Opposition on November 8, 2019. On November 22, 2019, we filed our Reply Brief with the District Court. On November 30, 2020, the District Court issued an order denying our motion.

On January 24, 2019, we entered into settlement and license agreements with AbbVie, that grant us global, royalty-bearing, non-exclusive license rights under AbbVie's intellectual property to commercialize YUSIMRY. The global settlements resolved all then pending disputes between the parties related to YUSIMRY. Under the United States settlement, our license period in the United States commences on July 1, 2023.

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

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

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

We do not know whether any of our pending patent applications will result in the issuance of any patents or whether the rights granted under any patents issuing from these applications will prevent any of our competitors from marketing similar products that may be competitive with our own. Moreover, even if we do obtain issued patents, they will not guarantee us the right to use our patented technology for commercialization of our product candidates. Third parties may have blocking patents that could prevent us from commercializing our own products, even if our products use or embody our own, patented inventions.

The validity and enforceability of patents are generally uncertain and involve complex legal and factual questions. Any patents that may issue on our pending applications may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing products similar to ours. Furthermore, our competitors may develop similar or alternative technologies not covered by any patents that may issue to us.

For technologies for which we do not seek patent protection, we may rely on trade secrets to protect our proprietary position. However, trade secrets are difficult to protect. We seek to protect our technology and product candidates, in part, by entering into confidentiality agreements with those who have access to our confidential information, including our employees, consultants, advisors, contractors or collaborators. We also seek to preserve the integrity and confidentiality of our proprietary technology and processes by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our employees, consultants, advisors, contractors and collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

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

We may discover that competitors are infringing our issued patents. Expensive and time-consuming litigation may be required to abate such infringement. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. If we or one of our collaboration partners were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including but not limited to lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could include an allegation that someone involved in the prosecution of the patent withheld relevant or material information related to the patentability of the invention from the USPTO or made a misleading statement during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable.

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

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during any

litigation we initiate to enforce our patents. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

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

We employ individuals, retain independent contractors and consultants and members on our board of directors or scientific advisory board who were previously employed at universities or other pharmaceutical companies, including our competitors or potential competitors. For example, our Chief Executive Officer, Dennis M. Lanfear is a former employee of Amgen. Mr. Lanfear was employed at Amgen during periods when Amgen's operations included the development and commercialization of Neulasta. Senior members of our commercial team and medical affairs team who will be responsible for any launch of additional presentations of UDENYCA formerly held positions at Amgen. Our board of directors and scientific advisory board include members who were former employees of Genentech, Amgen and Abbott Laboratories. Although we have procedures in place to try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees or consultants have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

On March 3, 2017, Amgen filed an action against us, KBI Biopharma, our employee Howard S. Weiser and Does 1-20 in the Superior Court of the State of California, County of Ventura. The complaint, which was amended, alleged that we engaged in unfair competition and improperly solicited and hired certain former Amgen employees in order to acquire and access trade secrets and other confidential information belonging to Amgen. The complaint, as amended, sought injunctive relief and monetary damages. On May 2, 2019, we and Amgen settled the trade secret action brought by Amgen. The details of the settlement are confidential but we will continue to market UDENYCA and began paying a mid-single digit royalty to Amgen for five years starting on July 1, 2019.

If we fail to comply with our obligations in the agreements under which we license intellectual property and other rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

We are a party to certain non-exclusive intellectual property license agreements with certain vendors (pertaining to mammalian cell lines), with Genentech (pertaining to Genentech's intellectual property related to CIMERLI) and with AbbVie (pertaining to AbbVie's intellectual property related to YUSIMRY) that are important to our business, and we expect to enter into additional license agreements in the future. Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty and other obligations on us. If we fail to comply with our obligations under these agreements or we are subject to a bankruptcy, we may be required to make certain payments to the licensor, we may lose the license or the licensor may have the right to terminate the license, in which event we would not be able to develop or market products covered by the license. Additionally, the milestone and other payments associated with these licenses will make it less profitable for us to develop our product candidates.

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

- the scope of rights granted under the license agreement and other interpretation-related issues;

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

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

We may not be successful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses.

We currently have rights to certain intellectual property, through licenses from third parties and under patent applications that we own, to develop our product candidates. Because we may find that our programs require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights. We may be unable to acquire or in-license compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary for our product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, financial resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment. 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. For example, on June 6, 2023 we received a notice letter from AbbVie alleging that we breached our settlement and license agreement with AbbVie (the “AbbVie Agreement”), which grants us a royalty-bearing, non-exclusive license under AbbVie’s intellectual property rights to commercialize YUSIMRY in the United States commencing on July 1, 2023, because of our announcement on June 1, 2023 of our pricing agreement with Mark Cuban Cost Plus Drug Company, PBC and its plans to offer YUSIMRY to its customers beginning in July 2023. The parties engaged in discussions to resolve the dispute and on June 14, 2023 entered into a stipulation resolving our motion for temporary restraining order, whereby AbbVie agreed that it will not seek to terminate the AbbVie Agreement based on its June 6, 2023 notice and that it will not terminate the AbbVie Agreement unless it first serves a new notice of breach and affords us an opportunity to cure any alleged breach.

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

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

The BPCIA created an elaborate and complex patent dispute resolution mechanism for biosimilars that, if we choose to implement it, could prevent us from launching our product candidates in the United States or could substantially delay such launches. However, even if we elect not to implement this mechanism, the launch of our products in the United States could still be prevented or substantially delayed by intellectual property disputes with originator companies that market the reference products on which our biosimilar products are based.

The BPCIA establishes a patent disclosure and briefing process between the biosimilar applicant and the originator that is demanding and time-sensitive. While certain aspects of this process are still being tested in the federal courts, the United States Supreme Court, as discussed further below, ruled in 2017 that this process is not mandatory, such that a biosimilar applicant may elect to engage in this process, but is not required to do so. The following is an overview of the patent exchange and patent briefing procedures established by the BPCIA for biosimilar applicants that elect to employ them:

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

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

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

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

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

Risks Related to the Discovery and Development of Our Product Candidates

We are heavily dependent on the development, clinical success, regulatory approval and commercial success of our product candidates. We cannot give any assurance that any of our product candidates will receive regulatory approval, which is necessary before they can be commercialized.

We invested substantially all of our efforts and financial resources to identify, acquire and develop our product candidates. Our future success is dependent on our ability to develop, obtain regulatory approval for, and then commercialize and obtain adequate third-party coverage and reimbursement for one or more of our product candidates. We currently have four approved products: UDENYCA, CIMERLI, YUSIMRY 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. For example, in 2020 during FDA's review of Bioeq's Section 351(k) BLA for CIMERLI, the FDA requested that Bioeq submit additional manufacturing data for the equipment in its new location, leading Bioeq to withdraw its Section 351(k) BLA for this candidate in order to provide the requested data and to resubmit the application thereafter. Neither we nor any collaboration partner has obtained regulatory approval for any of our products and product candidates, other than UDENYCA, which has received approval from the FDA and EMA, YUSIMRY, and CIMERLI which have received approval from the FDA, and 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.

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

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

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

In the event that regulatory authorities require us to conduct additional clinical trials or other lengthy processes, the commercialization of our proposed biosimilar products could be delayed or prevented. Delays in the

commercialization of or the inability to obtain regulatory approval for these products could adversely affect our operating results by restricting or significantly delaying our introduction of new biosimilars.

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

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we or our collaboration partners, or both, as the case may be, must conduct clinical studies to demonstrate the safety and efficacy of the product candidates in humans.

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

We cannot guarantee that any clinical studies will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical studies can occur at any stage of testing, and our future clinical studies may not be successful. Events that may prevent successful or timely completion of clinical development include but are not limited to:

- inability to generate sufficient preclinical, toxicology or other *in vivo* or *in vitro* data to support the initiation of human clinical studies;
- delays in reaching a consensus with regulatory agencies on study design;
- delays in reaching agreement on acceptable terms with prospective CROs, and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical study sites;
- delays in obtaining required IRB approval at each clinical study site;
- imposition of a clinical hold by regulatory agencies, after review of an IND or amendment or equivalent application or amendment, or an inspection of our clinical study operations or study sites or as a result of adverse events reported during a clinical trial;
- delays in recruiting suitable patients to participate in our clinical studies sponsored by us or our partners;
- difficulty collaborating with patient groups and investigators;
- failure by our CROs, other third parties or us to adhere to clinical study requirements;
- failure to perform in accordance with the FDA's good clinical practices requirements or applicable regulatory guidelines in other countries;
- delays in patients completing participation in a study or return for post-treatment follow-up, or patients dropping out of a study;

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

In addition, disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, or conducting our planned clinical trials. Any inability to successfully complete nonclinical and clinical development could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes to our product candidates, we may need to conduct additional studies to bridge our modified product candidates to earlier versions.

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

We and our collaboration partners intend to pursue market authorization globally. In the United States, an abbreviated pathway for approval of biosimilar products was established by the BPCIA, enacted on March 23, 2010, as part of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the "ACA"). The BPCIA established this abbreviated pathway under Section 351(k) of the PHSA. Subsequent to the enactment of the BPCIA, the FDA issued guidance documents regarding the demonstration of biosimilarity and interchangeability as well as the submission and review of biosimilar applications. Moreover, market acceptance of biosimilar products in the United States is unclear. Numerous states are considering or have already enacted laws that regulate or restrict the substitution by state pharmacies of biosimilars for originator products already licensed by the FDA. Market success of biosimilar products will depend on demonstrating to patients, physicians, payers and relevant authorities that such products are similar in quality, safety and efficacy as compared to the reference product.

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

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

Under current E.U. regulations, an application for regulatory approval of a biosimilar drug cannot be submitted in the E.U. until expiration of an eight-year data exclusivity period for the reference (originator) product, measured from the date of the reference product's initial marketing authorization. Furthermore, once approved, the biosimilar cannot be marketed until expiration of a ten-year period following the initial marketing authorization of the reference product,

such ten-year period being extendible to 11 years if the reference product received approval of an additional therapeutic indication, within the first eight years following its initial marketing authorization, representing a significant clinical benefit in comparison with existing therapies.

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

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

If other biosimilars of pegfilgrastim (Neulasta) or adalimumab (Humira) are determined to be interchangeable and our biosimilar products and product candidates for these originator products are not, our business could suffer.

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

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

The labelling of "interchangeability" is important because, in the United States for example, the first biosimilar determined to be interchangeable with a particular reference, or originator, product for any condition of use is eligible for a period of market exclusivity that delays an FDA determination that a second or subsequent biosimilar product is interchangeable with that originator product for any condition of use until the earlier of: (1) one year after the first commercial marketing of the first interchangeable product; (2) 18 months after resolution of a patent infringement suit instituted under 42 U.S.C. § 262(l)(6) against the applicant that submitted the application for the first interchangeable product, based on a final court decision regarding all of the patents in the litigation or dismissal of the litigation with or without prejudice; (3) 42 months after approval of the first interchangeable product, if a patent infringement suit

instituted under 42 U.S.C. § 262(l)(6) against the applicant that submitted the application for the first interchangeable product is still ongoing; or (4) 18 months after approval of the first interchangeable product if the applicant that submitted the application for the first interchangeable product has not been sued under 42 U.S.C. § 262(l)(6). Thus, a determination that another company's product is interchangeable with the originator biologic before we obtain approval of our corresponding biosimilar product candidates may delay the potential determination that our products are interchangeable with the originator product, which could materially adversely affect our results of operations and delay, prevent or limit our ability to generate revenue.

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

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

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

We may not be successful in our efforts to identify, develop or commercialize additional product candidates.

Although a substantial amount of our effort will focus on the continued clinical testing, potential approval and commercialization of our existing product candidates, the success of our business also depends upon our ability to identify, develop and commercialize additional product candidates. Research programs to identify new product candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful. Our development efforts may fail to yield additional product candidates suitable for clinical development and commercialization for a number of reasons, including but not limited to the following:

- we may not be successful in identifying potential product candidates that pass our strict screening criteria;
- we may not be able to overcome technological hurdles to development or a product candidate may not be capable of producing commercial quantities at an acceptable cost or at all;
- we may not be able to assemble sufficient resources to acquire or discover additional product candidates;
- our product candidates may not succeed in nonclinical or clinical testing;
- our potential product candidates may fail to show sufficient biosimilarity to originator molecules; and

- competitors may develop alternatives that render our product candidates obsolete or less attractive or the market for a product candidate may change such that a product candidate may not justify further development.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs or we may not be able to identify, develop or commercialize additional product candidates, which would have a material adverse effect on our business and could potentially cause us to cease operations.

Risks Related to Our Compliance with Applicable Laws

Healthcare reform measures, including the IRA, may increase the difficulty and cost for us to obtain marketing approval for and commercialize our products, affect the prices we may set, and have a material adverse effect on our business and results of operations.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the ACA, was passed, which substantially changed the way health care is financed by both governmental and private insurers and has impacted and continues to impact the United States pharmaceutical industry. The ACA, among other things, modified the AMP definition under the MDRP for drugs that are inhaled, infused, instilled, implanted or injected and not generally distributed through the retail channel; expanded rebate payments under the MDRP to include utilization by individuals enrolled in Medicaid managed care organizations; added a provision to increase the Medicaid rebate for line extension drugs; established annual fees and taxes on manufacturers of certain branded prescription drugs; expanded the entities eligible for discounts under the Public Health Service 340B drug pricing program; and established the Medicare Part D coverage gap discount program, in which manufacturers must agree to offer point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

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

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

Most significantly, on August 16, 2022, President Biden signed the IRA into law. This statute marks the most significant action by Congress with respect to the pharmaceutical industry since adoption of the ACA in 2010. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. 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 and other transparency measures, and, in some cases, measures designed to encourage importation from other countries and bulk purchasing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures, such as a single reimbursement code for biosimilar products.

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

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

We may be subject, directly or indirectly, to federal and state healthcare laws, including fraud and abuse, false claims and physician payment transparency laws. If we are unable to comply or have not fully complied with such laws, we could face substantial penalties.

Our operations are directly or indirectly through our customers subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act and physician sunshine laws and regulations. These laws impact, among other things, sales, marketing and education programs. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, to induce or in return for the purchase, recommendation, order or furnishing of an item or service reimbursable, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation;
- federal civil and criminal false claims laws, including the False Claims Act, which prohibit, among other things, individuals or entities from knowingly presenting or causing to be presented claims for payment from Medicare, Medicaid or other third-party payers that are false or fraudulent and which may apply to entities that provide coding and billing advice to customers. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- federal civil monetary penalties laws, which impose civil fines for, among other things, the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception applies;
- HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- the federal physician "sunshine" requirements under the ACA, which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services information related to payments and other transfers of value made by such manufacturers to physicians (defined to include doctors, dentists, optometrists, podiatrists, chiropractors, and certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants and certified nurse midwives)), and teaching hospitals and ownership and investment interests held by physicians and their immediate family members; and
- state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payer, including commercial insurers, state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened these laws.

Efforts to ensure that our operations and business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. If we are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Further, defending against any such actions can be costly, time-consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

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

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

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

340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities for 340B eligible drugs. HRSA has also finalized an administrative dispute resolution process through which 340B covered entities may pursue claims against participating manufacturers for overcharges.

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

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

Pricing and rebate calculations vary across products and programs, are complex, and are often subject to interpretation by us, governmental or regulatory agencies, and the courts, which can change and evolve over time. Such pricing calculations and reporting, along with any necessary restatements and recalculations, could increase costs for complying with the laws and regulations governing the MDRP and other governmental programs, and under the MDRP could result in an overage or underage in Medicaid rebate liability for past quarters. Price recalculations under the MDRP also may affect the ceiling price at which we are required to offer products under the 340B program. Civil monetary penalties can be applied if we are found to have knowingly submitted any false price or product information to the government, if we are found to have made a misrepresentation in the reporting of ASP, if we fail to submit the required price data on a timely basis, or if we are found to have charged 340B covered entities more than the statutorily mandated ceiling price. CMS could also terminate our Medicaid drug rebate agreement, in which case federal payments may not be available under Medicaid or Medicare Part B for our covered outpatient drugs. We cannot assure you that our submissions will not be found by CMS or other governmental agencies to be incomplete or incorrect.

Risks Related to Ownership of Our Common Stock

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

The market price of our common stock has been highly volatile since our Initial Public Offering (“IPO”) and the intraday sales price per share has ranged from $3.60 to $38.10 per share during the period from November 6, 2014 through September 30, 2023 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 Quarterly Report on Form 10-Q and others such as:

- adverse results or delays in preclinical or clinical studies;

- any inability to obtain additional funding;
- any delay in filing an IND, NDA, BLA, Section 351(k) BLA or other regulatory submission for any of our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory agency's review of that IND, NDA, BLA, Section 351(k) BLA or other regulatory submission;
- the perception of limited market sizes or pricing for our products and product candidates;
- failure to successfully develop and commercialize our product candidates;
- post-marketing safety issues relating to our product candidates or biosimilars generally;
- failure to maintain our existing strategic collaborations or enter into new collaborations;
- failure by us or our licensors and strategic collaboration partners to prosecute, maintain or enforce our intellectual property rights;
- changes in laws or regulations applicable to our products;
- future outbreaks of COVID-19 and other viral pandemics;
- any inability to obtain adequate product supply for our product candidates or the inability to do so at acceptable prices;
- difficulties in the implementation of the shift in our clinical, commercial, manufacturing, regulatory, marketing and general historical focus on biosimilars to a new strategy to build a leading immuno-oncology franchise funded with cash generated by our commercial biosimilar business;
- adverse regulatory decisions;
- introduction of new products, services or technologies by our competitors;
- failure to meet or exceed financial projections we may provide to the public;
- failure to meet or exceed the financial projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us, our strategic collaboration partners or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key scientific or management personnel;
- lawsuits, including but not limited to complaints initiated by stockholders, customers and collaboration partners, and litigation filed by us or filed against us pertaining to patent infringement or other violations of intellectual property rights;
- the outcomes of any citizen petitions filed by parties seeking to restrict or limit the approval of biosimilar products;
- if securities or industry analysts do not publish research or reports about our business or if they issue an adverse or misleading opinion regarding our stock;
- changes in the market valuations of similar companies;
- general market or macroeconomic conditions, including rising interest rates and inflation;
- sales of our common stock by us or our stockholders in the future;

- trading volume of our common stock;
- issuance of patents to third parties that could prevent our ability to commercialize our product candidates;
- reductions in the prices of originator products that could reduce the overall market opportunity for our product candidates intended as biosimilars to such originator products; and
- changes in biosimilar regulatory requirements that could make it more difficult for us to develop our product candidates.

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

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

As of September 30, 2023, our executive officers, directors, five percent stockholders and their affiliates beneficially owned approximately 43.6% of our voting stock (assuming no exercise of outstanding options or conversion of our outstanding convertible notes). These stockholders have the ability to influence us through their ownership positions, which may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may believe are in your best interest as one of our stockholders.

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

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

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

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

This indebtedness could be due sooner upon the triggering of certain covenants in our debt agreements and or upon the occurrence of an event of default. If and when our indebtedness becomes due, if we do not have sufficient cash or access to capital to pay such indebtedness, we will default on our obligations which will adversely harm our business. We entered into a Loan Agreement that contains affirmative and negative covenants that restrict our operations, including, among other restrictions, the requirement to maintain minimum trailing twelve-month net sales in an amount that begins at $200.0 million in the first quarter of 2022 and increases to $210.0 million for the quarter

ended March 31, 2024 and increases to be as much as $300.0 million for the quarter ended December 31, 2024. Further, the Loan Agreement includes certain other affirmative covenants and negative covenants, including, covenants and restrictions that among other things, restrict our ability to incur liens, incur additional indebtedness, make investments, engage in certain mergers and acquisitions or asset sales, and declare dividends or redeem or repurchase capital stock. We may need to request additional waivers from time to time with respect to the 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 recently sold shares of our common stock in the Public Offering and we may authorize our sales agent to sell our common stock from time to time as part of the ATM Offering. Further, we expect to issue a significant number of shares of our common stock in connection with the consummation of our acquisition of Surface later this year. As of September 30, 2023, there were 109.1 million shares of common stock outstanding.

In addition, as of September 30, 2023, approximately 31.5 million shares of common stock that are either subject to outstanding options and restricted stock units or reserved for future issuance under our equity incentive plans were eligible or may become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules and Rule 144 and Rule 701 under the Securities Act. Certain of our outstanding options have exercise prices that are above our current stock price. See the tables describing our outstanding stock options in Note 11. Stock-Based Compensation and Employee Benefits to our financial statements included in our Annual Report for the Fiscal Year ended December 31, 2022. 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 Public Offering or the ATM Offering, the exchange of our shares for shares of outstanding stock of Surface as part of the proposed acquisition of Surface or the shares of common stock that may be issued after we enter into the Definitive Agreements, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders. In addition, if we raise additional funds through licensing arrangements, it may be necessary to grant potentially valuable rights to our product candidates or grant licenses on terms that are not favorable to us.

Pursuant to our 2014 Equity Incentive Award Plan (the “2014 Plan”), our management is authorized to grant stock options and other equity-based awards to our employees, directors and consultants. The number of shares available for future grant under the 2014 Plan will be increased by (i) the number of shares pursuant to outstanding awards under the 2010 Plan that are forfeited or lapse unexercised and which following the effective date are not issued under the 2010 Plan and (ii) an annual increase on the first day of each fiscal year beginning in 2015 and ending in 2024, equal to 4% of the shares of stock outstanding as of the last day of the preceding fiscal year, or such smaller number of shares as determined by our board of directors. Pursuant to our ESPP, eligible employees are able to acquire shares of our common stock at a discount to the prevailing market price, and an aggregate of 320,000 shares are initially available for issuance under the ESPP. The number of shares available for issuance under the ESPP will automatically increase on the first day of each fiscal year beginning in 2015 and ending in 2024, equal to 1% of the shares of common stock outstanding on the last day of the immediately preceding fiscal year or such smaller number of shares as determined by our board of

directors. If our board of directors elects to increase the number of shares available for future grant under the 2014 Plan or the ESPP, our stockholders may experience additional dilution, which could cause our stock price to fall. Pursuant to our 2016 Employment Commencement Incentive Plan (the "2016 Plan"), our management is authorized to grant stock options and other equity-based awards to our new employees. The 2016 Plan is designed to comply with the inducement exemption contained in Nasdaq's Rule 5635(c)(4), which provides for the grant of non-qualified stock options, restricted stock units, restricted stock awards, performance awards, dividend equivalents, deferred stock awards, deferred stock units, stock payment and stock appreciation rights to a person not previously an employee or director, or following a bona fide period of non-employment, as an inducement material to the individual's entering into employment with us. As of September 30, 2023, we reserved for future issuance under the 2016 Plan a total of 1.9 million shares of common stock for new employees. The 2016 Plan does not provide for any annual increases in the number of shares available.

In April 2020, we issued and sold $230.0 million aggregate principal amount of our 1.5% senior convertible notes due April 2026 (the "2026 Convertible Notes"). The holders may convert their 2026 Convertible Notes at their option at any time prior to the close of business on the second scheduled trading day immediately before April 15, 2026. Upon conversion of the 2026 Convertible Notes by a holder, the holder will receive shares of our common stock, together, if applicable, with cash in lieu of any fractional share. 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.

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 ("FDIC") and subsequently had all of its customer deposits and other liabilities and substantially all loans and other assets acquired by First-Citizens Bank & Trust Company. We had approximately $131.1 million of cash, cash equivalents and marketable securities as of September 30, 2023 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 return to stockholders will therefore be limited to any appreciation of their stock.

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

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

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

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

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

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

General Risk Factors

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

We are subject to risks related to public health crises such as the global pandemic associated with the COVID-19 pandemic. As a result of the COVID-19 outbreak, we have experienced and may continue to experience disruptions that could severely impact our business, competitive position, clinical trials and preclinical studies.

Factors arising from the COVID-19 pandemic could result in us not being able to maintain UDENYCA's market position or increase its penetration against all of Neulasta's dosage forms, achieve a successful launch of new products or recently launched products like YUSIMRY, and could result in our inability to meet development milestones for our product candidates, each of which would harm our business, financial condition, results of operations and growth.

Numerous state and local jurisdictions have imposed, and others in the future may impose, "shelter-in-place" orders, quarantines, executive orders and similar government orders and restrictions for their residents to control the spread of COVID-19. Such orders or restrictions, have resulted in slowdowns and delays, travel restrictions and cancellation of events, among other effects, thereby negatively impacting our operations. In addition, there was a lockdown order in all of Shanghai, China in 2022, where our partner Junshi Biosciences has its headquarters. Such orders or restrictions may be re-instated upon future outbreaks of COVID-19, thereby causing negative impacts on our operations. Although orders and restrictions have been relaxed in China, ongoing impacts remain during the ongoing recovery from the COVID-19 pandemic throughout China. In addition, the spread of more contagious and deadly variants could cause severe and widespread outbreaks of COVID-19. We have no ability to predict the future spread of severe and deadly pandemics that could disrupt our business and materially impact our financial position.

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

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:

- failure of the FDA to conduct required inspections in foreign countries such as China or accept clinical trial data obtained by our product candidates in clinical trials in China, which could result in an inability to obtain acceptance or increased costs to pursue clinical trials in the United States;
- multiple, conflicting and changing laws and regulations such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses, including those that affect our work with a collaboration partner in China;
- failure by us or our collaboration partners to obtain and maintain regulatory approvals for the use of our products in various countries;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining protection and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations by us or our collaboration partners;

- complexities associated with managing multiple payer reimbursement regimes, government payers or patient self-pay systems by our collaboration partners;
- limits in our or our collaboration partners' ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions;
- certain expenses including, among others, expenses for travel, translation and insurance;
- expose us to sanctions, such as the sanctions levied by United States, E.U. and Russian regulatory bodies in connection with Russia's invasion of Ukraine in February 2022; and
- regulatory and compliance risks that relate to maintaining accurate information and control over sales and activities that may fall within the purview of the United States Foreign Corrupt Practices Act, its books and records provisions or its anti-bribery provisions.

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

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

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

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

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

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

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

Examples of submarine patents include Brockhaus, et al., United States patents 8,063,182 and 8,163,522 (controlled by Amgen), which are directed to the fusion protein in Enbrel. On July 1, 2020, the United States Court of Appeals for the Federal Circuit issued a decision that affirmed the lower court's decision upholding the validity of these patents. As a result, we discontinued the development of CHS-0214 (our etanercept (Enbrel) biosimilar candidate).

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

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

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

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

Many patents may cover a marketed product, including but not limited to the composition of the product, methods of use, formulations, cell line constructs, vectors, growth media, production processes and purification processes. The identification of all patents and their expiration dates relevant to the production and sale of an originator product is extraordinarily complex and requires sophisticated legal knowledge in the relevant jurisdiction. It may be impossible to identify all patents in all jurisdictions relevant to a marketed product. Our determination of the expiration

date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our products.

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

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

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

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

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

In addition, changes to United States patent laws provide additional procedures for third parties to challenge the validity of issued patents based on patent applications filed after March 15, 2013. If the breadth or strength of protection provided by the patents and patent applications we hold or pursue with respect to our current or future product candidates is challenged, then it could threaten our ability to prevent competitive products using our proprietary technology. Further, because patent applications in the United States and most other countries are confidential for a period of time, typically for 18 months after filing, we cannot be certain that we were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our patents or patent applications. Furthermore, for applications filed before March 16, 2013 or patents issuing from such applications, an interference proceeding can be provoked by a third party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications and patents. As of March 16, 2013, the

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

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

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

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

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

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

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. In many cases, an inadvertent lapse can be

cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case.

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

Filing, prosecuting, defending and enforcing patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Further, licensing partners may choose not to file patent applications in certain jurisdictions in which we may obtain commercial rights, thereby precluding the possibility of later obtaining patent protection in these countries. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States or importing products made using our inventions into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export infringing products to territories where we have patent protection, but the ability to enforce our patents is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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

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

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

breach. Our confidential information and trade secrets thus may become known by our competitors in ways we cannot prove or remedy.

Although we expect all of our employees and consultants to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed. We cannot guarantee that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. For example, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may have a material adverse effect on our business. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. We cannot guarantee that our employees, former employees or consultants will not file patent applications claiming our inventions. Because of the “first-to-file” laws in the United States and the EU, such unauthorized patent application filings may defeat our attempts to obtain patents on our own inventions.

We may be subject to claims challenging the inventorship of our patent filings and other intellectual property.

Although we are not currently aware of any claims challenging the inventorship of our patent applications or ownership of our intellectual property, we may in the future be subject to claims that former employees, collaborators or other third parties have an interest in our patent applications or patents we may be granted or other intellectual property as an inventor or co-inventor. For example, we may have inventorship or ownership disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of or right to use valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

We or the third parties upon whom we depend may be adversely affected by earthquakes or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our corporate headquarters and laboratory are located in the San Francisco Bay Area and in Southern California (Camarillo), respectively. These locations have in the past experienced severe earthquakes, floods and other natural disasters. We do not carry earthquake insurance. Earthquakes or other natural disasters could severely disrupt our operations or those of our collaboration partners and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure (such as the manufacturing facilities of our third-party contract manufacturers) or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business.

The continuation of the war in Ukraine and the war between Israel and Hamas 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. The outbreak of war between Israel and Hamas 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 wars between Russia and Ukraine or between Israel and Hamas, escalate or expand, risks that we have identified in this Quarterly Report on Form 10-Q 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 cyber security measures. These and other risks are described more fully in this “Risk Factors” section.

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

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

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

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

Our information technology systems, or those used by our third-party CROs or other contractors or consultants, may fail or suffer security breaches and geopolitical tensions or conflicts, such as the ongoing war in Ukraine, may create a heightened risk of cyberattacks.

Despite the implementation of security measures, our internal computer, server, and other information technology systems as well as those of our third-party collaborators, consultants, contractors, suppliers, and service providers, may be vulnerable to damage from physical or electronic break-ins, computer viruses, "phishing" attacks, malware, ransomware, denial of service and other cyberattacks or disruptive incidents that could result in unauthorized access to, use or disclosure of, corruption of, or loss of sensitive, and/ or proprietary data, including health-related information or other personal information, and could subject us to significant liabilities and regulatory and enforcement actions, and reputational damage. In addition, geopolitical tensions or conflicts, such as the war between Russia and Ukraine or the war between Israel and Hamas, may create a heightened risk of cyberattacks. We have also outsourced elements of our information technology infrastructure, and as a result a number of third-party vendors may or could have access to our confidential information. If we or any of our third-party collaborators or service providers were to experience any material failure or security breach, it could result in a material disruption of our development programs, reputation, and business operations. For example, the loss of clinical study data from completed or ongoing clinical studies could result in delays in any regulatory approval or clearance efforts and significantly increase our costs to recover or reproduce the data, and subsequently commercialize the product.

We and certain of our service providers are from time to time subject to cyberattacks and security incidents. While we do not believe that we have experienced any significant system failure, accident or security breach to date, if we or our third-party collaborators, consultants, contractors, suppliers, or service providers were to suffer an attack or breach, for example, that resulted in the unauthorized access to or use or disclosure of personal information, including health-related information, we may have to notify individuals, collaborators, government authorities, and the media, and may be subject to investigations, civil penalties, administrative and enforcement actions, and litigation, any of which could harm our business and reputation. Likewise, we rely on our third-party CROs and other third parties to conduct clinical studies, and similar events relating to their computer systems could also have a material adverse effect on our business.

Attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. Further, the 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 an incident, 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, proprietary, or other sensitive, personal information, including health-related information, we could incur liability and suffer reputational harm, and the development and commercialization of our products could be delayed. Federal, state and international laws and regulations can expose us to enforcement actions and investigations by regulatory authorities, and potentially result in regulatory penalties, fines and significant legal liability, if our information technology security efforts fail. We may also be exposed to a risk of loss or litigation and potential liability, which could materially and adversely affect our business, results of operations or financial condition. Our insurance policies may not be adequate to compensate us for the potential losses arising from such disruptions, failure, or security breach. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made

against us and defending a suit, regardless of its merit, could be costly, divert management attention, and harm our reputation.

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

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

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

Even when HIPAA does not apply, according to the Federal Trade Commission (“FTC”), failing to take appropriate steps to keep consumers’ personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act. The FTC expects a company’s data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities.

In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same requirements, thus complicating compliance efforts. By way of example, California enacted the California Consumer Privacy Act (the “CCPA”) on June 28, 2018, which went into effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that has increased the likelihood of, and risks associated with, data breach litigation. Further, the California Privacy Rights Act (“CPRA”) generally went into effect on January 1, 2023, and significantly amends the CCPA. It imposes additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It also creates a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. Additional compliance investment and potential business process changes may also be required. Similar laws have passed in 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, the CPRA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

In addition, the regulatory framework for the receipt, collection, processing, use, safeguarding, sharing and transfer of personal and confidential data is rapidly evolving and is likely to remain uncertain for the foreseeable future as new global privacy rules are being enacted and existing ones are being updated and strengthened. For example, on May 25, 2018, the GDPR took effect. The GDPR is applicable in each EEA member state and applies to companies established in the EEA as well as companies that collect and use personal data to offer goods or services to, or monitor the behavior of, individuals in the EEA, including, for example, through the conduct of clinical trials. GDPR introduces more stringent data protection obligations for processors and controllers of personal data. Among other things, the GDPR requires the establishment of a lawful basis for the processing of data, includes requirements relating to the consent of the individuals to whom the personal data relates, including detailed notices for clinical trial subjects and investigators, as well as requirements regarding the security of personal data and notification of data processing obligations or security incidents to appropriate data protection authorities or data subjects. 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 October 7, 2022, President Biden signed an Executive Order on 'Enhancing Safeguards for United States Intelligence Activities' which introduced new redress mechanisms and binding safeguards to address the concerns raised by the CJEU in relation to data transfers from the EEA to the United States and which formed the basis of the new EU-US Data Privacy Framework ("DPF"), as released on December 13, 2022. The European Commission adopted its Adequacy Decision in relation to the DPF on July 10, 2023, rendering the DPF effective as a GDPR transfer mechanism to U.S. entities self-certified under the DPF. The DPF also introduced a new redress mechanism for EU citizens which addresses a key concern in the previous CJEU judgments and may mean transfers under standard contractual clauses are less likely to be challenged in future. We currently rely on the EU standard contractual clauses and the UK Addendum to the EU standard contractual clauses as relevant to transfer personal data outside the EEA and the UK, including to the United States, with respect to both intragroup and third party transfers. 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 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 total worldwide annual turnover, 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 imposes separate but similar obligations to those under the GDPR and comparable penalties, including fines of up to £17.5 million or 4% of a noncompliant company's global annual revenue for the preceding financial year, whichever is greater. On October 12, 2023, the UK Extension to the DPF came into effect (as approved by the UK government), as a UK GDPR data transfer mechanism to U.S. entities self-certified under the UK Extension to 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 and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. We do not currently carry biological or hazardous waste insurance coverage.

ITEM 2. Unregistered Sales of Equity Securities and Use of Proceeds, and Issuer Purchases of Equity Securities

Issuer Purchases of Equity Securities

We did not repurchase any of our equity securities during the third quarter ended September 30, 2023. A total of 90,873 shares were surrendered to us in the third quarter of 2023, to satisfy minimum tax withholding obligations in connection with the vesting or exercise of stock-based awards.

ITEM 3. Defaults Upon Senior Securities

Not applicable

ITEM 4. Mine Safety Disclosures

Not applicable

ITEM 5. Other Information

(a) None.

(b) None.

(c) During the three months ended September 30, 2023, no director or officer of the Company 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 6. Exhibits

Reference is made to the Index to Exhibits included in this Quarterly Report on Form 10-Q.

INDEX TO EXHIBITS

Exhibit Number	Description	Incorporated by Reference			Filed Herewith
		Form	Exhibit	Date Filed	
3.1	Amended and Restated Certificate of Incorporation.	8-K	3.1	11/13/2014	
3.2	Amended and Restated Bylaws.	8-K	3.1	11/18/2020	
4.1	Reference is made to exhibits 3.1 and 3.2.				
4.2	Form of Common Stock Certificate.	S-1/A	4.2	10/24/2014	
4.3	Indenture, dated as of April 17, 2020, between Coherus Biosciences, Inc. and U.S. Bank National Association, as Trustee.	8-K	4.1	4/17/2020	
4.4	Form of certificate representing the 1.5% Convertible Senior Subordinated Notes due 2026.	8-K	4.2	4/17/2020	
4.5	Notice of Successor Trustee to Indenture dated February 7, 2022.	10-Q	4.5	5/5/2022	
10.1	Settlement and License Agreement among Coherus BioSciences, Inc., AbbVie Inc. and AbbVie Biotechnology Ltd dated January 24, 2019.				X
10.2	Amendment No. 2 to Sales Agreement between Coherus BioSciences, Inc. and Cowen and Company, LLC dated September 11, 2023.				X
31.1	Certification of Principal Executive Officer Required under Securities Exchange Act Rule 13a-14(a) and 15d-14(a).				X
31.2	Certification of Principal Financial Officer under Securities Exchange Act Rule 13a-14(a) and 15d-14(a).				X
32.1	Certifications of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. 1350 and Securities Exchange Act Rule 13a-14(b).				X

Exhibit Number	Description	Incorporated by Reference			Filed Herewith
		Form	Exhibit	Date Filed	
101	The following materials from Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2023 formatted in iXBRL (Inline eXtensible Business Reporting Language) includes: (i) Condensed Consolidated Balance Sheets, (ii) Condensed Consolidated Statements of Operations, (iii) Condensed Consolidated Statements of Comprehensive Loss, (iv) Condensed Consolidated Statements of Stockholders' Equity (Deficit), (v) Condensed Consolidated Statements of Cash Flows, and (vi) Notes to the Condensed Consolidated Financial Statements.				X
104	Cover page Interactive Data File (formatted in Inline XBRL and contained in Exhibit 101).				X

* Certain exhibits and schedules have been omitted pursuant to Item 601(b)(2) of Regulation S-K. We hereby undertake to furnish supplemental copies of any of the omitted exhibits and schedules upon request by the SEC; provided, however, that we may request confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, for any exhibits or schedules so furnished.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Company has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

COHERUS BIOSCIENCES, INC.

Date: November 6, 2023

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

Date: November 6, 2023

/s/ McDavid Stilwell
McDavid Stilwell
Chief Financial Officer
(Principal Financial Officer)

Date: November 6, 2023

/s/ Bryan McMichael
Bryan McMichael
Executive Vice President, Accounting, Corporate Controller and Principal Accounting Officer
(Principal Accounting Officer)

EXHIBIT 10.1

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

SETTLEMENT AND LICENSE AGREEMENT

THIS SETTLEMENT AND LICENSE AGREEMENT ***("Agreement"),*** effective January 24, 2019 ***("Effective Date"),*** is entered into by and among AbbVie Inc., a corporation organized and existing under the laws of Delaware, having its corporate headquarters at 1 North Waukegan Road, North Chicago, Illinois 60064, on behalf of itself and its Affiliates, and AbbVie Biotechnology Ltd, a corporation organized and existing under the laws of Bermuda with a place of business at Clarendon House, 2 Church Street, Hamilton HMl 1 Bermuda (collectively and including their Affiliates, ***"AbbVie");*** and Coherus BioSciences, Inc., a corporation organized and existing under the laws of Delaware, having a place of business at 333 Twin Dolphin Drive, Suite 600, Redwood City, CA 94065, on behalf of itself and its Affiliates (including its Affiliates, ***"Coherus").***

WHEREAS, AbbVie manufactures and markets a fully human anti-TNFa monoclonal antibody with the brand name HUMIRA® and international non-proprietary name adalimumab (the ***"Humira Product"),*** which was invented by AbbVie (or its predecessors);

WHEREAS, AbbVie Inc. owns or has exclusively licensed from AbbVie Biotechnology Ltd more than [***] issued U.S. Patents related to the Humira Product, the last of which will expire in [***];

WHEREAS, AbbVie Biotechnology Ltd owns or has licensed from AbbVie Inc. more than [***] issued U.S. Patents related to the Humira Product, the last of which will expire in [***];

WHEREAS, AbbVie markets the Humira Product in the Territory pursuant to Biologics License Application No. 125057 (together with any replacements or supplements thereto, as amended now or in the future, the ***"Humira BLA");***

WHEREAS, Coherus seeks to market a biosimilar version of the Humira Product pursuant to a marketing authorization to be obtained under the Biologics Price Competition and Innovation Act ***("BPCIA");***

WHEREAS, Coherus intends to file, but has not yet filed, a Biologics License Application pursuant to 42 U.S.C. § 262(k) of the BPCIA seeking approval to market a biosimilar of the Humira Product (together with any supplements and replacement thereto, as amended now or in the future, the ***"Coherus BLA*** ") prior to the expiration of at least one of the U.S. Patents related to the Humira Product;

WHEREAS, the biosimilar of the Humira Product that will be the subject of the Coherus BLA may be labeled for indications including, but not limited to, [***] and for each indication will have the same route of administration and dosing regimen as the Humira Product;

WHEREAS, AbbVie previously asserted in litigation pursuant to the BPCIA [***] U.S. Patents related to the Humira Product that AbbVie asserted were infringed by biosimilar products of adalimumab sought to be marketed by Amgen Inc. and Amgen Manufacturing

Limited (collectively and including their respective Affiliates, ***"Amgen")*** and reserved the right to assert at least an additional [***] patents if and when Amgen provided commercial notice of its intent to market its biosimilar adalimumab product;

WHEREAS, AbbVie and Amgen resolved all pending BPCIA and future patent litigation related to its biosimilar adalimumab product in the U.S. via a settlement announced publicly on September 28, 2017;

WHEREAS, AbbVie has filed litigation pursuant to the BPCIA against Boehringer lngelheim International GmbH, Boehringer Ingelheim Pharmaceuticals, Inc. and Boehringer lngelheim Fremont, Inc. (collectively, ***"BI")*** asserting BI's biosimilar adalimumab product infringes [***] U.S. Patents related to the Humira Product and has reserved the right to assert at least an additional [***] patents if and when BI provides commercial notice of its intent to market its biosimilar adalimumab product;

WHEREAS, Samsung Bioepis Co., Ltd. (including its Affiliates, ***"Samsung")*** intends to market a biosimilar version of the Humira Product pursuant to the BPCIA, which it identifies as SB5; AbbVie and Samsung resolved all BPCIA disputes related to Samsung's biosimilar adalimumab product in the U.S. via a settlement announced publicly on April 5, 2018;

WHEREAS, AbbVie previously asserted in litigation pursuant to the BPCIA [***] U.S. Patents related to the Humira Product that AbbVie asserted were infringed by biosimilar products of adalimumab sought to be marketed by Sandoz Inc., Sandoz International GmbH, and Sandoz GmbH (collectively, ***"Sandoz")*** and reserved the right to assert at least an additional [***] patents if and when Sandoz provided commercial notice of its intent to market its biosimilar adalimumab product;

WHEREAS, AbbVie and Sandoz resolved all pending BPCIA litigation, any pending inter partes review proceedings, and future patent litigation related to its biosimilar adalimumab product in the U.S. via a settlement announced publicly on October 11, 2018;

WHEREAS, Mylan Pharmaceuticals, Inc. (including its Affiliates, ***"Mylan")*** intends to market a biosimilar version of the Humira Product pursuant to the BPCIA; AbbVie and Mylan resolved all BPCIA disputes related to the Mylan biosimilar adalimumab product in the U.S. via a settlement announced publicly on July 17, 2018;

WHEREAS, Fresenius Kabi Deutschland GmbH (including its Affiliates, ***"Fresenius")*** intends to market a biosimilar version of the Humira Product pursuant to the BPCIA; AbbVie and Fresenius resolved all BPCIA disputes related to the Fresenius biosimilar adalimumab product in the U.S. via a settlement announced publicly on October 18, 2018;

WHEREAS, Momenta Pharmaceuticals, Inc. (including its Affiliates, ***"Momenta")*** intends to market a biosimilar version of the Humira Product pursuant to the BPCIA; AbbVie and Momenta resolved all BPCIA disputes related to the Momenta biosimilar adalimumab product in the U.S. via a settlement announced publicly on November 6, 2018;

WHEREAS, Pfizer Inc. (including its Affiliates, ***"Pfizer")*** intends to market a biosimilar version of the Humira Product pursuant to the BPCIA; AbbVie and Pfizer resolved all BPCIA disputes related to the Pfizer biosimilar adalimumab product in the U.S. via a settlement announced publicly on November 30, 2018;

WHEREAS, Amgen filed two petitions seeking *inter partes* review of U.S. Patent Nos. [***], which cover formulations comprising adalimumab; and on January 14, 2016 the Patent Trial and Appeal Board of the U.S. Patent and Trademark Office ***("PTAB")*** denied institution, holding that Amgen failed to establish a reasonable likelihood that any challenged claim would be held unpatentable;

WHEREAS, Coherus filed a petition seeking *inter partes* review of U.S. Patent No. [***], which covers formulations comprising adalimumab; and on November 7, 2016 the PTAB denied institution, holding that Coherus failed to establish a reasonable likelihood that any challenged claim would be held unpatentable;

WHEREAS, Coherus filed four petitions seeking *inter partes* review of U.S. Patent No. [***], which covers formulations comprising adalimumab; and on September 7, 2017 the PTAB denied institution, holding that Coherus failed to establish a reasonable likelihood that any challenged claim would be held unpatentable;

WHEREAS, Sandoz Inc. filed a petition seeking *inter partes* review of U.S. Patent No. [***], which covers formulations comprising adalimumab; and on February 9, 2018 the PTAB denied institution, holding that Sandoz failed to establish a reasonable likelihood that any challenged claim would be held unpatentable;

WHEREAS, Sandoz Inc. filed two petitions seeking *inter partes* review of U.S. Patent No. [***], which covers methods of treating chronic plaque psoriasis with adalimumab, which method would be included in the instructions for use for the biosimilar of the Humira Product that will be the subject of the Coherus BLA; and on February 9, 2018 and May 3, 2018 the PTAB denied institution, holding that Sandoz failed to establish a reasonable likelihood that any challenged claim would be held unpatentable;

WHEREAS, Sandoz Inc. filed a petition seeking *inter partes* review of U.S. Patent No. [***], which covers methods of treating ulcerative colitis with adalimumab, which method would be included in the instructions for use for the biosimilar of the Humira Product that will be the subject of the Coherus BLA; and on March 9, 2018 the PTAB denied institution, holding that Sandoz failed to establish a reasonable likelihood that any challenged claim would be held unpatentable;

WHEREAS, Sandoz Inc. filed a petition seeking *inter partes* review of U.S. Patent No. [***], which covers methods of treating Crohn's disease with adalimumab, which method would be included in the instructions for use for the biosimilar of the Humira Product that will be the subject of the Coherus BLA; and on March 9, 2018 the PTAB denied institution, holding that Sandoz failed to establish a reasonable likelihood that any challenged claim would be held unpatentable;

WHEREAS, Sandoz Inc. filed a petition seeking *inter partes* review of U.S. Patent No. [***], which covers methods of treating Crohn's disease and ulcerative colitis with adalimumab, which method would be included in the instructions for use for the biosimilar of the Humira Product that will be the subject of the Coherus BLA; and on June 5, 2018 the PTAB denied institution, holding that Sandoz failed to establish a reasonable likelihood that any challenged claim would be held unpatentable;

WHEREAS, Coherus filed three petitions seeking *inter partes* review of U.S. Patent Nos. [***] in IPR 2016-00172; IPR 2016-00188; IPR 2016-00189, respectively, each of which covers methods of treating rheumatoid arthritis with adalimumab, which method would be included in the instructions for use for the biosimilar of the Humira Product that will be the subject of the Coherus BLA;

WHEREAS, the PTAB instituted the *inter partes* review proceedings for each of U.S. Patent Nos. [***], and held the claims of those patents unpatentable in final decisions issued May 16, 2017 and June 9, 2017; and where AbbVie has appealed said decisions to the U.S. Court of Appeals for the Federal Circuit, which appeals were docketed as Nos. 2017-2304, -2305, -2306, which appeals remain pending ***("Federal Circuit Appeals");***

WHEREAS, in the absence of this settlement and license agreement, upon filing of the Coherus BLA, Coherus would comply with the patent identification provisions of the BPCIA, which the Parties agree would culminate in litigation under the BPCIA ***("BPCIA Litigation");***

WHEREAS, the Parties wish to settle the Federal Circuit Appeals (as between the Parties), the BPCIA Litigation and any related disputes between them in the Territory;

WHEREAS, no Party has received any consideration from the other Party for its entry into this Agreement other than that which is described in this Agreement.

NOW, THEREFORE, in consideration of the mutual promises and covenants contained in this Agreement and for other good and valuable consideration, the receipt of and sufficiency of which is hereby acknowledged, the Parties agree as follows:

ARTICLE 1: DEFINITIONS

Terms when used herein with initial capital letters shall have the meanings set forth below or as otherwise defined in this Agreement.

1.1 ***"AbbVie"*** has the meaning set forth in the introductory paragraph of this Agreement.

1.2 ***"AbbVie Releasees"*** has the meaning set forth in Section 3.2.

1.3 ***"AbbVie Releasors"*** has the meaning set forth in Section 3.1.

1.4 ***"Affiliate"*** means, with respect to a Person, any Person that, directly or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with, such Person, provided however, that in each case any such other Person shall be considered to be an Affiliate only during the time period during which such control exists. For purposes of this definition, "control" means ownership, directly or through one or more Affiliates, of (a) more than fifty percent (50%) of the shares of stock entitled to vote for the election of directors, in the case of a corporation, or (b) more than fifty percent (50%) of the equity interests in the case of any other type of legal entity or status as a general partner in any partnership, or (c) any other arrangement whereby a Person controls or has the right to control the Board of Directors or equivalent governing body of a corporation or other entity. For purposes of clarity, if a Person loses its status as an Affiliate, such Person thereafter will not benefit from rights granted in this Agreement.

1.5 ***"Agreement"*** has the meaning set forth in the introductory paragraph of this Agreement.

1.6 ***"Amgen"*** has the meaning set forth in the WHEREAS clauses.

1.7 ***"BPCIA"*** has the meaning set forth in the WHEREAS clauses.

1.8 ***"BPCIA Litigation"*** has the meaning set forth in the WHEREAS clauses.

1.9 ***"BI"*** has the meaning set forth in the WHEREAS clauses.

1.10 ***"BLA"*** means a Biologic License Application as defined in the U.S. Public Health Service (PHS) Act and the U.S. Federal Food, Drug, and Cosmetic Act.

1.11 ***"Coherus"*** has the meaning set forth in the introductory paragraph of this Agreement.

1.12 ***"Coherus Biosimilar Product"*** means [***].

1.13 ***"Coherus BLA"*** has the meaning set forth in the WHEREAS clauses.

1.14 ***"Coherus Releasees"*** has the meaning set forth in Section 3.1.

1.15 ***"Coherus Releasors"*** has the meaning set forth in Section 3.2.

1.16 ***"Commercialization Partner"*** [***].

1.17 ***"Contract Manufacturer"*** means the Person that is party to a valid sublicense with Coherus pursuant to Section 9.2(a) and that meets the criteria set forth in Sections 9.2(a), 9.2(d) and 9.2(e), as applicable, to perform activities directed to the manufacture of the Coherus Biosimilar Product in the Territory, including but not limited to bulk drug substance manufacture and fill-finish activities such as packaging and labeling, importation or storage of the Coherus Biosimilar Product.

1.18 ***"Contract Sales Organization"*** means a Person that is party to a valid sublicense with Coherus pursuant to Section 9.2(c) and that meets the criteria set forth in Sections 9.2(c), 9.2(d) and 9.2(e), as applicable, to perform activities directed to the commercialization of Coherus Biosimilar Product on behalf of Coherus in the Territory.

1.19 ***"Effective Date"*** means the date on which this Agreement was executed by the latest-signing Party, which date is memorialized on page one (1) of this Agreement.

1.20 ***"Federal Circuit Appeals"*** has the meaning set forth in the WHEREAS clauses.

1.21 ***"Fresenius"*** has the meaning set forth in the WHEREAS clauses.

1.22 ***"Humira Biosimilar Product"*** means any biologic product for which marketing approval was sought by means of a BLA filed pursuant to 42 U.S.C. *§* 262(k) that lists the Humira Product or any product containing adalimumab as the sole active pharmaceutical ingredient (including all strengths) as the reference product.

1.23 ***"Humira BLA"*** has the meaning set forth in the WHEREAS clauses.

1.24 ***"Humira Product"*** has the meaning set forth in the WHEREAS clauses.

1.25 ***"IPR"*** means Inter Partes Review pursuant to 35 U.S.C. *§* 311 *et seq.*

1.26 ***"License Entry Date"*** has the meaning set forth in Section 6.1.

1.27 ***"Licensed Humira Patents"*** means, collectively, [***]

1.28 ***"License Term(s)"*** has the meaning set forth in Section 5.5.

1.29 ***"Momenta"*** has the meaning set forth in the WHEREAS clauses.

1.30 ***"Mylan"*** has the meaning set forth in the WHEREAS clauses.

1.31 ***"Net Sales"*** means [***].

1.32 ***"Party"*** means AbbVie or Coherus, and **"Parties"** means all of the foregoing.

1.33 ***"Person"*** means an individual, a corporation, a partnership, an association, a trust or other entity or organization, including a government or political subdivision or an agency or instrumentality thereof.

1.34 ***"Pfizer"*** has the meaning set forth in the WHEREAS clauses.

1.35 ***"PGR"*** means post-grant review pursuant to 35 U.S.C. *§* 321 *et seq.*

1.36 ***"PTAB"*** has the meaning set forth in the WHEREAS clauses.

1.37 ***"Royalty Rate"*** has the meaning set forth in Section 5.4.

1.38 ***"Royalty Termination Date"*** has the meaning set forth in Section 5.6.

1.39 ***"Samsung"*** has the meaning set forth in the WHEREAS clauses.

1.40 ***"Sandoz"*** has the meaning set forth in the WHEREAS clauses.

1.41 ***"Sublicensee(s)"*** means any Person that is party to a valid sublicense with Coherus pursuant to Section 9.2 and that meets all the criteria set forth in Sections 9.2(a), 9.2(b),

9.2(c), 9.2(d) and 9.2(e), as applicable. [***]. For the avoidance of doubt, prior to the Royalty Termination Date, no Sublicensee has any rights under this Agreement until AbbVie approves the sublicense in writing and the executed sublicense is provided to AbbVie in accordance with Section 9.2(e).

1.42 ***"Territory"*** means the United States of America, and its territories, districts, and possessions, including the District of Columbia and the Commonwealth of Puerto Rico.

1.43 ***"Third Party"*** means a Person or entity that is not a Party, a Sublicensee, or an Affiliate of a Sublicensee.

1.44 ***"Third Party Humira Biosimilar Product"*** means [***].

1.45 ***"Third Party License"*** means [***].

1.46 ***"Third Party Rate"*** has the meaning set forth in Section 5.4(b).

ARTICLE 2: TERMINATION OF LITIGATION

2.1 Withdrawal from Federal Circuit Appeals. Within [***] of execution of this Agreement, Licensee shall cause its attorneys to file a motion in the U.S. Court of Appeals for the Federal Circuit seeking to withdraw Licensee from the Federal Circuit Appeals. As of the date of filing such motion to withdraw, Licensee will cease all participation in all of the Federal Circuit Appeals (other than cooperating to take any necessary steps to effect its withdrawal) and will not assist any third party directly or indirectly in any way in the Federal Circuit Appeals. It is understood and agreed that such Federal Circuit Appeals will not be dismissed and that Licensor may continue to proceed with and participate in such Federal Circuit Appeals notwithstanding the withdrawal of Licensee. For clarity, if in any of the Federal Circuit Appeals, the U.S. Court of Appeals for the Federal Circuit remands any of the cases to the PTAB for further proceedings, Licensee's obligation not to participate in the Federal Circuit Appeals or to assist any third party with respect to such Federal Circuit Appeals will extend to those further proceedings on remand and any subsequent appeals thereof.

ARTICLE 3: RELEASE

3.1 AbbVie Release. In settlement of the BPCIA Litigation and the Federal Circuit Appeals, and in consideration of the releases, representations, warranties, and covenants contained in this Agreement and subject to execution by the Parties of this Agreement, as of the Effective Date, AbbVie and its parents, subsidiaries, related companies and predecessors,

successors, and assigns, [***].

3.2 Coherus Release. In settlement of the BPCIA Litigation and the Federal Circuit Appeals, and in consideration of the releases, representations, warranties, and covenants (including the license) contained in this Agreement and subject to execution by the Parties of this Agreement, as of the Effective Date, Coherus and its parents, subsidiaries, Sublicensees, related companies and predecessors, successors, and assigns, [***].

3.3 Acknowledgements. It is expressly understood and agreed that the Parties hereby waive any statutes or common law doctrines under which a general release would not extend to claims which the party releasing such claim does not know or suspect to exist in its favor at the time of executing the release, including but not limited to any and all rights and benefits conferred by § 1542 of the California Civil Code (if and to the extent applicable). Each Party represents, warrants, and covenants that it has not heretofore assigned or transferred, and will not assign or otherwise transfer, to any Person any matters released by such Party in this Section 3, and such Party agrees to indemnify and hold harmless the other Parties from and against all such released matters arising from any such alleged or actual assignment or transfer. This Agreement may be pleaded as a full and complete defense to, and used as a basis for injunction against, any proceeding that may be instituted, prosecuted or attempted in breach hereof.

3.4 [***].

3.5 [***].

3.6 Exceptions. Nothing in this Section 3 shall prevent (a) either Party from seeking any remedy for breach of this Agreement, (b) any AbbVie Releasor from enforcing the Licensed Humira Patents in the event of such breach or (c) any Coherus Releasor from asserting any and all affirmative defenses, counterclaims, and the like in response to an AbbVie Releasor seeking to enforce the Licensed Humira Patents in the event of such a breach and termination.

ARTICLE 4: PATENT ENFORCEABILITY

4.1 Enforceability of Licensed Humira Patents. Coherus admits that the Licensed Humira Patents are valid and enforceable.

ARTICLE 5: GRANT OF LICENSE AND ROYALTIES

5.1 License Grant. AbbVie hereby grants to Coherus, effective on and from the License Entry Date as described in Section 6.1 of this Agreement, a nonexclusive, royalty bearing (as set forth in Section 5.4 below), non-transferable (except as expressly permitted by Sections 9.2 and 9.4) license under the Licensed Humira Patents to make, import, use, distribute, sell and offer for sale the Coherus Biosimilar Product in the Territory.

5.2 Coherus Restrictions. In return for AbbVie's grant of a license including under Sections 5.1 and 5.3, and for other good and valuable consideration, including the compromise of AbbVie's claims that the making, having made, importing, using, marketing, distributing, having distributed, selling or offering to sell the Coherus Biosimilar Product or any biosimilar version of the Humira Product in the Territory infringes one or more claims of the Licensed Humira

Patents, except as expressly set forth in Section 5.3, [***].

5.3 Additional Licenses. In addition to the above, (a) AbbVie hereby grants Coherus a nonexclusive, non-transferable (except as expressly permitted by Sections 9.2 and 9.4) license under the Licensed Humira Patents to manufacture, import and store the Coherus Biosimilar Product in the Territory [***] prior to the License Entry Date in anticipation of selling the Coherus Biosmilar Product in the Territory on and after the License Entry Date; and (b) AbbVie hereby grants Coherus a nonexclusive, non-transferable (except as expressly permitted by Sections 9.2 and 9.4) license under the Licensed Humira Patents to manufacture in, import for purposes of manufacturing, and export from the Territory the Coherus biosimilar version of the Humira Product beginning on the Effective Date for use or sale solely in countries outside the Territory. For avoidance of doubt, nothing in this Agreement gives Coherus any rights to any AbbVie patent outside the Territory.

5.4 Royalties. Coherus hereby agrees to pay a royalty to AbbVie of [***]% (the ***"Royalty Rate")*** of the Net Sales of the Coherus Biosimilar Product in the Territory. For each calendar quarter, Coherus shall pay such royalties to AbbVie within [***] of the end of such calendar quarter. Notwithstanding the foregoing, the Royalty Rate shall be increased for any Net Sales of the Coherus Biosimilar Product pursuant to Section 6.1(b), 6.1(c) or 6.1(d) prior to [***] as follows:

(a) [***].
(b) [***].

5.5 [***].

5.6 Termination of Royalty Payments. The obligations of Coherus to pay royalties under this Section 5 shall terminate on the earlier of (i) [***]; or (ii) a decision by the United States Court of Appeals for the Federal Circuit holding that all unexpired claims of each of the Licensed Humira Patents are invalid or unenforceable (the ***"Royalty Termination Date"),*** at which time the non-exclusive, non-transferable (except as permitted by Sections 9.2 and 9.4) license granted hereunder will be deemed fully paid up and irrevocable.

5.7 Quarterly Statements. Not later than [***] after the end of each calendar quarter, Coherus will provide AbbVie with statements setting forth the gross sales of the Coherus Biosimilar Product in the Territory for such calendar quarter, Net Sales of the Coherus Biosimilar Product in the Territory for such calendar quarter, the royalty amount payable for such calendar quarter, the calculation used to determine the royalty amount, all information necessary to calculate the royalty amount, and any other details or particulars that AbbVie may reasonably request.

5.8 Record Retention and Audit Rights. Coherus and its Sublicensees will retain their books and records pertaining to the Net Sales of the Coherus Biosimilar Product in the Territory for each calendar quarter for at least [***] from the end of such calendar quarter. Until [***] after the Royalty Termination Date, AbbVie may provide Coherus with reasonable notice of its request to have an independent public accounting firm licensed to practice in the United States audit records of Coherus and its Sublicensees required to determine the Net Sales of the Coherus Biosimilar Product in the Territory and the royalty due under this

Agreement. Coherus and its Sublicensees will accommodate such an audit and use reasonable efforts to accommodate such request within [***] of AbbVie's request; provided however, any audit under this Section 5.8 shall be conducted during normal business hours of Coherus and its Sublicensees. The audit will be at AbbVie's sole expense unless the audit shows an underpayment in the royalties due to AbbVie of [***] or more in any calendar quarter in which case Coherus will pay for the audit. In the event that an audit reveals any underpayment in royalties due to AbbVie, Coherus shall promptly, but in no event later than [***] after receipt of written notice thereof, pay such underpayment to AbbVie. AbbVie's audit rights may only be exercised once during any [***] period. No set of books and records for any given period shall be audited more than once. Notwithstanding any provision herein to the contrary, Coherus and its Sublicensees shall not have the right to audit any books and records of AbbVie or any of its agents.

ARTICLE 6: LICENSE ENTRY DATE FOR THE COHERUS BIOSIMILAR PRODUCT

6.1 License Entry Date. The ***"License Entry Date"*** for the Coherus Biosimilar Product will be the earliest to occur of the following dates:

(a) [***];

(b) [***];

(c) [***];

(d) [***].

ARTICLE 7: ADDITIONAL COVENANTS

7.1 Certain Remedies. Each Party acknowledges and agrees that the restrictions and other terms and conditions set forth herein regarding the use, sale, offer for sale, marketing, manufacture or importation of the Coherus Biosimilar Product by Coherus and its Sublicensees are reasonable and necessary to protect the respective legitimate interests of AbbVie and Coherus, and that in the event of a breach or threatened breach of those restrictions or other terms or conditions by either Party or any Sublicensee(s), the other Party shall have the right to seek from any court of competent jurisdiction injunctive relief, whether temporary, preliminary, or permanent, and specific performance, which rights shall be cumulative and in addition to any other rights or remedies to which such Party may be entitled in law or equity. [***]. Nothing in this Section 7.1 is intended, or shall be construed, to limit the Parties' rights to equitable relief or any other remedy for a breach of any provision of this Agreement. [***].

7.2 Confidentiality. Except as set forth below in Section 7.3, the Parties shall keep the terms of this Agreement, the underlying settlement and the information set forth in Section 9.2(±) confidential using at least the level of care they use for their own proprietary information, and shall not disclose to any Third Party (other than the Parties' respective financial advisors, legal advisors, and insurers, or in connection with a potential or actual sublicense pursuant to Section 9.2 or in connection with a potential or actual assignment pursuant to Section 9.4, in each such case subject

to appropriate confidentiality protections).

7.3 Exceptions to Confidentiality. Notwithstanding Section 7.2, a Party may upon the execution of this Agreement and without prior written consent, publicly disclose: (a) that the Parties have settled the BPCIA Litigation and the Federal Circuit Appeals, that this Agreement exists, and that the Agreement includes the license set forth in Section 5.1; (b) the information contained in Sections 1.42, 4.1 and 6.l(a); (c) any information required to be so disclosed by a court, governmental agency, or other regulatory authority; and (d) any information that is, in the opinion of the disclosing Party's counsel, required by law or the rules of a stock exchange on which the securities of the disclosing Party are listed; provided, however, that in the event that a disclosure under Section 7.3(c) or 7.3(d) is made, the disclosing Party shall submit the proposed disclosure in writing to the other Party as far in advance as reasonably practicable so as to provide reasonable notice and an opportunity to provide comments. A Party receiving a request, subpoena, or order for the disclosure of the terms or conditions of this Agreement shall notify the

other Party as soon as practicable and, if at all possible, in sufficient time to allow the other Party to oppose disclosure or seek an appropriate protective order.

ARTICLE 8: REPRESENTATIONS AND WARRANTIES

8.1 Representations and Warranties. Each Party represents, warrants, and covenants to the other Parties that as of the Effective Date:

(a) it has the corporate power and authority to enter into this Agreement and to perform its obligations and bind itself and its Sublicensees to perform their obligations hereunder, and that the persons executing this Agreement on behalf of each of the Parties are authorized to do so;

(b) the execution and delivery of this Agreement and the performance of the transactions contemplated hereunder have been duly authorized by all necessary corporate actions of the Party;

(c) this Agreement has been duly executed and delivered by it and is a binding obligation of it, enforceable against it and its Sublicensees in accordance with its terms; and

(d) the execution and delivery of this Agreement and the performance by the Party or its Sublicensees of any of its obligations hereunder do not and will not conflict with (i) any judgment of any court or governmental body applicable to the Party or its respective properties, or (ii) any other agreements to which it may be a party, or (iii) to the Party's knowledge, any statute, decree, order, rule or regulation of any court or governmental agency or body applicable to the Party or its properties.

8.2 Additional AbbVie Representations and Warranties.

(a) AbbVie further represents and warrants that it has the necessary rights, title, interest, and authority to grant Coherus the license to the Licensed Humira Patents contained herein.

(b) [***].

8.3 Additional Coherus Representations and Warranties.

(a) [***].

(b) [***].

8.4 Limitations. Except as expressly provided in this Agreement, neither Party makes any representations or warranties, express or implied, either in fact or by operation of applicable law. Specifically, AbbVie makes no representation that, as of the License Entry Date, Coherus or its Sublicensees will be able to launch the Coherus Biosimilar Product. The Parties herein acknowledge that the ability of Coherus or its Sublicensees to launch the Coherus Biosimilar Product may be limited by (a) the FDA's failure to finally approve, or revocation of approval of, the Coherus Biosimilar Product; (b) the inability of Coherus or its Sublicensees to manufacture, package, and otherwise prepare a sufficient amount of the Coherus Biosimilar Product by the License Entry Date; or (c) other situations not currently within the Parties' contemplation. Without limiting any other provision of this Agreement, AbbVie therefore makes no warranty and no representation with respect to the actual date that the Coherus Biosimilar Product will be available for sale.

ARTICLE 9: SCOPE OF THE PARTIES' AGREEMENT

9.1 Right to Prosecute Licensed Humira Patents. AbbVie shall have the sole right to prosecute, maintain, enforce, and defend any of the Licensed Humira Patents.

9.2 Sublicensing.

(a) Subject to written approval from AbbVie as set out in Section 9.2(d) and the provision of the sublicense as set out in Section 9.2(e), Coherus may sublicense the license grants in Sections 5.1 and 5.3 to up to [***] Contract Manufacturers solely for the purpose of having the Coherus Biosimilar Product made, imported, or stored for sale in the Territory; provided, however, [***], Coherus may exercise the sublicense rights of this Section 9.2(a) without written approval from AbbVie if and only if conditions (i), (ii) and (iv) of Section 9.2(d) are met by any Sublicensee granted license rights under this Section 9.2(a).

(b) Subject to written approval from AbbVie as set out in Section 9.2(d) and the provision of the sublicense as set out in Section 9.2(e), Coherus may sublicense the license grants in Section 5.1 to [***] to import, use, distribute, have distributed, sell and offer for sale the Coherus Biosimilar Product in the Territory; provided, however, [***], Coherus may exercise the sublicense rights of this Section 9.2(b) without written approval from AbbVie if and only if conditions (i), (ii) and (iv) of Section 9.2(d) are met by any Sublicensee granted license rights under this Section 9.2(b).

(c) Subject to written approval from AbbVie as set out in Section 9.2(d) and the provision of the sublicense as set out in Section 9.2(e), Coherus may sublicense the license grants in Section 5.1 to one Contract Sales Organization to sell and offer for sale or otherwise commercialize the Coherus Biosimilar Product in the Territory; provided, however, [***], Coherus may exercise the sublicense rights of this Section 9.2(c) without written approval from AbbVie if and only if conditions (i), (ii) and (iv) of Section 9.2(d) are met by any Sublicensee granted license rights under this Section 9.2(c).

(d) AbbVie will respond to any request for approval pursuant to Section 9.2(a), 9.2(b) or 9.2(c) within [***]. AbbVie will not withhold approval for a sublicense under this Section 9 if the sublicense meets all of the following conditions: [***]

(e) In order for a Sublicensee to have any rights under this agreement, Coherus must provide AbbVie with a copy of executed sublicense, which may be redacted as reasonably appropriate with respect to subject matter not applicable to this Agreement. [***]

(f) The identity of any Sublicensee and the contents of the executed sublicense shall be kept confidential under the provisions of Section 7.2, except that the identity of the Commercialization Partner shall be within the exceptions to confidentiality as set out in Section 7.3 after the first public disclosure by Coherus of the identity of its Commercialization Partner in the Territory.

9.3 Reservation of Rights. All rights not expressly granted to Coherus in this Agreement are reserved to AbbVie, and no other license or rights under the Licensed Humira Patents or any other intellectual property of AbbVie is granted or intended to be granted under this Agreement, either expressly, by implication, estoppel, or otherwise.

9.4 No Assignment. This Agreement and the rights herein shall not be assigned by any Party without the written consent of all Parties, which consent shall not be unreasonably

withheld, delayed or conditioned, *except* that each Party may upon notice to the other Party but without obtaining the consent of the other Party, assign or sublicense any or all of its rights and obligations under this Agreement to any one or more of its Affiliates or assign to any successor in interest to such Party's or assignee's business relating to this Agreement in connection with a merger, reorganization, change of control, or sale of all or substantially all of its assets to which this Agreement relates. Any purported assignment or transfer in violation of the foregoing shall be null and void *ab initio* and of no force or effect. In the event of a permitted assignment, this Agreement shall be binding upon and inure solely to the benefit of the Parties and their respective successors and permitted assigns.

ARTICLE 10: GENERAL PROVISIONS

10.1 Termination.

(a) If Coherus or its Sublicensees or their Affiliates breach any obligation or restriction under Section 5.2, AbbVie will provide written notice of such breach (if known to AbbVie) and Coherus will have [***] from written notice by AbbVie in which to cure said breach. Notwithstanding the cure period, AbbVie will be entitled to bring an action at any time before, on, or after expiration of the [***] cure period to enforce the terms of Section 5.2 of this Agreement and to seek any relief to which it is entitled, including, but not limited to, injunctive relief, whether temporary, preliminary, or permanent, and specific performance, which relief shall be cumulative and in addition to any other rights or remedies to which AbbVie may be entitled in law or equity. [***]. If Coherus fails to cure within [***] from written notice by AbbVie, AbbVie may also terminate this Agreement and all licenses granted under this Agreement by AbbVie and the Parties' rights and obligations under Sections 3 and 5 of this Agreement shall terminate immediately upon written notice from AbbVie to Coherus of such termination.

(b) If Coherus or its Sublicensees or its Sublicensees' Affiliates breaches any of its obligations and restrictions under Sections 2, 3.2, 3.5, 4, 5.4, 5.7, 5.8, 7.2, 8.1, 8.3 or 9.2, AbbVie will provide written notice of such breach (if known to AbbVie) and Coherus will have [***] from written notice by AbbVie in which to cure said breach. If Coherus fails to cure within [***], AbbVie may terminate this Agreement and all licenses granted under this Agreement by AbbVie and the Parties' rights and obligations under Sections 3 and 5 of this Agreement shall terminate upon written notice from AbbVie to Coherus of such termination.

(c) In addition, if Coherus or its Sublicensees [***] challenge the patentability, validity, or enforceability, or assert the noninfringement of any of the Licensed Humira Patents or any claims thereof; [***] in the Territory, this Agreement and all licenses granted under this Agreement by AbbVie and the Parties' rights and obligations under Sections 3 and 5 of this Agreement shall terminate upon written notice from AbbVie to Coherus of such termination. [***].

(d) If AbbVie breaches any of its obligations and restrictions under Sections 3.1, 3.4, 5.1, 5.3, 5.5, 7.2, 8.1 or 8.2, Coherus will provide written notice of the breach (if known to Coherus) and AbbVie will have [***] from receipt of written notice by Coherus in which to cure said breach. If AbbVie fails to cure within [***], Coherus may terminate this Agreement and all licenses granted under this Agreement and the Parties' rights and obligations under Sections 3 and 5 of this

Agreement shall terminate upon written notice from Coherus to AbbVie of such termination.

I 0.2 Governing Law; Venue. This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware, without giving effect to its conflicts of law principles that would result in the application of the laws of any other jurisdiction. The Parties hereby consent to the exclusive jurisdiction of the courts located in the State of Delaware in connection with any dispute arising out of or relating to this Agreement and expressly waive any objections or defenses based on lack of personal jurisdiction or venue.

I 0.3 Severability. If a court of competent jurisdiction holds any provision of this Agreement to be illegal, unenforceable, or invalid, in whole or in part for any reason: (a) all other provisions hereof shall remain in full force and effect and shall be liberally construed in order to carry out the intent of the Parties as near as possible, and (b) the Parties agree to use their commercially reasonable efforts to negotiate a provision, in replacement of the provision held illegal, unenforceable, or invalid, that is consistent with applicable law and accomplishes, as nearly as possible, the original intention of the Parties with respect thereto and without materially changing the economic value of the transactions contemplated hereby.

I0.4 Entire Agreement. This Agreement and any exhibits, appendices, and attachments to this Agreement, constitute the final, complete, and exclusive statement of the terms of the agreement among the Parties pertaining to the subject matter of this Agreement and supersedes all prior and contemporaneous understandings or agreements of the Parties (other than those referenced in this Agreement). No Party has been induced to enter into this Agreement by, nor is any Party relying on, any representation or warranty outside those expressly set forth in this Agreement.

10.5 Amendment. No terms or conditions of this Agreement will be varied or modified by any prior or subsequent statement, conduct or act of any Party, except that the

Parties may supplement, amend, or modify this Agreement by a subsequent written agreement executed by the Parties through their authorized representatives.

10.6 No Joint Venture. In making and performing this Agreement, AbbVie, on the one hand, and Coherus, on the other, are acting, and intend to be treated, as independent entities and nothing contained in this Agreement shall be construed or implied to create an agency, partnership, joint venture, or employer and employee relationship among AbbVie and Coherus. Except as otherwise provided herein, AbbVie and Coherus may not make any representation, warranty, or commitment, whether express or implied, on behalf of or incur any charges or expenses for or in the name of each other. AbbVie and Coherus shall not be liable for each other's acts unless such act is expressly authorized in writing.

10.7 Waiver. No waiver of a breach, failure of any condition, or any right or remedy contained in or granted by the provisions of this Agreement will be effective unless it is in writing and signed by the Party waiving the breach, failure, right, or remedy. No waiver of any breach, failure, right, or remedy will be deemed a waiver of any other breach, failure, right, or remedy, whether or not similar, nor will any waiver constitute a continuing waiver unless the writing so specifies.

10.8 Interpretation. Each Party and its counsel have participated fully in the review and revision of this Agreement. Any rule of construction to the effect that ambiguities are to be resolved against the drafting Party will not apply in interpreting this Agreement. References to any law, rule or regulation in this Agreement include all replacements, successors, amendments, and supplements thereto. The term "including" means "including, without limitation," and "herein", "hereof', and "hereunder" refer to this Agreement as a whole.

10.9 Counterparts. This Agreement may be executed in any number of counterparts, and each counterpart will be deemed an original instrument, but all counterparts together will constitute but one agreement.

10.10 Headings. The descriptive headings contained in this Agreement are for convenience of reference only and shall not in any way affect the meaning or interpretation of this Agreement.

10.11 Survival. Subject to Section 10.1 above, the provisions in Sections 7, 8 and 10 of this Agreement (and any other provisions of this Agreement that by their express terms survive) shall survive the expiration or termination of this Agreement in accordance with their terms.

10.12 Third Party Beneficiaries. Except as expressly provided herein, nothing in this Agreement, either express or implied, is intended to or shall confer upon any Third Party any legal or equitable right, benefit or remedy of any nature whatsoever under or by reason of this Agreement.

10.13 Notices.

(a) All notices, requests, demands, or other communications under this Agreement will be in writing. All notices shall be made by personal delivery, reputable overnight express courier (e.g., Federal Express/Airborne/United Parcel Service/DHL Worldwide), or by United States Registered or Certified Mail, charges prepaid or charged to the sender's account, in which case notice is effective on delivery.

(b) Addresses for purpose of giving notice are as follows:

If to AbbVie:

Attention: [***] and Attention: [***]
1 N. Waukegan Road, Building AP-34 North Chicago, IL 60064

If to Coherus:

Attention: [***]
333 Twin Dolphin Drive, Suite 600 Redwood City, CA 94065

10.14 Evidence. This Agreement and all of the terms herein constitute compromises and offers to compromise covered by Federal Rule of Evidence 408. Nothing in this Agreement may be used as evidence in any action or proceeding between the Parties hereto, except in connection with any action or proceeding relating to enforcement of this Agreement.

[remainder of this page intentionally left blank]

IN WITNESS WHEREOF, the Parties, through their authorized officers, have executed this Agreement as of the Effective Date.

AbbVie Inc.

By: /s/ William J. Chase
Name: William J. Chase
Title: Executive Vice President, Finance and Administration
Date: January 24, 2019

Coherus BioSciences, Inc.

By: /s/ Dennis M. Lanfear
Name: Dennis M. Lanfear
Title: Chairman & Chief Executive Officer
Date: January 24, 2019

AbbVie Biotechnology Ltd

By: /s/ William J. Chase
Name: William J. Chase
Title: Executive Vice President, Finance and Administration
Date: January 24, 2019

EXHIBIT 10.2

COHERUS BIOSCIENCES, INC.

COMMON STOCK

AMENDMENT NO. 2 TO SALES AGREEMENT

September 11, 2023

Cowen and Company, LLC

599 Lexington Avenue

New York, NY 10022

Ladies and Gentlemen:

Reference is made to the Sales Agreement, dated November 8, 2022, as amended by that certain Amendment No. 1 to Sales Agreement, dated May 15, 2023 (together, the " **Agreement**"), by and between Coherus BioSciences, Inc., a Delaware corporation (the "**Company**"), and Cowen and Company, LLC ("**TD Cowen**"). The Company and TD Cowen (collectively, the "**Parties**") wish to amend the Agreement, pursuant to Section 15 of the Agreement, to increase the aggregate offering price under the Agreement (this "**Amendment**"). The Parties therefore hereby agree as follows:

1. Issuance and Sale of Shares. The first paragraph of Section 1 of the Agreement is hereby amended and restated in its entirety to read as follows:

> 'The Company agrees that, from time to time during the term of this Agreement, on the terms and subject to the conditions set forth herein, it may issue and sell through TD Cowen, acting as agent and/or principal, shares (the "**Placement Shares**") of the Company's common stock, par value $0.0001 per share (the "**Common Stock**"), having an aggregate offering price of up to $92,500,000 (the "**Maximum Amount**"). Notwithstanding anything to the contrary contained herein, the parties hereto agree that compliance with the limitation set forth in this Section 1 on the number of shares of Common Stock issued and sold under this Agreement shall be the sole responsibility of the Company, and TD Cowen shall have no obligation in connection with such compliance. The issuance and sale of Common Stock through TD Cowen will be effected pursuant to the Registration Statement (as defined below) filed by the Company and after such Registration Statement has been declared effective by the Securities and Exchange Commission (the "**Commission**"), although nothing in this Agreement shall be construed as requiring the Company to use the Registration Statement (as defined below) to issue the Common Stock.'

2. Agreement Heading. The reference to "$63,750,000" in the heading of the Agreement shall be removed and replaced with "$92,500,000".

3. A new Section 20 as set forth below is hereby added to the Sales Agreement immediately following Section 19 thereof:

"20. Recognition of the U.S. Special Resolution Regimes.

(a) In the event that TD Cowen is a Covered Entity and becomes subject to a proceeding under a U.S. Special Resolution Regime, the transfer from TD Cowen of this Agreement, and any interest and obligation in or under this Agreement, will be effective to the same extent as the transfer would be effective under the U.S. Special Resolution Regime if this Agreement, and any such interest and obligation, were governed by the laws of the United States or a state of the United States.

(b) In the event that TD Cowen is a Covered Entity and TD Cowen or a BHC Act Affiliate of TD Cowen becomes subject to a proceeding under a U.S. Special Resolution Regime, Default Rights under this Agreement that may be exercised against TD Cowen are permitted to be exercised to no greater extent than such Default Rights could be exercised under the U.S. Special Resolution Regime if this Agreement were governed by the laws of the United States or a state of the United States.

(c) For purposes of this Section 20; (a) "**BHC Act Affiliate**" has the meaning assigned to the term "affiliate" in, and shall be interpreted in accordance with, 12 U.S.C. § 1841(k), (b) "**Covered Entity**" means any of the following: (i) a "covered entity" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 252.82(b); (ii) a "covered bank" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 47.3(b); or (iii) a "covered FSI" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 382.2(b), (c) "**Default Right**" has the meaning assigned to that term in, and shall be interpreted in accordance with, 12 C.F.R. §§ 252.81, 47.2 or 382.1, as applicable, and (d) "**U.S. Special Resolution Regime**" means each of (i) the Federal Deposit Insurance Act and the regulations promulgated thereunder and (ii) Title II of the Dodd-Frank Wall Street Reform and Consumer Protection Act and the regulations promulgated thereunder."

3. Governing Law. THIS AMENDMENT AND ANY CLAIM, CONTROVERSY OR DISPUTE ARISING UNDER OR RELATED TO THIS AMENDMENT SHALL BE GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH, THE LAWS OF THE STATE OF NEW YORK, WITHOUT REGARD TO ITS CHOICE OF LAW PROVISIONS.

4. Counterparts. This Amendment may be executed in any number of counterparts, each of which shall be deemed to be an original, but all such counterparts shall together constitute one and the same agreement. Counterparts may be delivered via facsimile, electronic mail (including any electronic signature covered by the U.S. federal ESIGN Act of 2000, Uniform Electronic Transactions Act, the Electronic Signatures and Records Act or other applicable law, e.g., www.docusign.com) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

5. Agreement Remains in Effect. Except as provided herein, all provisions, terms and conditions of the Agreement shall remain in full force and effect. As amended hereby, the Agreement is ratified and confirmed in all respects.

Terms used herein but not otherwise defined are used herein as defined in the Agreement.

(*Signature page follows)*

If the foregoing is in accordance with your understanding of our agreement, please sign and return to the Company a counterpart hereof; whereupon this instrument, along with all counterparts, will become a binding agreement by the Company and Cowen in accordance with its terms.

Very truly yours,

COHERUS BIOSCIENCES, INC.

By: /s/ Dennis M. Lanfear

Name: Dennis M. Lanfear

Title: President and Chief Executive Officer

The foregoing Amendment No. 2 to the Agreement is hereby confirmed and accepted as of the date first written above.

COWEN AND COMPANY, LLC

By: /s/ Michael J. Murphy

Name: Michael J. Murphy

Title: Managing Director

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO
SECTION 13(a) OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Dennis M. Lanfear, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Coherus BioSciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 6, 2023

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

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO
SECTION 13(a) OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, McDavid Stilwell, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Coherus BioSciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 6, 2023

/s/ McDavid Stilwell
McDavid Stilwell
Chief Financial Officer

Exhibit 32.1

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

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officers of Coherus BioSciences, Inc. (the "Registrant") certify that the Quarterly Report of Coherus BioSciences, Inc. on Form 10-Q for the quarterly period ended September 30, 2023 (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 that information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

Date: November 6, 2023

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

Date: November 6, 2023

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

This certification accompanies the Form 10-Q 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.