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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, 2022

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

For the transition period from to

Commission File Number: 001-36721

Coherus BioSciences, Inc.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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, 2022, 77,777,938 shares of the registrant's common stock were outstanding.

COHERUS BIOSCIENCES, INC.
FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2022
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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 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 in the United States;*
- *our expectations regarding our ability to develop and commercialize toripalimab, CHS-006 and our other product candidates in the United States and Canada, including whether the trial results, data package or biologics license application ("BLA") for toripalimab will be sufficient to support regulatory approval;*
- *our ability to address comments raised in the complete response letter for the original BLA for toripalimab and timing of the review for the original BLA resubmission for toripalimab;*
- *our ability to receive marketing authorization for the on-body injector presentation of UDENYCA®, including the timing of receiving such marketing authorization, if approved;*
- *our ability to maintain regulatory approval for our products and our ability to obtain and maintain regulatory approval of our product candidates, if and when approved;*
- *our expectations regarding government and third-party payer coverage and reimbursement;*
- *our ability to manufacture our product candidates in conformity with regulatory requirements and to scale up manufacturing capacity of these products for commercial supply;*
- *our reliance on third-party contract manufacturers to supply our product candidates for us;*
- *our expectations regarding the potential market size and the size of the patient populations for our product candidates, if approved for commercial use;*
- *our expectations about making required future interest and principal payments as they become due in connection with our debt obligations;*
- *our financial performance, including, but not limited to, projected future performance of our gross margins, research and development expenses and selling and general administrative expenses;*
- *the implementation of strategic plans for our business, product 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 product candidates;*

- *our expectations regarding the scope or enforceability of third-party intellectual property rights, or the applicability of such rights to our 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 product candidates;*
- *the rate and degree of market acceptance of our current or any future product candidates;*
- *our ability to compete with companies currently producing competitor products, including Neulasta, Humira and Lucentis;*
- *developments and projections relating to our competitors, our market opportunity and our industry; and*
- *the potential impact of COVID-19 and the continuation of the war in Ukraine on our business and prospects.*

We have based these forward-looking statements on our current expectations about future events. These statements are not guarantees of future performance and involve risks, uncertainties and assumptions that are difficult to predict. Our actual results may differ materially from those suggested by these forward-looking statements for various reasons, including those identified in Part 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.

This Quarterly Report on Form 10-Q also contains estimates, projections and other information concerning our industry, our business, and the markets for certain diseases, including data regarding the estimated size of those markets, and the incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data, 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, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 286,805	$ 417,195
Trade receivables, net	91,186	123,022
Inventory	27,719	37,642
Prepaid manufacturing	20,633	13,666
Other prepaid and other assets	21,932	10,798
Total current assets	448,275	602,323
Property and equipment, net	9,571	7,813
Inventory, non-current	77,438	55,610
Goodwill and intangible assets	5,996	3,563
Other assets, non-current	9,627	10,025
Total assets	$ 550,907	$ 679,334
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 9,917	$ 16,159
Accrued rebates, fees and reserves	54,021	79,027
Accrued compensation	21,391	22,014
Accrued and other current liabilities	85,990	48,127
Total current liabilities	171,319	165,327
Term loans	245,246	75,513
Convertible notes	225,250	332,767
Lease liabilities, non-current	6,123	7,251
Other liabilities, non-current	102	750
Total liabilities	648,040	581,608
Commitments and contingencies (Note 8)		
Stockholders' equity (deficit):		
Common stock ($0.0001 par value; shares authorized: 300,000,000; shares issued and outstanding: 77,770,593 and 76,930,096 at September 30, 2022 and December 31, 2021, respectively)	7	7
Additional paid-in capital	1,185,868	1,147,843
Accumulated other comprehensive loss	(270)	(270)
Accumulated deficit	(1,282,738)	(1,049,854)
Total stockholders' equity (deficit)	(97,133)	97,726
Total liabilities and stockholders' equity (deficit)	$ 550,907	$ 679,334

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,	
	2022	2021	2022	2021
Net revenue	$ 45,424	$ 82,503	$ 165,690	$ 253,180
Costs and expenses:				
Cost of goods sold	35,234	21,280	55,881	45,487
Research and development	45,808	54,085	170,336	312,343
Selling, general and administrative	44,831	39,925	144,860	119,661
Total costs and expenses	125,873	115,290	371,077	477,491
Loss from operations	(80,449)	(32,787)	(205,387)	(224,311)
Interest expense	(7,540)	(5,771)	(23,089)	(17,166)
Loss on debt extinguishment	—	—	(6,222)	—
Other income (expense), net	1,339	30	1,814	102
Loss before income taxes	(86,650)	(38,528)	(232,884)	(241,375)
Income tax provision	—	—	—	—
Net loss	$ (86,650)	$ (38,528)	$ (232,884)	$ (241,375)
Basic and diluted net loss per share	$ (1.11)	$ (0.49)	$ (3.00)	$ (3.22)
Weighted-average number of shares used in computing basic and diluted net loss per share	77,746,895	79,013,240	77,520,244	74,984,811

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,	
	2022	2021	2022	2021
Net loss	$ (86,650)	$ (38,528)	$ (232,884)	$ (241,375)
Other comprehensive loss:				
Unrealized loss on available-for-sale securities, net of tax	—	(6)	—	(3)
Comprehensive loss	$ (86,650)	$ (38,534)	$ (232,884)	$ (241,378)

See accompanying notes.

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 restricted stock units ("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 employee stock purchase plan ("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 Stockholders' Equity
(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	Equity
Balances at December 31, 2020	72,513,348	$ 7	$1,043,991	$ (270)	$ (762,754)	$ 280,974
Net loss	—	—	—	—	(172,947)	(172,947)
Issuance of common stock upon exercise of stock options	451,883	—	4,429	—	—	4,429
Issuance of common stock upon vesting of RSUs	252,846	—	—	—	—	—
Taxes paid related to net share settlement of RSUs	(95,169)	—	(1,730)	—	—	(1,730)
Stock-based compensation expense	—	—	16,982	—	—	16,982
Other comprehensive loss, net of tax	—	—	—	(37)	—	(37)
Balances at March 31, 2021	73,122,908	7	1,063,672	(307)	(935,701)	127,671
Net loss	—	—	—	—	(29,900)	(29,900)
Issuance of common stock upon exercise of stock options	686,145	—	4,009	—	—	4,009
Issuance of common stock upon vesting of RSUs	9,334	—	—	—	—	—
Issuance of common stock to Shanghai Junshi Biosciences Ltd. ("Junshi Biosciences"), net of issuance costs	2,491,988		40,903	—	—	40,903
Issuance of common stock under the ESPP	154,325	—	1,985	—	—	1,985
Stock-based compensation expense	—	—	11,512	—	—	11,512
Other comprehensive gain, net of tax	—	—	—	40	—	40
Balances at June 30, 2021	76,464,700	7	1,122,081	(267)	(965,601)	156,220
Net loss	—	—	—	—	(38,528)	(38,528)
Issuance of common stock upon exercise of stock options	116,246	—	1,288	—	—	1,288
Issuance of common stock upon vesting of RSUs	2,333	—	—	—	—	—
Stock-based compensation expense	—	—	11,786	—	—	11,786
Other comprehensive loss, net of tax	—	—	—	(6)	—	(6)
Balances at September 30, 2021	76,583,279	$ 7	$1,135,155	$ (273)	$ (1,004,129)	$ 130,760

See accompanying notes.

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

	Nine Months Ended September 30,	
	2022	2021
Operating activities		
Net loss	$ (232,884)	$ (241,375)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Depreciation and amortization	2,649	2,618
Stock-based compensation expense	39,011	40,418
Write-off of prepaid manufacturing services related to the termination of CHS-2020	—	3,210
Inventory reserves and write offs, net	26,000	5,192
Non-cash interest expense from amortization of debt discount & issuance costs	5,631	3,150
Upfront and option payments to Junshi Biosciences	35,000	136,000
Loss on debt extinguishment	6,222	—
Other non-cash adjustments, net	1,844	2,708
Changes in operating assets and liabilities:		
Trade receivables, net	31,849	20,722
Inventory	(37,556)	2,936
Prepaid manufacturing	(6,967)	(2,884)
Other prepaid, current and non-current assets	(12,509)	(4,590)
Accounts payable	(6,149)	30,495
Accrued rebates, fees and reserves	(25,006)	3,215
Accrued compensation	(623)	(3,451)
Accrued and other current and non-current liabilities	32,317	16,526
Net cash (used in) provided by operating activities	(141,171)	14,890
Investing activities		
Purchases of property and equipment	(1,952)	(821)
Purchases of investments in marketable securities	—	(171,779)
Proceeds from maturities of investments in marketable securities	—	62,700
Upfront and option payments to Junshi Biosciences	(35,000)	(136,000)
Net cash used in investing activities	(36,952)	(245,900)
Financing activities		
Proceeds from 2027 Term Loans, net of debt discount & issuance costs	240,679	—
Proceeds from issuance of common stock to Junshi Biosciences, net of issuance costs	—	40,903
Proceeds from issuance of common stock upon exercise of stock options	631	9,726
Proceeds from purchase under the employee stock purchase plan	1,655	1,985
Taxes paid related to net share settlement of RSUs	(3,621)	(1,730)
Repayment of 2022 Convertible Notes and premiums	(109,000)	—
Repayment of 2025 Term Loan, premiums and exit fees	(81,750)	—
Other financing activities	(861)	(492)
Net cash provided by financing activities	47,733	50,392
Net decrease in cash, cash equivalents and restricted cash	(130,390)	(180,618)
Cash, cash equivalents and restricted cash at beginning of period	417,635	541,598
Cash, cash equivalents and restricted cash at end of period	$ 287,245	$ 360,980

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 cancer treatments and commercialization of its portfolio of United States Food and Drug Administration ("FDA")-approved biosimilars. The Company's strategy is to develop and commercialize innovative cancer treatments funded with cash generated through net sales of its diversified portfolio of FDA-approved therapeutics. The Company's headquarters and laboratories are located in Redwood City, California and in Camarillo, California, respectively. The Company sells UDENYCA (pegfilgrastim-cbqv), a biosimilar to Neulasta, a long-acting granulocyte-colony stimulating factor, in the United States. The FDA approved YUSIMRY™ (adalimumab-aqvh) in December 2021, which the Company plans to launch in the United States on or after July 1, 2023, per the terms of an agreement with Humira manufacturer, AbbVie Inc. ("AbbVie"). On August 2, 2022, the FDA approved CIMERLI™ (ranibizumab-eqrn), a Lucentis biosimilar, and commercial launch commenced on October 3, 2022 in the United States.

The Company's product pipeline comprises the following three product candidates: toripalimab, an anti-PD-1 antibody being developed in collaboration with Junshi Biosciences; CHS-006, an antibody targeting TIGIT being developed in collaboration with Junshi Biosciences; and one wholly-owned preclinical immuno-oncology program, CHS-1000, an antibody targeting ILT4. In May 2022, the Company discontinued development of its bevacizumab (Avastin) biosimilar product candidate from Innovent Biologics (Suzhou) Co., Ltd. ("Innovent"). In October 2022, the Company discontinued development of its preclinical immuno-oncology program, CHS-3318, an antibody targeting CCR8, in order to focus on external molecules targeting CCR8.

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, 2021 (the "2021 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 for the nine months ended September 30, 2022 and 2021:

(in thousands)	January 1,	
At beginning of period:	2022	2021
Cash and cash equivalents	$ 417,195	$ 541,158
Restricted cash	440	440
Total cash, cash equivalents and restricted cash	$ 417,635	$ 541,598

	September 30,	
At end of period:	2022	2021
Cash and cash equivalents	$ 286,805	$ 360,540
Restricted cash	440	440
Total cash, cash equivalents and restricted cash	$ 287,245	$ 360,980

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.

Investments in Marketable Securities

Investments in marketable securities primarily consist of corporate debt obligations and commercial paper. Management determines the appropriate classification of investments in marketable securities at the time of purchase based upon management's intent with regards to such investment and reevaluates such designation as of each balance sheet date. The Company's investment policy requires that it only invests in highly rated securities and limit its exposure to any single issuer. All investments in debt marketable securities are held as "available-for-sale" and are carried at the estimated fair value as determined based upon quoted market prices or pricing models for similar securities. There were no investments in marketable securities as of September 30, 2022 or December 31, 2021.

The Company classifies investments in marketable securities as short-term when they have remaining contractual maturities of one year or less from the balance sheet date. Unrealized gains and losses on available-for-sale 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 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 on available-for-sale securities are included in other income, net, based on the specific identification method.

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, 2022 and December 31, 2021.

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 recorded net revenue of $45.4 million and $165.7 million during the three and nine months ended September 30, 2022, respectively, and $82.5 million and $253.2 million during the three and nine months ended September 30, 2021, respectively.

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

	Three Months Ended		Nine Months Ended	
	September 30, 2022	September 30, 2021	September 30, 2022	September 30, 2021
McKesson Corporation	37 %	40 %	37 %	39 %
AmeriSource-Bergen Corporation	45 %	40 %	45 %	39 %
Cardinal Health, Inc.	17 %	19 %	17 %	20 %

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, 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	(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

(in thousands)	Nine Months Ended September 30, 2021 Chargebacks and Discounts for Prompt Payment	Rebates	Other Fees, Co-pay Assistance and Returns	Total
Balances at December 31, 2020	$ 40,580	$ 54,058	$ 28,760	$ 123,398
Provision related to sales made in:				
Current period	356,663	90,965	73,289	520,917
Prior period	(2,859)	(2,821)	(3,035)	(8,715)
Payments and customer credits issued	(362,241)	(78,600)	(75,716)	(516,557)
Balances at September 30, 2021	$ 32,143	$ 63,602	$ 23,298	$ 119,043

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

3. Fair Value Measurements

The fair values of financial instruments are classified into one of the following categories:

- 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.

A financial instrument's categorization within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement. Where quoted prices are available in an active market, securities are classified as Level 1. Level 1 assets consist of highly liquid money market funds that are included in cash and cash equivalents, and restricted cash.

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

Financial assets and liabilities subject to fair value measurements on a recurring basis and the level of inputs used in such measurements were as follows:

(in thousands)	Fair Value Measurements September 30, 2022 Level 1	Level 2	Level 3	Total
Financial Assets:				
Cash and cash equivalents (money market funds)	$ 286,805	$ —	$ —	$ 286,805
Restricted cash (money market funds)	440	—	—	440
Total financial assets	$ 287,245	$ —	$ —	$ 287,245

(in thousands)	Fair Value Measurements December 31, 2021 Level 1	Level 2	Level 3	Total
Financial Assets:				
Cash and cash equivalents (money market funds)	$ 417,165	$ —	$ —	$ 417,165
Restricted cash (money market funds)	440	—	—	440
Total financial assets	$ 417,605	$ —	$ —	$ 417,605

4. Inventory

Inventory consisted of the following:

(in thousands)	September 30, 2022	December 31, 2021
Raw materials	$ 10,432	$ 4,870
Work in process	77,296	65,117
Finished goods	17,429	23,265
Total	$ 105,157	$ 93,252

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 and 2021, the Company recorded write-downs of inventory of $26.0 million and $5.2 million, respectively, in cost of goods sold in the condensed consolidated statements of operations. The write-down during the third quarter of 2022 was due to the competitive environment and lower demand for UDENYCA resulting in certain inventory becoming at risk of expiration, which increased net loss by $26.0 million and basic and diluted net loss per share by $0.33 and $0.34 per share for the three- and nine-month periods ended September 30, 2022, respectively. The inventory write-down during the third quarter of 2021 was for inventory that did not meet acceptance criteria. Inventory reserves were $26.0 million and $0.2 million as of September 30, 2022 and December 31, 2021, respectively.

The Company began capitalizing YUSIMRY inventory in the second quarter of 2022 and had $24.6 million of such inventory recognized on the condensed consolidated balance sheets at September 30, 2022. 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, 2022 and December 31, 2021, the non-current portion of inventory consisted of raw materials, work in process and a portion of finished goods. The following tables presents the inventory balance sheet classifications:

(in thousands)	September 30, 2022	December 31, 2021
Inventory	$ 27,719	$ 37,642
Inventory, non-current	77,438	55,610
Total	$ 105,157	$ 93,252

Prepaid manufacturing of $20.6 million as of September 30, 2022 includes prepayments of $16.6 million to contract manufacturing organizations (“CMOs”) for manufacturing services for our products, which the Company expects to be converted into inventory within the next twelve months; and prepayments of $4.0 million to various CMOs for research

and development pipeline programs. Prepaid manufacturing of $13.7 million as of December 31, 2021 included prepayments of $8.3 million to a CMO for manufacturing services for UDENYCA; and prepayments of $5.4 million to various CMOs for research and development pipeline programs.

In February 2021, the Company announced the discontinuation of the development of CHS-2020, a biosimilar of Eylea® as part of a realignment of research and development resources toward other development programs. As a result, during the quarter ended March 31, 2021, the Company recognized $11.5 million within research and development expenses on its condensed consolidated statement of operations, which included an impairment charge of $3.2 million for the write-off of prepaid manufacturing services no longer deemed to have future benefits. No material expense relating to the discontinuation of CHS-2020 was recognized after March 31, 2021.

5. Balance Sheet Components

Property and Equipment, Net

Property and equipment, net consists of the following:

(in thousands)	September 30, 2022	December 31, 2021
Machinery and equipment	$ 12,878	$ 11,876
Computer equipment and software	3,055	3,033
Furniture and fixtures	1,246	1,129
Leasehold improvements	6,145	5,942
Finance lease right of use assets	4,721	2,294
Construction in progress	845	388
Total property and equipment	28,890	24,662
Accumulated depreciation and amortization	(19,319)	(16,849)
Property and equipment, net	$ 9,571	$ 7,813

Depreciation and amortization expense was $0.9 million and $2.6 million for the three and nine months ended September 30, 2022, respectively, and $0.9 million and $2.6 million for the three and nine months ended September 30, 2021, respectively.

Accrued and Other Current Liabilities

Accrued and other current liabilities are summarized as follows:

(in thousands)	September 30, 2022	December 31, 2021
Accrued commercial and research and development manufacturing	$ 51,523	$ 30,541
Accrued co-development costs payable to Junshi Biosciences	17,544	1,926
Lease liabilities, current	4,097	3,492
Accrued other	12,826	12,168
Total Accrued and other current liabilities	$ 85,990	$ 48,127

6. Collaborations and Other Arrangements

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 toripalimab, Junshi Biosciences' anti-PD-1 antibody, in the United States and Canada.

Under the terms of the Collaboration Agreement, the Company paid $150.0 million upfront for exclusive rights to toripalimab in the United States and Canada, an option in these territories to Junshi Biosciences' anti-TIGIT antibody CHS-006, an option in these territories to a next-generation engineered IL-2 cytokine, and certain negotiation rights to two undisclosed preclinical immuno-oncology drug candidates. The Company will have the right to conduct all commercial activities of toripalimab in the United States and Canada. The Company will be obligated to pay Junshi Biosciences a 20% royalty on net sales of toripalimab and up to an aggregate $380.0 million in one-time payments for the achievement of various regulatory and sales milestones.

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

The licensing transaction and the exercise of the option were accounted for as asset acquisitions under the relevant accounting rules. Research and development expenses recognized for obligations to Junshi Biosciences were $7.6 million in the third quarter of 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, and $15.4 million and $173.6 million for the three and nine months ended September 30, 2021, respectively. The first quarter of 2021 included $145.0 million for the upfront payment for the exclusive rights to toripalimab and the second quarter of 2021 included a credit of $9.0 million for the discount for lack of marketability ("DLOM"), discussed below. Accrued and other current liabilities on the condensed consolidated balance sheet as of September 30, 2022 included $17.5 million related to the co-development, regulatory and technology transfer costs related to these programs. The Company entered into a right of first negotiation agreement with Junshi Biosciences and paid a fee of $5.0 million which was fully expensed as research and development expense in the fourth quarter of 2020. The right of first negotiation fee was fully credited against the total upfront license fee obligation under the Collaboration Agreement.

As of September 30, 2022, the Company did not have any outstanding milestone or royalty payment obligations to Junshi Biosciences. The additional milestone payments, option fee for the IL-2 cytokine and royalties are contingent upon future events and, therefore, will be recorded if and when it becomes probable that a milestone will be achieved, or when an option fee or royalties are incurred.

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

following its effective date. The Collaboration Agreement and the Stock Purchase Agreement were negotiated concurrently and were therefore evaluated as a single agreement. The Company used the “Finnerty” and “Asian put” valuation models and determined the fair value for the DLOM was $9.0 million at the date the shares were issued. The fair value of the DLOM was attributable to the Collaboration Agreement and was included as an offset against the research and development expense in the condensed consolidated statement of operations for the three months ending June 30, 2021.

Innovent Biologics (Suzhou) Co., Ltd.

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

Under the License Agreement, the Company committed to pay Innovent a $5.0 million upfront payment and an aggregate of up to $40.0 million in milestone payments in connection with the achievement of certain development, regulatory and sales milestones with respect to the bevacizumab Licensed Product and, if the Company’s option was exercised, an aggregate of up to $40.0 million in milestone payments in connection with the achievement of certain development, regulatory and sales milestones with respect to the rituximab Licensed Product. The Company accounted for the licensing transaction as an asset acquisition under the relevant accounting rules. During the three and nine months ended September 30, 2022, the Company’s research and development expense related to bevacizumab Licensed Product development activities directly with Innovent was immaterial. During the three and nine months ended September 30, 2021, the Company recognized research and development expense of $0.5 million and $1.2 million, respectively, related to bevacizumab Licensed Product development activities directly with Innovent. As of September 30, 2022, the Company did not have any outstanding milestone or royalty payment obligations to Innovent.

On May 3, 2022, the Company provided notice of termination of the License Agreement to Innovent pursuant to Section 13.6 of the License Agreement. In connection therewith, the Company has discontinued development of the bevacizumab Licensed Product.

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. 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 which occurred on October 3, 2022 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 as of September 29, 2022 (the “Bioeq Manufacturing Agreement”) and 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 must use commercially reasonable efforts to commercialize the Bioeq Licensed Products in accordance with a commercialization plan. Additionally, the Company must 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 which occurred on August 2, 2022 and certain other criteria which were satisfied in October 2022. The obligation to pay this milestone was recorded in accrued and other current liabilities on the condensed consolidated balance sheet as of September 30, 2022. The Company will share a percentage of gross profits on sales of Bioeq Licensed Products in the United States with Bioeq in the low to mid fifty percent range. The 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 or when royalties are incurred.

7. Debt Obligations

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

	At September 30, 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	$ (4,754)	$ 245,246	$ 245,246	Level 2*
2026 Convertible Notes	$ 230,000	$ (4,750)	$ 225,250	$ 175,950	Level 2

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

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

2027 Term Loans

The Company entered into a loan agreement (including as subsequently amended, 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”) to be funded at the Company’s option between April 1, 2022 and March 17, 2023, subject to certain conditions including the first FDA approval of a BLA for the Company’s product candidate toripalimab in the United States; and (iv) a Tranche D Loan in an aggregate principal amount of $50.0 million that was funded on September 14, 2022 (the “Tranche D Loan” and, together with the Tranche A Loan, the Tranche B Loan, and the Tranche C Loan, the “2027 Term Loans”). The Company has the right to request an uncommitted additional facility amount of up to $100.0 million that is subject to new terms and conditions.

The 2027 Term Loans mature on either (i) the fifth anniversary of the Tranche A Closing Date; or (ii) October 15, 2025, if the outstanding aggregate principal amount of the Company’s 2026 Convertible Notes is greater than $50.0 million on October 1, 2025. The 2027 Term Loans bear interest at 8.25% plus three-month LIBOR per annum with a LIBOR floor of 1.0%; the interest rate for the third quarter of 2022 was 10.54% for Tranches A and B and 11.73% for Tranche D. In the event of the cessation of LIBOR, the benchmark governing the interest rate will be replaced with a rate based on the secured overnight financing rate published by the Federal Reserve Bank of New York as described in the Loan Agreement. 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 and will be used to fund the Company’s general corporate and working capital requirements except for the following: in January 2022, proceeds of the Tranche A Loan were used to repay in full all amounts outstanding under the 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, 2022, the Company was in full compliance with these covenants and there were no events of default under the 2027 Term Loans.

In connection with the closing of Tranche A, the Company incurred $7.8 million in debt discounts and issuance costs of which $6.8 million related to all the tranches of the 2027 Term Loans and was thus allocated pro rata between the tranches. The unamortized debt discount and issuance costs allocated to funded tranches are presented as deductions to the 2027 Term Loan balance and are amortized into interest expense using the effective interest method. The $2.3 million allocated to Tranche B was fully amortized over the commitment period prior to funding and recognized as interest expense in the first quarter of 2022. Until unfunded tranches are drawn, the associated debt discounts and issuance costs are deferred as assets and amortized into interest expense using the straight-line method over the commitment period of the respective tranches. At the closing dates of Tranche B on March 31, 2022 and Tranche D on September 14, 2022, the Company incurred an additional $1.0 million and $0.5 million, respectively, in debt issuance costs. As of September 30, 2022, the total remaining unamortized debt discount and debt offering costs related to Tranches A, B and D of $4.8 million will be amortized using the effective interest rate over the remaining term of 4.3 years.

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

(in thousands)	Three Months Ended September 30, 2022	Nine Months Ended September 30, 2022
Stated coupon interest	$ 5,665	$ 12,577
Amortization of debt discount and debt issuance costs	622	4,122
Total interest expense	$ 6,287	$ 16,699

Future payments on the 2027 Term Loans as of September 30, 2022 are as follows:

Year ending December 31, (in thousands)	
Remainder of 2022 - interest only	$ 6,887
2023 - interest only	27,327
2024 - interest only	27,402
2025 - interest only	27,327
2026 and thereafter	269,151
Total minimum payments	358,094
Less amount representing interest	(108,094)
2027 Term Loans, gross	250,000
Less unamortized debt discount and debt issuance costs, net	(4,754)
Net carrying amount of 2027 Term Loans	$ 245,246

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 $14.815 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, 2022, the Company was in full compliance with these covenants and there were no events of default under the 2026 Convertible Notes.

The Company evaluated the features embedded in the 2026 Convertible Notes under the relevant accounting rules and concluded that the embedded features do not meet the requirements for bifurcation, and therefore do not need to be separately accounted for as an equity component. The proceeds received from the issuance of the convertible debt were recorded as a liability 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 "option counterparties"). The capped call transactions are generally expected to reduce the potential dilution upon conversion of the 2026 Convertible Notes in the event that the market price per share of the Company's common stock, as measured under the terms of the capped call transactions, is greater than the strike price of the capped call transactions, which initially corresponds to the conversion price of the 2026 Convertible Notes, and is subject to anti-dilution adjustments generally similar to those applicable to the conversion rate of the 2026 Convertible Notes. Since inception, the cap price has been $25.9263 per share, which represents a premium of approximately 75.0% over the last reported sale price of the Company's common stock of $14.815 per share on April 14, 2020, and is subject to certain adjustments under the terms of the capped call transactions.

The 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.

If the 2026 Convertible Notes were converted on September 30, 2022, the holders of the 2026 Convertible Notes would have received common shares with an aggregate value of $114.8 million based on the Company's closing stock price of $9.61.

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. The remaining unamortized debt discount and debt offering costs related to the Company's 2026 Convertible Notes of $4.7 million as of September 30, 2022, 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.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2022	2021	2022	2021
Stated coupon interest	$ 863	$ 862	$ 2,588	$ 2,587
Amortization of debt discount and debt issuance costs	322	316	962	942
Total interest expense	$ 1,185	$ 1,178	$ 3,550	$ 3,529

Future payments on the 2026 Convertible Notes as of September 30, 2022 are as follows:

Year ending December 31, (in thousands)	
Remainder of 2022 - interest only	$ 1,725
2023 - interest only	3,450
2024 - interest only	3,450
2025 - interest only	3,450
2026 and thereafter	231,725
Total minimum payments	243,800
Less amount representing interest	(13,800)
2026 Convertible Notes, principal amount	230,000
Less unamortized debt discount and debt issuance costs	(4,750)
Net carrying amount of 2026 Convertible Notes	$ 225,250

8.2% Convertible Notes due 2022

On February 29, 2016, the Company issued and sold $100.0 million aggregate principal amount of its 8.2% Convertible Senior Notes. The 2022 Convertible Notes constituted general, senior unsubordinated obligations of the Company and were guaranteed by certain subsidiaries of the Company. The 2022 Convertible Notes bore interest at a fixed coupon rate of 8.2% per annum payable quarterly in arrears on March 31, June 30, September 30 and December 31 of each year, since March 31, 2016, and matured on March 31, 2022. The 2022 Convertible Notes also had a premium of 9% of the principal amount which was payable when the 2022 Convertible Notes matured or were repurchased or redeemed by the Company.

In March 2022, the Company fully repaid the 2022 Convertible Notes, and as a result had no continuing obligations associated with them thereafter. The payoff amount of $111.1 million included the repayment of the entire outstanding principal amount, the 9% premium of the outstanding principal amount and accrued and unpaid interest.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2022	2021	2022	2021
Stated coupon interest	$ —	$ 2,050	$ 2,050	$ 6,150
Amortization of debt discount and debt issuance costs	—	497	521	1,457
Total interest expense	$ —	$ 2,547	$ 2,571	$ 7,607

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"). Starting January 1, 2020, the Borrowings under the 2025 Term Loan bore interest at 6.75% per annum plus three-month LIBOR. Interest was payable quarterly in arrears.

Pursuant to the terms of the 2025 Term Loan, the Company was required to begin paying principal on the Borrowings in equal quarterly installments beginning on 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. As of September 30, 2022, the Company had no continuing obligations associated with the 2025 Term Loan.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2022	2021	2022	2021
Stated coupon interest	$ —	$ 1,773	$ 154	$ 5,261
Amortization of debt discount and debt issuance costs	—	273	16	751
Total interest expense	$ —	$ 2,046	$ 170	$ 6,012

8. Commitments and Contingencies

Purchase Commitments

The Company entered into agreements with certain vendors to secure raw materials and certain CMOs to manufacture its supply of products. As of September 30, 2022, the Company's contractual obligations under the terms of the agreements are as follows:

Years ending December 31, (in thousands)	
Remainder of 2022	$ 9,448
2023	28,740
2024	911
2025	911
2026	208
Total obligations	$ 40,218

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 other claims that arise in the ordinary, routine course of business and that have not been fully resolved. The most significant of these are described below. The outcome of such legal proceedings and other claims is inherently uncertain. Accruals are recognized for such legal proceedings and other 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. The Company did not have any accruals related to such matters on the condensed consolidated balance sheets as of September 30, 2022 and December 31, 2021, respectively.

In late April of 2022, the Company received a demand letter from Zinc Health Services, LLC ("Zinc") asserting Zinc was entitled to approximately $14 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 is unable to reasonably estimate the amount or range of loss that may be incurred, if any, in connection with this matter. At this time, the Company has not made an accrual in connection with this matter.

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

9. 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:

(in thousands)	Three Months Ended September 30, 2022	Three Months Ended September 30, 2021	Nine Months Ended September 30, 2022	Nine Months Ended September 30, 2021
Cost of goods sold [1]	$ 184	$ 394	$ 555	$ 896
Research and development	5,173	4,126	14,707	14,642
Selling, general and administrative	6,925	7,419	23,749	24,880
Stock-based compensation expense	$12,282	$11,939	$ 39,011	$ 40,418
Stock-based compensation expense capitalized into inventory	$ 290	$ 241	$ 904	$ 758

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

10. 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, 2022	Three Months Ended September 30, 2021	Nine Months Ended September 30, 2022	Nine Months Ended September 30, 2021
Stock options, including shares subject to ESPP	22,535,371	19,543,671	22,267,304	19,847,917
Restricted stock units	2,305,743	1,916,002	2,401,188	1,812,799
Shares issuable upon conversion of 2022 Convertible Notes	—	4,473,871	1,442,127	4,473,871
Shares issuable upon conversion of 2026 Convertible Notes	11,942,152	11,942,152	11,942,152	11,942,152
Total	36,783,266	37,875,696	38,052,771	38,076,739

11. Related Party Transactions

Consulting services

In October 2020, the Company entered into a consulting agreement with Lanfear Advisors owned by Jonathan Lanfear who is the brother of Dennis Lanfear, the Company's President, Chief Executive Officer and Chairman of the Board of Directors. Jonathan Lanfear provided consulting services with respect to the Collaboration Agreement executed with Junshi Biosciences in February 2021 (See Note 6). In addition to the hourly consulting fee paid to Lanfear Advisors under the consulting agreement, the Company granted fully vested stock options to purchase 65,000 shares of common stock with an exercise price of $17.60 per share to Jonathan Lanfear in February 2021 upon the execution of the Collaboration Agreement with Junshi Biosciences. During the first quarter of 2021, the Company recognized non-cash

stock-based compensation expense of $0.8 million and consulting service expense of $0.2 million related to these services. There have been no subsequent material related party expenses. Total liabilities recognized on the condensed consolidated balance sheets with respect to these services were immaterial as of September 30, 2022 and December 31, 2021.

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, 2021, and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, contained in the 2021 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 cancer treatments and the commercialization of our portfolio of FDA-approved biosimilars. Our strategy is to build a leading immuno-oncology franchise funded with cash generated through net sales of our diversified portfolio of FDA-approved therapeutics.

Our commercial portfolio includes three FDA-approved biosimilar biologics. 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. 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. The FDA also granted CIMERLI 12 months of interchangeability exclusivity. We launched CIMERLI commercially in the United States on October 3, 2022. In December 2021, the FDA-approved YUSIMRY (adalimumab-aqvh), formerly CHS-1420, our Humira (adalimumab) biosimilar product, which we plan to launch in the United States on or after July 1, 2023, per the terms of an agreement with Humira manufacturer, AbbVie.

In addition to our three FDA-approved biosimilar biologics, we also have an original biologic license application submitted under Section 351(a) of the Public Health Service Act ("original BLA") under review by the FDA for toripalimab. Toripalimab is being developed for its ability to block PD-1 interactions with its ligands, PD-L1 and PD-L2 by binding to the FG loop on the PD-1, and for enhanced PD-1 receptor internalization (endocytosis function). We believe blocking PD-1 interactions with PD-L1 and PD-L2 have the potential to promote the immune system's ability to attack and kill tumor cells. The original BLA for toripalimab seeks FDA approval for the use of toripalimab in combination with gemcitabine and cisplatin for first-line treatment of adults with metastatic or recurrent locally advanced nasopharyngeal carcinoma ("NPC"), and for use as a monotherapy in the second- or later-line treatment of patients with recurrent unresectable or metastatic NPC that have progressed on or after a platinum-containing chemotherapy. On April 29, 2022, we received a complete response letter ("CRL") from the FDA for the original BLA for toripalimab requesting certain manufacturing process changes that we and Junshi Biosciences believe are readily addressable. On July 6, 2022, we announced that the FDA accepted the resubmission of the original BLA for toripalimab. The FDA has set a Prescription Drug User Fee Act ("PDUFA") action date for December 23, 2022. We are still working with the FDA to set a date for a required inspection in China. We plan to launch toripalimab in the United States in the first quarter of 2023, if approved by the December 23, 2022 PDUFA action date. In May 2022, we discontinued development of CHS-305, an Avastin biosimilar candidate. We have built an experienced and robust oncology market access, key account management and medical affairs capability in the United States, supporting the successful commercialization of UDENYCA. We expect to leverage these capabilities as we build and launch our immuno-oncology franchise.

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

Business Update

Tranche D Loan

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. The Tranche D Loan of the 2027 Term Loans funded an aggregate principal amount of $50.0 million on September 14, 2022, in connection with the FDA approval of the BLA for CIMERLI. The principal amount outstanding on our 2027 Term Loans is $250.0 million as of September 30, 2022.

CIMERLI – Genentech Agreement

On June 22, 2022, we entered into a license agreement with Genentech, Inc. ("Genentech") and our partner Bioeq (the "Genentech Agreement"). Under the agreement, Genentech granted us and Bioeq a non-exclusive, royalty-bearing, license under certain of its patent rights to commercially launch and sell CIMERLI in the United States which started on the launch date on October 3, 2022. Pursuant to the terms of the Genentech Agreement, the royalty is a low single-digit percentage of net sales of CIMERLI that must be paid through December 13, 2023. In addition, we obtained the right to make non-binding offers to sell and engage in manufacturing and stockpiling activities during specified time periods prior to the launch date pursuant to the terms of the Genentech Agreement. The term of the Genentech Agreement will expire when all of the valid claims in the patent rights licensed under the agreement expire. The agreement may be terminated by either party if a party materially breaches one or more of its material obligations, subject to customary cure period. If we, Bioeq or either party's respective affiliates initiate, participate, or assist any other person in bringing or prosecuting any challenge to the validity of any patent rights licensed under the Genentech Agreement, Genentech may terminate the licenses granted under such licensed patent rights or terminate the Genentech Agreement in its entirety, unless we, Bioeq, or the applicable affiliates withdraw all such challenges or stop assisting in any such challenges. Genentech may also terminate the agreement in the event of our insolvency.

Products and Product Candidates

Our portfolio includes the following products and product candidates:

Oncology

- UDENYCA is a biosimilar to Neulasta, a long-acting G-CSF. We launched UDENYCA commercially in the United States in January 2019 following approval by the FDA in November 2018. In the first nine months of 2022, we recorded $165.7 million of net revenue, primarily from sales of UDENYCA. In addition to the currently marketed pre-filled syringe ("PFS") presentation, we are also developing additional presentations of UDENYCA, such as a proprietary on-body injector ("OBI"). In October 2021, we announced positive results from a randomized, open-label, crossover study assessing the pharmacokinetic and pharmacodynamic bioequivalence of UDENYCA administered via OBI compared to our currently marketed UDENYCA PFS. We are planning a 2023 launch of UDENYCA OBI, if approved by the FDA.

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

  Together with Junshi Biosciences, in the third quarter of 2021 we completed the submission of the original BLA for toripalimab to the FDA seeking approval for the use of toripalimab in combination with gemcitabine and cisplatin for first-line treatment of adults with metastatic or recurrent locally advanced NPC, and for use

as a monotherapy in the second- or later-line treatment of patients with recurrent unresectable or metastatic NPC that have progressed on or after a platinum-containing chemotherapy. The FDA issued a CRL for the original BLA for toripalimab requesting certain manufacturing process changes. On July 6, 2022, we announced that the FDA accepted the resubmission of the original BLA for toripalimab. The FDA has set a PDUFA action date for December 23, 2022. We are still working with the FDA to set a date for a required inspection in China. We plan to launch toripalimab in the United States in the first quarter of 2023, if approved by the December 23, 2022 PDUFA action date. We believe there is potentially a high unmet need in NPC based on the current FDA-approved treatment alternatives and the lack of any approved immunotherapies.

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

- CHS-006 is an investigational recombinant humanized 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 could be a crucial underlying mechanism for tumor immune evasion and resistance to PD-1 blockade therapy in some tumor types. Combination of TIGIT and PD-1/PD-L1 antibodies showed a synergistic potential to enhance antitumor response, to overcome anti-PD-1 resistance and possibly broaden the cancer patient population that can benefit from immunotherapy.

  A dose escalation, dose expansion clinical trial (clinicaltrials.gov identifier# NCT05061628) evaluating the safety, tolerability and pharmacokinetic properties of CHS-006 as monotherapy and in combination with PD-1 inhibitor toripalimab in patients with advanced solid tumors is ongoing in China. The FDA has allowed clinical trials for CHS-006 to proceed in the United States under an IND, and we plan to advance toripalimab in combination with CHS-006 in a clinical trial in North America later in 2022 or early 2023.

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

Immunology

- YUSIMRY (adalimumab-aqvh), is a biosimilar of Humira, a monoclonal antibody that can bind to tumor necrosis factor ("TNF"). YUSIMRY provides certain therapeutic benefits for treatment of patients with certain inflammatory diseases characterized by increased production of TNF in the body, including rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn’s disease, psoriasis and ulcerative colitis. In December 2021, the FDA approved YUSIMRY, which we plan to launch in the United States on or after July 1, 2023, per the terms of an agreement with Humira manufacturer, AbbVie. We are developing high-concentration formulations of YUSIMRY.

Ophthalmology

- CIMERLI (ranibizumab-eqrn), formerly known as CHS-201, is a Lucentis biosimilar. In November 2019, we entered into a license agreement with Bioeq for the commercialization of CIMERLI, a biosimilar version of ranibizumab (Lucentis) in certain dosage forms in both a vial and PFS presentation. Under this 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 (ranibizumab-eqrn) 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. The FDA also granted CIMERLI 12 months of interchangeability exclusivity. On October 3, 2022, we launched CIMERLI commercially in the United States in both 0.3 mg and 0.5 mg dosage forms. CIMERLI achieved leading biosimilar market share within the first four weeks of launch. The launch of CIMERLI builds on the success we demonstrated with UDENYCA, our first product, that also rapidly overtook a large, first-to-market competitor.

Discontinued Product Candidates

In January 2020, we entered into a license agreement with Innovent for the development and commercialization of a biosimilar version of bevacizumab (Avastin) in any dosage form and presentations in the United States and Canada. On May 3, 2022, we provided notice of termination of the License Agreement to Innovent pursuant to Section 13.6 of the License Agreement to discontinue development of CHS-305, a bevacizumab (Avastin) biosimilar candidate, because regulatory approval of the licensed product could not be reasonably obtained within the agreed time period.

In October 2022, we discontinued development of our preclinical immuno-oncology program, CHS-3318, an antibody targeting CCR8, in order to focus on external molecules targeting CCR8.

License Agreement with Junshi Biosciences

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

Under the terms of the Collaboration Agreement, we obtained exclusive rights to toripalimab in the United States and Canada, an option in these territories to Junshi Biosciences' anti-TIGIT antibody CHS-006, an option in these territories to a next-generation engineered IL-2 cytokine, and certain negotiation rights to two undisclosed preclinical immuno-oncology drug candidates. We will have the right to conduct all commercial activities of toripalimab in the United States and Canada. We will be obligated to pay Junshi Biosciences a 20% royalty on net sales of toripalimab and up to an aggregate $380.0 million in one-time payments for the achievement of various regulatory and sales milestones.

In March 2022, we paid $35.0 million for the exercise of our option to license CHS-006. We will lead further development of CHS-006 and be responsible for the associated development costs as set forth in the Collaboration Agreement. If we exercise our remaining option for the IL-2 cytokine, we will be obligated to pay an additional option exercise fee of $35.0 million. Additionally, for each exercised option, we will be obligated to pay Junshi Biosciences an 18% royalty on net sales, up to $85.0 million for the achievement of certain regulatory approvals, and up to $170.0 million for attainment of certain sales thresholds. Under the Collaboration Agreement, we retain the right to collaborate in the development of toripalimab and the other licensed compounds, including CHS-006, and will pay for a portion of these co-development activities up to a maximum of $25.0 million per licensed compound per year. Additionally, we are responsible for certain associated regulatory and technology transfer costs for toripalimab and other licensed compounds and will reimburse Junshi Biosciences for such costs. We recognized research and development expense of $7.6 million in the third quarter of 2022 and $67.6 million in the nine months ended September 30, 2022, inclusive of the $35.0 million option fee in the first quarter. Research and development expense was $15.4 million and $173.6 million for the three and nine months ended September 30, 2021, respectively; the nine months ended September 30, 2021 included $136.0 million for the upfront payment for the exclusive rights to toripalimab. Accrued and other current liabilities on the condensed consolidated balance sheet as of September 30, 2022 included $17.5 million related to the co-development, regulatory and technology transfer costs related to these programs.

As of September 30, 2022, we did not have any outstanding milestone or royalty payment obligations to Junshi Biosciences. The additional milestone payments, option fee for the IL-2 cytokine and royalties are contingent upon future events and, therefore, will be recorded when it is probable that a milestone will be achieved, or when an option fee or royalties are incurred.

COVID-19 Update

As a result of the COVID-19 pandemic, we have experienced and may continue to experience disruptions that could severely impact our business, clinical trials and preclinical studies. See “Risk Factors – Risks Related to COVID-19.” These and other factors arising from the COVID-19 pandemic could result in us not being able to maintain UDENYCA’s market position or increase its penetration against all Neulasta’s dosage forms and could result in our inability to meet development or regulatory milestones for our product candidates, each of which would harm our business, financial condition, results of operations and growth. Although cases and deaths from the COVID-19 pandemic have generally declined in the United States recently, spread of COVID-19 in China recently resulted in a protracted lockdown covering all of Shanghai where our partner Junshi Biosciences has its headquarters. The spread of COVID-19 in China may impact the timeline to manufacture toripalimab and the FDA has communicated to us the COVID-19 pandemic will impact the FDA’s ability to conduct foreign inspections of our partner’s manufacturing facilities in China. Until the COVID-19 pandemic is controlled, we expect it may continue to adversely impact our sales growth. In addition, the spread of more contagious and/or deadly variants, such as the omicron subvariant BA.2, could cause the COVID-19 pandemic to last longer than expected and could result in the reinstatement of restrictive orders that could disrupt our business.

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

Financial Operations Overview

Revenue

Our first FDA-approved product, UDENYCA, was approved in November 2018, and we initiated United States sales of UDENYCA on January 3, 2019. In December 2021, the FDA approved YUSIMRY, which we plan to launch in the United States on or after July 1, 2023, per the terms of an agreement with Humira manufacturer, AbbVie. On August 2, 2022, the FDA approved CIMERLI, which we launched on October 3, 2022. Net revenues, primarily from sales of UDENYCA, were $45.4 million and $82.5 million during the three months ended September 30, 2022 and 2021, respectively, and $165.7 million and $253.2 million during the nine months ended September 30, 2022 and 2021, respectively.

Cost of Goods Sold

Cost of goods sold consists primarily of third-party manufacturing, distribution, and certain overhead costs. During the third quarter of 2022, we recorded an inventory write-down of $26.0 million for inventory at risk of expiration. Prior to the second quarter of 2021, a portion of the costs of producing UDENYCA sold was expensed as research and development before the FDA approval of UDENYCA and therefore is not reflected in cost of goods sold. All the inventory expensed prior to approval of UDENYCA was fully utilized by March 31, 2021; thus, the costs of producing UDENYCA are fully reflected in cost of goods sold beginning April 1, 2021. On May 2, 2019, we settled a trade secret action brought by

Amgen 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.

Research and Development Expense

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

- expense incurred under agreements with consultants, third-party contract research organizations (“CROs”), and investigative sites where a substantial portion of our preclinical studies and all of our clinical trials are conducted;
- costs of acquiring originator comparator materials and manufacturing preclinical study and clinical trial supplies and other materials from CMOs, and related costs associated with release and stability testing;
- costs associated with manufacturing process development activities; 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.

Products manufactured prior to regulatory approval may not be sold unless regulatory approval is obtained. For all the periods presented, we expensed manufacturing costs as incurred as research and development expense for products that had not been approved. UDENYCA and YUSIMRY received regulatory approval in November 2018 and December 2021, respectively. In the second quarter of 2022, we began to capitalize YUSIMRY costs and had $24.6 million in inventory recognized on the condensed consolidated balance sheet at September 30, 2022.

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, as well as costs associated with supporting the commercialization of UDENYCA including certain legal disputes and establishing commercial capabilities. 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 debt agreements.

Loss on Debt Extinguishment

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

Results of Operations

Comparison of Three and Nine months ended September 30, 2022 and 2021

Revenue

	Three Months Ended September 30,			Nine Months Ended September 30,		
(in thousands)	**2022**	**2021**	**Change**	**2022**	**2021**	**Change**
Net revenue	$45,424	$82,503	$(37,079)	$165,690	$253,180	$(87,490)

The decrease in net revenue for the three and nine months ended September 30, 2022 compared to the same periods in the prior year was primarily due to decrease in the number of UDENYCA units sold and a reduction in the average net selling price per unit resulting from competition and lower patient enrollment. Our net revenue and market penetration may continue to be adversely impacted by pricing trends and competitive dynamics in the overall pegfilgrastim market. In addition, the COVID-19 pandemic has negatively impacted the pre-filled syringe pegfilgrastim market due to preferences to administer medication at home.

We expect our net revenue to decrease during the remainder of 2022 as compared to the same period in the previous year as a result of increased competition for UDENYCA, with the potential for such decreases to be slightly offset by net revenues from CIMERLI, which launched in early October of 2022.

Cost of Goods Sold

	Three Months Ended September 30,			Nine Months Ended September 30,		
(in thousands)	**2022**	**2021**	**Change**	**2022**	**2021**	**Change**
Cost of goods sold	$35,234	$21,280	$13,954	$55,881	$45,487	$10,394
Gross margin	22 %	74 %		66 %	82 %	

The increase in cost of goods sold for the three and nine months ended September 30, 2022 compared to the same periods in the prior year resulted from the $26.0 million write-down in the third quarter of 2022 of inventory at risk of expiration compared to the $5.2 million write-off of inventory in the third quarter of 2021 for inventory that did not meet acceptance criteria. The increase was partially offset by decreases in the number of UDENYCA units sold as well as lower royalty costs of $1.9 million and $4.4 million for the three and nine months ended September 30, 2022,

respectively. In addition, a portion of the costs of producing UDENYCA sold through the first quarter of 2021 was expensed as research and development prior to the FDA approval of UDENYCA and, therefore, was not reflected in the cost of goods sold. During the first quarter of 2021, the UDENYCA inventory with no inventory value was fully utilized, and since then cost of goods sold fully reflects per unit acquisition cost of UDENYCA. The cost basis of product sold that was expensed prior to approval was $3.3 million in the first quarter of 2021. Had such inventories been valued at acquisition cost, it would have resulted in corresponding increases in cost of goods sold and corresponding decreases in gross margin.

We expect our gross margin for the full year 2022 to be lower than the full year 2021, as a result of declining net realized price per unit of UDENYCA sold, the impact of the third quarter of 2022 write-down of $26.0 million of inventory at risk of expiration and higher average annual costs per unit of UDENYCA sold primarily due to the transition in the first quarter of 2021 from inventory with manufacturing costs that were partly recognized as research and development expenses prior to the regulatory approval of UDENYCA.

Research and Development Expense

	Three Months Ended September 30,			Nine Months Ended September 30,		
(in thousands)	**2022**	**2021**	**Change**	**2022**	**2021**	**Change**
Research and development	$45,808	$54,085	$(8,277)	$170,336	$312,343	$(142,007)

The decrease in research and development expense in the three months ended September 30, 2022 was primarily due to:

- a decrease of $6.5 million in co-development costs for toripalimab and CHS-006;
- a decrease of $3.4 million related to the development of additional presentations of UDENYCA; and
- a decrease of $1.7 million in costs for the development of bevacizumab (Avastin) biosimilar, a former product candidate which we discontinued development in May 2022.

The decrease was partially offset by:

- an increase of $2.7 million related to the development of YUSIMRY mainly due to higher costs in the current year associated with FDA pre-approval inspections and scaling up process performance qualification production runs; and
- an increase of $1.3 million in stock-based compensation expense mainly related to the acceleration of awards to a certain individual and additional expense related to equity awards granted since the third quarter of 2021.

The decrease in research and development expense in the nine months ended September 30, 2022 was primarily due to:

- higher license fees in the first nine months of 2021, including $145.0 million in expense pursuant to the Collaboration Agreement with Junshi Biosciences in February 2021, which was partially offset by a $9.0 million credit related to the fair value of the DLOM on the common shares purchased under the Stock Purchase Agreement, as compared to the first nine months of 2022 which included an upfront payment of $35.0 million to exercise our option to license CHS-006, a TIGIT-targeted antibody, in the United States and Canada;

- a decrease of $13.6 million related to the development of additional presentations of UDENYCA;
- a decrease of $11.5 million in costs related to CHS-2020 due to the discontinuation of its development in the first quarter of 2021;
- a decrease of $8.0 million in costs for the development of bevacizumab (Avastin) biosimilar, a former product candidate which we discontinued development in May 2022; and
- a decrease of $7.6 million related to the development of YUSIMRY mainly due to higher costs in the prior year associated with FDA pre-approval inspections and scaling up process performance qualification production runs.

The decrease was partially offset by an increase of $1.1 million in personnel and consulting costs to advance our research and development programs.

We expect our research and development expense for the full year 2022 to be lower than the prior year because 2021 included $136.0 million of expense for the upfront license with Junshi Biosciences.

Selling, General and Administrative Expense

	Three Months Ended September 30,			Nine Months Ended September 30,		
(in thousands)	**2022**	**2021**	**Change**	**2022**	**2021**	**Change**
Selling, general and administrative	$ 44,831	$ 39,925	$ 4,906	$144,860	$119,661	$25,199

The increase in selling, general and administrative expense for the three months ended September 30, 2022 was primarily due to an increase of $4.0 million for personnel, consulting, professional services, marketing, advertising and other expenses resulting from an increase in sales force and related commercial functions to support our product sales.

The increase in selling, general and administrative expense for the nine months ended September 30, 2022 was primarily due to the following:

- an increase of $21.4 million for personnel, consulting, professional services, marketing, advertising and other expenses resulting from an increase in sales force and related commercial functions to support our product sales;
- an increase of $2.5 million in facilities, supplies and materials and other infrastructure related expenses to support our commercial infrastructure for our products; and
- an increase of $2.4 million in travel expenses as a result of curtailed travel in 2021 due to COVID-19.

The increase in selling, general and administrative expense for the nine months ended September 30, 2022 was partially offset by a decrease of $1.1 million in stock-based compensation expense resulting from the grant of fully vested stock options to certain employees and consultants upon the execution of the Collaboration Agreement with Junshi Biosciences in 2021.

We expect our selling, general and administrative expense in the fourth quarter of 2022 to be higher than in the same period in 2021, as a result of increased commercial headcount and activities to support the launch of CIMERLI which occurred on October 3, 2022 and expenses incurred in connection with preparation activities for the planned launch of YUSIMRY in 2023.

Interest Expense

(in thousands)	Three Months Ended September 30, 2022	2021	Change	Nine Months Ended September 30, 2022	2021	Change
Interest expense	$ 7,540	$ 5,771	$ 1,769	$ 23,089	$ 17,166	$ 5,923

The increase in interest expense for the three months ended September 30, 2022 was primarily due to the third quarter of 2022 having a higher average outstanding debt balance with a higher weighted-average interest rate than the third quarter of 2021.

The increase in interest expense for the nine months ended September 30, 2022 was due to $3.6 million of interest expense in the nine months of 2022 related to the 2027 Term Loan discount and debt issuance costs that was allocated to unfunded tranches and then amortized over the respective commitment periods for the tranches, including $2.3 million allocated to Tranche B that was fully amortized in the first quarter of 2022. In addition, the first nine months of 2022 had a higher average outstanding debt balance and interest rate hikes in the U.S. in 2022 has led to a higher weighted-average interest rate in the first nine months of 2022 as compared to the first nine months of 2021.

Our 2027 Term Loans have a variable interest rate component that resets the first day of every quarter and resulted in a 10.54% interest rate for Tranches A and B applicable for the third quarter of 2022 which increased to 12.00% on October 1, 2022. As a result of the higher interest rate and the $50.0 million in additional borrowings drawn through the Tranche D Loan in September 2022, we expect higher interest expense in the fourth quarter than the third quarter of 2022.

Loss on debt extinguishment

(in thousands)	Nine Months Ended September 30, 2022	2021	Change
Loss on debt extinguishment	$ 6,222	$ —	$ 6,222

The $6.2 million loss on debt extinguishment recorded in the nine months ended September 30, 2022 resulted from voluntarily prepaying all amounts outstanding under the 2025 Term Loan in January 2022.

Liquidity and Capital Resources

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

(in thousands)	September 30, 2022	December 31, 2021
Financial assets		
Total Cash, cash equivalents and marketable securities	$ 286,805	$ 417,195
Debt obligations:		
2027 Term Loans	$ 245,246 (1)	$ —
2025 Term Loan	—	75,513 (1)
2022 Convertible Notes	—	108,479 (1)
2026 Convertible Notes	225,250	224,288
Total debt obligations	$ 470,496	$ 408,280

(1) The 2027 Term Loans were entered into during the first nine months of 2022 in connection with the payoff and refinancing of existing debt facilities. See below for further discussion and Note 7. Debt Obligations in the Notes to Condensed Consolidated Financial Statements contained in Part I, Item 1 of this Quarterly Report on Form 10-Q.

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

As of September 30, 2022, we had an accumulated deficit of $1.3 billion and cash, cash equivalents, and marketable securities of $286.8 million. We believe that our available cash, cash equivalents, marketable securities, cash collected from product sales and additional funding available under the 2027 Term Loan Agreement 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.

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 to be funded at our option between April 1, 2022 and March 17, 2023, subject to certain conditions including the first FDA approval of a BLA for our product candidate CHS-007 (toripalimab) in the United States; 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 bear interest at 8.25% plus three-month LIBOR per annum with a LIBOR floor of 1.00%. In the event of the cessation of LIBOR, the benchmark governing the interest rate will be replaced with a rate based on the secured overnight financing rate published by the Federal Reserve Bank of New York as described in the 2027 Term Loans agreement. 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 and will be used to fund our general corporate and working capital requirements except for the following: in January 2022, proceeds of the Tranche A Loan were used to voluntarily repay in full all amounts outstanding under the 2025 Term Loan, as well as all associated costs and expenses; and proceeds of the Tranche B Loan were drawn in connection with the full repayment of our 2022 Convertible Notes due in March 2022.

2025 Term Loan

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

2022 Convertible Notes

As of December 31, 2021, the carrying amount of our $100.0 million aggregate principal amount convertible senior notes due March 31, 2022 was $108.5 million, inclusive of a 9% premium due at maturity or redemption, if not earlier converted. During the first quarter 2022, we fully repaid these notes, and in connection with the repayment, drew $100.0 million from the Tranche B Loan of the 2027 Term Loans. Excluding accrued interest, the payoff amount of the 2022 Convertible Notes was $109.0 million.

2026 Convertible Notes

As of September 30, 2022, the carrying amount of our $230.0 million aggregate principal amount convertible senior subordinated notes due 2026 was $225.3 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 $14.815 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 30, 2022, the holders of the 2026 Convertible Notes would have received common shares with an aggregate value of $114.8 million based on the Company's closing stock price of $9.61.

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 the Company's common stock of $14.815 per share on April 14, 2020, and is subject to certain adjustments under the terms of the capped call transactions

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. As of September 30, 2022, the €2.5 million milestone to Bioeq related to the FDA approval of the CIMERLI Section 351(k) BLA milestone was determined to be probable of becoming due and payable and thus accrued in other current liabilities on the condensed consolidated balance sheet. Because the achievement of other milestones had not reached the threshold for recognition as of September 30, 2022, 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:

Counterparty	Description	Potential Aggregate Milestone Amounts
Junshi Biosciences	Toripalimab	$380.0 million (1)
	CHS-006 anti-TIGIT antibody	$255.0 million (2)
Bioeq	CIMERLI	€12.5 million (3)

(1) The FDA issued a CRL for the original BLA we had submitted for toripalimab requesting a quality process change that we and Junshi Biosciences believe is readily addressable. On July 6, 2022, we announced that the FDA accepted the resubmission of the original BLA for toripalimab. The FDA has set a PDUFA action date for December 23, 2022. If such regulatory approval is achieved, we will be required to pay Junshi Biosciences a milestone payment of $25.0 million.

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

(3) The €12.5 million potential aggregate milestone amount includes a €2.5 million milestone amount related to the FDA approval of the CIMERLI Section 351(k) BLA, which occurred on August 2, 2022, and certain other criteria, that were satisfied in October 2022. The obligation to pay this €2.5 million milestone amount was recorded in accrued and other current liabilities on the condensed consolidated balance sheet as of September 30, 2022.

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, 2022 were $40.2 million, as outlined in Note 8. 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 or contingent payment to InteKrin stockholders during the nine months ended September 30, 2022, as compared to the discussion in the 2021 Form 10-K.

Summary Statement of Cash Flows

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

	Nine Months Ended September 30,	
(in thousands)	**2022**	**2021**
Net cash (used in) provided by operating activities	$ (141,171)	$ 14,890
Net cash used in investing activities	(36,952)	(245,900)
Net cash provided by financing activities	47,733	50,392
Net decrease in cash, cash equivalents and restricted cash	$ (130,390)	$ (180,618)

Net cash (used in) provided by operating activities

Cash used in operating activities was $141.2 million for the nine months ended September 30, 2022, which was primarily due to the following:

- net loss of $232.9 million;
- a net increase in inventory of $37.6 million, excluding the $26.0 million inventory write-down in the third quarter of 2022 for inventory at risk of expiration, primarily due to production of YUSIMRY inventory in anticipation of that product's planned July 2023 launch and continuing to maintain adequate supplies of our other products to meet future demand;
- a decrease in accrued rebates, fees and reserves of $25.0 million as a result of lower UDENYCA sales;
- an increase in other prepaid, current and non-current assets of $12.5 million primarily due to timing of clinical services and payments for insurance, software implementation costs, debt issuance fees, and other services;
- an increase in prepaid manufacturing of $7.0 million primarily due to prepaid contract manufacturing related to our research and development programs; and
- a decrease in accounts payable of $6.1 million primarily due to the timing of receiving and processing invoices from our vendors.

The cash used in operating activities for the nine months ended September 30, 2022 was partially offset by the following:

- the reclassification of cash flows associated with the license fee payment of $35.0 million to exercise our option to license CHS-006 to investing activities in the condensed consolidated statement of cash flows;

- an increase in accrued and other current and non-current liabilities of $32.3 million primarily due to amounts accrued to Junshi Biosciences and Bioeq pursuant to the Collaboration Agreement and Bioeq License Agreement, respectively, as well as contract manufacturing accruals, clinical and regulatory accruals related to our research and development programs and other accrued liabilities;

- a decrease in trade receivables of $31.8 million primarily due to lower revenue in 2022 and the timing of payments from our customers; and

- non-cash charges related to stock-based compensation of $39.0 million, write-down of inventory at risk of expiration of $26.0 million, loss on debt extinguishment of $6.2 million, non-cash interest expense from amortization of debt discount and issuance costs of $5.6 million, depreciation and amortization of property and equipment of $2.6 million, and other non-cash adjustments of $1.8 million.

Cash provided by operating activities was $14.9 million for the nine months ended September 30, 2021, which was primarily due to the following:

- the reclassification of cash flows associated with the license fee payment to Junshi Biosciences of $145.0 million pursuant to the Collaboration Agreement, partially offset by a $9.0 million adjustment related to the fair value of the DLOM on our common stock purchased by Junshi Biosciences, to investing activities in the condensed consolidated statement of cash flows to provide better alignment between the cash flows and the underlying nature of the transactions;

- an increase in accounts payable of $30.5 million primarily due to the timing of receiving and processing invoices from our vendors and amounts payable to Junshi Biosciences pursuant to the Collaboration Agreement;

- a decrease in trade receivables of $20.7 million primarily due to the timing of payments from our customers and lower revenue in 2021;

- an increase in accrued and other current and non-current liabilities of $16.5 million primarily due to clinical, regulatory and manufacturing accruals related to our research and development programs, partially offset by lower contract manufacturing accruals for UDENCYA;

- an increase in accrued rebates, fees and reserves of $3.2 million as a result of higher rebates per unit and timing of rebate payments;

- a decrease in inventory of $2.9 million primarily driven by inventory depletion due to the timing of our manufacturing campaign for UDENYCA that planned for a level of sales of UDENYCA that were not achieved; and

- non-cash charges related to stock-based compensation of $40.4 million, a $5.2 million write-off of inventory that did not meet our acceptance criteria, write-off of prepaid manufacturing services of $3.2 million related to the termination of CHS-2020 development, non-cash interest expense from amortization of debt discount and issuance costs of $3.2 million, depreciation and amortization of property and equipment of $2.6 million, and other non-cash adjustments of $2.7 million.

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

- net loss of $241.4 million;
- an increase in other prepaid, current and non-current assets of $4.6 million primarily due to timing of clinical services and payments for interest, insurance and other services;
- a decrease in accrued compensation of $3.5 million primarily due to the payment of 2020 employee bonuses, which was partially offset by an increase in ESPP contributions and the additional bonus accrual for the nine months ended September 30, 2021; and
- an increase in prepaid manufacturing services of $2.9 million primarily due to increased prepaid contract manufacturing related to our research and development programs partially offset by lower prepaid commercial manufacturing services.

Net cash used in investing activities

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.

Cash used in investing activities of $245.9 million for the nine months ended September 30, 2021 was primarily due to the upfront license fee of $145.0 million to Junshi Biosciences pursuant to the Collaboration Agreement, partially offset by a $9.0 million adjustment related to the fair value of the DLOM on our common stock purchased by Junshi Biosciences, purchases of investments in marketable securities of $171.8 million and purchases of property and equipment of $0.8 million, partially offset by proceeds from maturities of investments in marketable securities of $62.7 million.

Net cash provided by financing activities

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.

Cash provided by financing activities of $50.4 million for the nine months ended September 30, 2021 was primarily due to $50.0 million of gross proceeds from issuance of our common stock to Junshi Biosciences partially offset by a credit of $9.0 million related to the fair value of the DLOM on the common stock purchased by Junshi Biosciences, $9.7 million proceeds from the exercise of stock options, and $2.0 million proceeds from purchases under the ESPP, partially offset by $1.7 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.

There have been no significant changes to our critical accounting estimates during the nine months ended September 30, 2022, as compared to the critical accounting estimates described in our 2021 Form 10-K. We believe that the critical accounting estimates discussed in the 2021 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. During the third quarter of 2022, we recorded an inventory write-down of $26.0 million for inventory at risk of expiration (see Note 4. Inventory in the Notes to Condensed Consolidated Financial Statements contained in Part 1, Item 1 of this Quarterly Report on Form 10-Q).

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

As of September 30, 2022, we had cash and cash equivalents of $286.8 million. A portion of our cash equivalents, which are in money market funds, may be subject to interest rate risk and could fall in value if market interest rates increase. However, because our cash equivalents are primarily short-term in duration, we believe that our exposure to interest rate risk on these investments is not significant and a 1% movement in market interest rates would not have a significant impact on the total value of our portfolio.

We are exposed to interest rate risk with respect to variable rate debt. As of September 30, 2022, we had $250.0 million principal outstanding on our 2027 Term Loans that bears interest at a rate equal to the 3-month LIBOR, subject to a 1% floor, plus 8.25% per year. We are monitoring risks from potential future interest rate increases. We currently do not hedge our variable interest rate debt. The interest rate for our variable rate debt during the quarter ended September 30, 2022 ranged between 10.54% to 11.73%, and the interest rate during the fourth quarter of 2022 will be 12.00% based on the 3-month LIBOR on October 1, 2022. 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, 2022.

All of our sales and most of our inventory purchases 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 our partner Bioeq that are denominated in the Euro and we are therefore subject to fluctuations due to changes in foreign currency exchange rates. Accordingly, fluctuations in the exchange rate between the U.S. Dollar and the Euro may impact our condensed consolidated statements of operations. We currently do not hedge foreign currency exposure related to fluctuations in the exchange rate between the U.S. Dollar and the Euro.

ITEM 4. Controls and Procedures

Evaluation of Effectiveness of Disclosure Controls and Procedures

We carried out an evaluation, under the supervision of our Chief Executive Officer and our Chief Financial Officer, and evaluated the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of the end of the period covered by this 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.

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.

We substantially completed the implementation of our new Enterprise Resource Planning ("ERP") system in August 2022. The implementation of that ERP system is expected to, among other things, upgrade a number of business, operational and financial processes as well as decrease the number of manual processes previously required. Except for the implementation of the new ERP system, 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 8. 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 two products that have been approved and marketed, with multiple products either approved and not yet marketed or not approved and still in development.

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

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

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

- As we have in-licensed development and/or commercial rights to toripalimab and CHS-006, we rely on prior and ongoing preclinical, clinical, regulatory and manufacturing expertise of our collaborators in order to advance these product candidates through regulatory approvals in the United States and other licensed territories.

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

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

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

the originator products. Toripalimab and CHS-006, if approved, face 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 toripalimab, CHS-006 and any other immuno-oncology products, if approved, will depend on our ability to successfully transition our company's clinical, commercial, manufacturing, regulatory, marketing and general historical focus on biosimilars to a new strategy to build a leading immuno-oncology franchise funded with cash generated by our commercial biosimilar business.

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

- Healthcare reform measures, including the 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 product candidates and presentations could substantially increase our costs and limit supply for our product candidates.

- The continuation of the war between Russia and Ukraine may exacerbate certain risks we face.

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

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

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

Risk Factors

Investing in the common stock of a biopharmaceutical company, including one with significant international partnerships and multiple products in development, is a highly speculative undertaking and involves a substantial degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information in this 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 the Company. Risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition, results of operations and/or prospects.

Risks Related to Our Financial Condition and Capital Requirements

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

We incurred net losses in each year from our inception in September 2010 through December 31, 2018, including a net loss of $287.1 million in 2021 and $232.9 million for the nine months ended September 30, 2022. However, while we did generate net income of $132.2 million and $89.8 million in 2020 and 2019, respectively, it is uncertain that we will be profitable in future periods as research and development is expensive and risky. The amount of our future net losses or 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, 2022, we had an accumulated deficit of $1.3 billion. The losses and accumulated deficit were primarily due to the substantial investments we made to identify, develop or license our product candidates, including conducting, among other things, analytical characterization, process development and manufacturing, formulation and clinical studies and providing general and administrative support for these operations.

We anticipate we will incur certain development and pre-commercial expenses for toripalimab, the anti-PD-1 antibody we licensed from Junshi Biosciences in 2021, and have agreed to pay up to $85.0 million for the achievement of certain regulatory approvals and up to $170.0 million for the attainment of certain sales thresholds. Advancing this and our other product candidates through clinical development will be expensive and could result in us continuing to experience future net losses.

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

Our expenses will increase substantially if and as we:

- further develop our sales, marketing and distribution infrastructure for our current products and develop such infrastructure for new products once they are launched;
- establish a sales, marketing and distribution infrastructure to commercialize any of our product candidates for which we may obtain marketing approval;
- make upfront, milestone, royalty or other payments under any license agreements;

- continue our nonclinical and clinical development of our product candidates;
- initiate additional nonclinical, clinical or other studies for our product candidates;
- expand the scope of our current clinical studies for our product candidates;
- advance our programs into more expensive clinical studies;
- change or add contract manufacturers, clinical research service providers, testing laboratories, device suppliers, legal service providers or other vendors or suppliers;
- seek regulatory and marketing approvals for our product candidates that successfully complete clinical studies;
- seek to identify, assess, acquire and/or develop other product candidates or products that may be complementary to our products;
- seek to create, maintain, protect and expand our intellectual property portfolio;
- engage legal counsel and technical experts to help us evaluate and avoid infringing any valid and enforceable intellectual property rights of third parties;
- 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, 2022, our cash and cash equivalents were $286.8 million. We expect that our existing cash and cash equivalents and cash collected from our product sales will be sufficient to fund our current operations for the foreseeable future. We have financed our operations primarily through the sale of equity securities, convertible notes, credit facilities, license agreements and through recent product sales of our products.

However, our operating or investing plans may change as a result of many factors that may currently be unknown to us, and we may need to seek additional funds sooner than planned. Our future funding requirements will depend on many factors, including but not limited to:

- our ability to continue to successfully commercialize our products;

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

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders, and the issuance of additional securities, whether equity or debt, by us or the possibility of such issuance may cause the market price of our shares to decline. The sale of additional equity or convertible securities would dilute the share ownership of our existing stockholders. The incurrence of indebtedness could result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as those contained in our Loan Agreement, 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 referenced as Exhibit 10.31 to our 2021 Annual Report on Form 10-K. We could also be required to seek funds through arrangements with collaborative partners or otherwise at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or for specific strategic considerations.

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

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

To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an “ownership change” (generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a rolling three-year period), such corporation’s ability to use its pre-change net operating loss carryforwards (“NOLs”) and other pre-change tax attributes (such as research tax credits) to offset its post-change income or taxes may be limited. We have experienced ownership changes in the past and may experience ownership changes in the future (some of which changes are outside our control). As a result, if we earn net taxable income, our ability to use our pre-change NOLs to offset such taxable income may be subject to limitations. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In

addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, 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 products. Although we have received upfront payments, milestone and other contingent payments and/or funding for development from some of our collaboration and license agreements, our only approved products include UDENYCA, YUSIMRY and CIMERLI which are approved for commercialization in the United States, and we have no products approved in any other territories.

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

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

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

- our ability to continue to successfully commercialize UDENYCA product presentations and CIMERLI;
- our ability to successfully launch and commercialize YUSIMRY;
- competing against numerous current and future pegfilgrastim 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 our 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 indication approved by regulatory authorities is narrower than we expect or the reasonably accepted population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. If we are unable to successfully complete development and obtain additional regulatory approval for our products, our business may suffer.

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

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

- the safety and efficacy of the product, as demonstrated in clinical studies, and potential advantages over competing treatments;
- the prevalence and severity of any side effects and any limitations or warnings contained in a product's approved labeling;
- the clinical indications for which approval is granted;
- for our immuno-oncology product candidates, our ability to compete in a competitive immuno-oncology market that may differ from the biosimilar market;
- inclusion, in either parity or better position, on commonly accepted clinical guidelines or pathways that influence prescribing patterns and/or affect reimbursement;
- for our biosimilar product candidates, the possibility that a competitor may achieve interchangeability and we may not;
- relative convenience, ease of administration and any real or perceived benefit from administration at home as opposed to in the clinic;
- policies and practices governing the naming of biosimilar product candidates;
- prevalence of the disease or condition for which the product is approved;
- the cost of treatment, particularly in relation to competing treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support and timing of market introduction of competitive products;
- the extent to which the product is approved for inclusion on formularies of hospitals, integrated delivery networks and managed care organizations;
- publicity concerning our products or competing products and treatments;

- the extent to which third-party payers (including government and national/regional commercial plans) provide adequate third-party coverage and reimbursement for our products and product candidates, if approved;
- the price at which we sell our products;
- the potential impact of the IRA on the pharmaceutical industry and the market for biosimilars;
- the actions taken by current and future competitors to delay, restrict or block customer usage of the product; and
- our ability to maintain compliance with regulatory requirements.

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

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

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

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

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

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, the U.S. Centers for Medicare & Medicaid Services (“CMS”) assigned a product specific Q-Code to UDENYCA, which is necessary to allow UDENYCA to have its own reimbursement rate with Medicare or other third-party payers. However, reimbursement is not guaranteed and rates may vary based on product life cycle, site of care, type of payer, coverage decisions, and provider contracts. Furthermore, while payers have adopted the Q-Code assigned by CMS for UDENYCA, there remains uncertainty as to whether such payers will continue to cover and pay providers for the administration and use of the product with each patient or may favor a competing product. If our products or any of our future product candidates, are not covered or adequately reimbursed by third-party payers, including Medicare, then the cost of the relevant product may be absorbed by healthcare providers or charged to patients. If this is the case, our expectations of the pricing we expect to achieve for such product and the related potential revenue, may be significantly diminished.

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

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

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

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

Manufacturers and manufacturers' facilities are required to comply with extensive FDA, and comparable foreign regulatory authority, requirements, including ensuring that quality control and manufacturing procedures conform to 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 new drug application ("NDA"), original BLA submitted under Section 351(a) of the Public Health Service Act ("PHSA") ("original BLA"), biosimilar application ("Section 351(k) BLA") or Marketing Authorization Application ("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 or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, and conduct foreign inspections of manufacturing facilities, or otherwise prevent new or modified products from being developed, or approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs and biologics or modifications to approved drugs and biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the United States 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, in March 2020, the FDA postponed most inspections of foreign and domestic manufacturing facilities. Subsequently, in July 2020, the FDA resumed certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA utilized this risk-based assessment system to assist in determining when and where it was safest to conduct prioritized domestic inspections. Additionally, on April 15, 2021, the FDA began conducting voluntary remote interactive evaluations of certain drug manufacturing facilities and clinical research sites, among other facilities in circumstances where the FDA determines that such remote evaluation would be appropriate based on mission needs and travel limitations. In July 2021, the FDA resumed standard inspectional operations of domestic facilities. Since that time, 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. 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 continue in regions such as China, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, including in China

where we partner with Junshi Biosciences for toripalimab, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. For example, in the CRL we received from the FDA for toripalimab, the FDA indicated that the review period for the resubmission of the original BLA for toripalimab would be impacted by travel restrictions and closures occurring in China as a result of the COVID-19 pandemic. While the FDA provided an initial estimate of such timing impacts, the ultimate delay could be substantially more for reasons outside of our control.

Risks Related to COVID-19

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

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

- decreased sales of our products;
- our ability to compete with Neulasta Onpro® during the period of time when the UDENYCA on-body injector is not approved and is not commercially available if a large number of patients demonstrate a preference to administer medication at home due to COVID-19, other viral pandemics, convenience or other factors;
- our ability to maintain or expand the commercial use of our products due to, among other factors, healthcare providers, payers and patients not utilizing or adopting our products due to resources being strained or otherwise focused on the COVID-19 pandemic and our sales team efficacy in selling our products being limited due to such strained resources or other factors such as travel restrictions;
- fewer individuals undertaking or completing cancer treatments, or participating in clinical trials, whether due to contracting COVID-19, self-isolating or quarantining to lower the risk of contracting COVID-19 or being unable to access care as a result of healthcare providers tending to COVID-19 patients;
- our third-party contract manufacturers and logistics providers not being able to maintain adequate (in amount and quality) supply to support the commercial sale of our products or the clinical development of our product candidates due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- delays and difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff, as well as delays or difficulties in enrolling patients or maintaining enrolled patients in our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by foreign, federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures (particularly any procedures that may be deemed non-essential), which may impact the integrity of subject data and clinical study endpoints;
- interruption or delays in the operations of the FDA and comparable foreign regulatory agencies, which may impact regulatory review and approval timelines;
- limitations on our employee resources, and those of our business partners, that would otherwise be focused on the conduct of our business in all aspects, including because of sickness or fear of sickness of employees or their families; and
- negative impact from government orders, quarantines and similar government orders and restrictions.

These and other factors arising from the COVID-19 pandemic could result in us not being able to maintain UDENYCA's market position or increase its penetration against all of Neulasta's dosage forms, achieve a successful launch

of new products, and could result in our inability to meet development milestones for our product candidates, each of which would harm our business, financial condition, results of operations and growth.

Numerous state and local jurisdictions have imposed, and others in the future may impose, "shelter-in-place" orders, quarantines, executive orders and similar government orders and restrictions for their residents to control the spread of COVID-19. Multiple times in 2021, the governor of California, where our headquarters and laboratory facilities are located, issued a "shelter-in-place" order restricting non-essential activities, travel and business operations for an indefinite period of time, subject to certain exceptions for necessary activities. Such orders or restrictions have resulted in our headquarters closing for certain periods, slowdowns and delays, travel restrictions and cancellation of events, among other effects, thereby negatively impacting our operations. In addition, there was a lockdown order in all of Shanghai, China in April and May 2022, where our partner Junshi Biosciences has its headquarters. Such orders or restrictions may continue or be re-instated, as the case may be, thereby causing additional negative impact on our operations. Further, because the full rollout of COVID-19 vaccines and booster doses has suffered from reluctance from eligible individuals to be fully inoculated, the COVID-19 pandemic may last longer than expected and could result in additional outbreaks that prompt additional closings. In addition, the spread of more contagious and deadly variants, such as the Delta variant and the omicron variant, could cause the COVID-19 pandemic to last longer or be more severe than expected. We have no ability to predict the future spread of severe and deadly pandemics that could disrupt our business and materially impact our financial position.

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

Risks Related to Competitive Activity

Our biosimilar products or our biosimilar product candidates, if approved, face significant competition from the reference products and from other biosimilar products or pharmaceuticals approved for the same indication as the originator products. Toripalimab and CHS-006, if approved, 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, obtain patents, develop, test and obtain regulatory approvals for products, as well as an ability to effectively commercialize, market and promote approved products. Numerous companies, universities and other research institutions are engaged in developing, patenting, manufacturing and marketing of products competitive with those that we are developing. Many of these potential competitors are large, experienced multinational pharmaceutical and biotechnology companies that enjoy significant competitive advantages, such as substantially greater financial, research and development, legal, governmental affairs, manufacturing, personnel, marketing resources, and the benefits of mergers and acquisitions.

UDENYCA faces competition in the United States from Amgen, Mylan N.V. (with partner Viatris / Biocon), Sandoz International GmbH ("Sandoz"), Pfizer Inc. ("Pfizer"), and may face competition from Amneal Pharmaceuticals, Inc. ("Amneal") and Fresenius Medical Care AG & Co. KGaA ("Fresenius"), companies that have pegfilgrastim biosimilars that were recently approved by the FDA.

CIMERLI, our ranibizumab (Lucentis) biosimilar product licensed from Bioeq, faces competition in the United States from Genentech (the manufacturer of Lucentis), Regeneron Pharmaceuticals, Inc. ("Regeneron"), and Biogen Inc., among others. Xbrane Biopharma AB ("Xbrane") (in collaboration with STADA Arzneimittel AG and Bausch & Lomb Incorporated) has also disclosed the development of a Lucentis biosimilar candidate.

Similarly, YUSIMRY may face competition from AbbVie (the manufacturer of Humira) as well as manufacturers of Humira biosimilars such as Pfizer, Boehringer Ingelheim GmbH ("Boehringer Ingelheim"), Amgen, Sandoz, Alvotech and Samsung Bioepis. Boehringer Ingelheim's biosimilar was approved as interchangeable of Humira which means that pharmacists may provide it instead of Humira without a specific prescription. There is no guarantee that YUSIMRY will be approved as interchangeable. There are a number of adalimumab biosimilar products that have been approved by the FDA in the United States, and Fujifilm Kyowa Kirin Biologics Co., Ltd. and Fresenius have each received approvals for Humira biosimilars. As a result of continued expected competition from Humira and a large number of potential adalimumab (Humira) biosimilar competitors, we may not be able to achieve substantial topline sales for YUSIMRY in the United States when we launch it as planned in July 2023.

Toripalimab and CHS-006 may face competition from Merck & Company, Inc. ("Merck"), Bristol-Myers Squibb Company ("BMS"), Novartis International AG ("Novartis"), AstraZeneca plc ("AstraZeneca"), Pfizer, Eli Lilly and Company ("Eli Lilly"), Regeneron, EQRx, Inc. and others who currently commercialize PD-1/PD-L1 blocking antibodies or are developing such compounds for commercialization 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 price offerings. It is possible our biosimilar competitors' compliance with price discounting demands in exchange for market share or volume requirements could exceed our capacity to respond in kind and reduce market prices beyond our expectations. 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 biosimilars of ranibizumab (Lucentis) or adalimumab (Humira), are approved and successfully commercialized before our product candidates and products for these originator products, our business would suffer. If other competitors to toripalimab are approved and successfully commercialized before our product candidates and products for these originator products, our business would suffer.

Approvals have already been obtained and we expect additional companies to continue to seek approval to manufacture and market biosimilar versions of Lucentis or Humira. Similarly, there are a number of companies that currently commercialize PD-1/PD-L1 blocking antibodies or are developing such compounds for commercialization in the United States. If other biosimilars of these branded biologics are approved and successfully commercialized before our biosimilar products and product candidates and if other competitors to toripalimab are successfully commercialized before our product candidates, we may never achieve meaningful market share for these products, our revenue would be reduced and, as a result, our business, prospects and financial condition could suffer.

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

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

Biologic reference products may also face competition as technological advances are made that may offer patients a more convenient form of administration or increased efficacy or as new products are introduced. External developments such as the COVID-19 pandemic can also result in changing preferences for convenient forms of administration of products that may impact our business. As new products are approved that compete with the reference product to our biosimilar product candidates, sales of the reference originator product may be adversely impacted or rendered obsolete. If the market for the reference product is impacted, we may lose significant market share or experience limited market potential for our approved biosimilar products or product candidates, and the value of our product pipeline could be negatively impacted. As a result of the above factors, our business, prospects and financial condition could suffer.

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

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

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

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

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

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

We will need to expand and effectively manage our managerial, scientific, operational, financial, commercial and other resources in order to successfully pursue our product development and commercialization efforts. Our success also depends on our continued ability to attract, retain and motivate highly qualified management and technical personnel. We may not be able to attract or retain qualified management and scientific and product development personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses, particularly those located in the San Francisco Bay Area. We also use equity compensation as a part of a comprehensive compensation package for our personnel and to the extent our stock price declines significantly due to a variety of factors outside of our control, our equity compensation packages may not provide the retention and motivation incentive that we believe it should. If we are not able to attract, retain and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

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

As of September 30, 2022, we had 376 employees. As our development and commercialization plans and strategies develop and evolve with our new corporate focus, we expect to need additional managerial, operational, sales, marketing, financial, legal and other resources, particularly those with expertise in immuno-oncology. Further, as we develop and build our immuno-oncology platform, such work could further divert internal resources. Our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities, including building our immuno-oncology platform. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of our current and potential future product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

Risks Related to Reliance on Third Parties

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

We have relied upon and plan to continue to rely upon third-party 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 an exclusive license from Junshi Biosciences to develop and commercialize toripalimab and CHS-006 in the United States and Canada. We have an exclusive license from Bioeq to commercialize CIMERLI in the United States. Our licensors are responsible for supplying us with drug substance and final drug products.

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

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

- our existing and potential collaboration partners may fail to provide sufficient amounts of commercial products, 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 and/or adversely affect perception of us in the business and financial communities; and
- our existing and potential licensees and collaboration partners may choose to pursue alternative, higher priority programs, which could affect their commitment to us.

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

Risks Related to Manufacturing and Supply Chain

We are subject to a multitude of manufacturing risks 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 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, if actual market conditions are less favorable than our projections, then additional write-downs of inventory may be required in the future, 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 December 2015, we entered into a strategic manufacturing agreement with KBI Biopharma for long-term commercial manufacturing of UDENYCA. Because we currently have engaged a limited number of back-up suppliers or vendors for these single-sourced services, and although we believe that there are alternate sources that could fulfill these activities, we cannot assure you that identifying and establishing relationships with alternate suppliers and vendors would not result in significant delay in the development of our product candidates. 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 BLA supplement, NDA supplement or MAA variation or equivalent foreign regulatory filing, which could result in further delay. The regulatory agencies may also require additional studies if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

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

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

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

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 Risk Evaluation and Mitigation Strategy ("REMS"), plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers and/or other elements to assure safe use;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

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

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

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

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

Risks Related to Intellectual Property

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

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

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

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

licensed biosimilar candidates, as well as our pipeline candidates, we cannot guarantee that any of our analyses are complete and thorough, nor can we be sure that we have identified each patent and pending application in the United States and abroad that is relevant or necessary to the commercialization of our product candidates. Moreover, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents covering our product candidates. With respect to products we are evaluating for inclusion in our future product pipeline, our freedom to operate analyses, including our research on the timing of potentially relevant patent expirations, are ongoing.

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

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

On May 10, 2017, Amgen Inc. and Amgen Manufacturing Inc. filed an action against us in the United States District Court for the District of Delaware alleging infringement of one or more claims of Amgen's US patent 8,273,707 (the "'707 patent") under 35 U.S.C. § 271. The complaint seeks injunctive relief, monetary damages and attorney fees. On December 7, 2017, the United States Magistrate Judge issued under seal a Report and Recommendation to the District Court recommending that the District Court grant, with prejudice, our pending motion to dismiss Amgen's complaint for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6). On March 26, 2018, Judge Stark of the District Court adopted the United States Magistrate Judge's Report and Recommendation to grant our motion pursuant to Federal Rule of Civil Procedure 12(b)(6) to dismiss with prejudice the patent infringement complaint alleging

infringement of the ‘707 patent on the grounds that such complaint failed to state a claim upon which relief may be granted. In May 2018, Amgen filed a Notice of Appeal in the United States Court of Appeals for the Federal Circuit. Amgen and Coherus filed briefs in this matter and oral argument was held on May 8, 2019. On July 29, 2019, the Federal Circuit issued a precedential opinion affirming the District Court’s judgment in our favor. The Federal Circuit held that the doctrine of prosecution history estoppel barred Amgen from succeeding on its infringement claim and affirmed the District Court’s dismissal. In a Joint Status Report, dated September 20, 2019, Amgen stated that it does not intend to further appeal the Federal Circuit’s decision. On October 11, 2019, we filed a Motion for Attorneys’ Fees with the District Court. Amgen filed its Answering Brief in Opposition on November 8, 2019. On November 22, 2019, we filed our Reply Brief with the District Court. On November 30, 2020, the District Court issued an order denying the Company’s motion.

On January 24, 2019, we entered into settlement and license agreements with AbbVie, that grant us global, royalty-bearing, non-exclusive license rights under AbbVie’s intellectual property to commercialize CHS-1420, our proposed adalimumab (Humira) biosimilar. The global settlements resolve all pending disputes between the parties related to CHS-1420. Under the 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 (including 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 the Company will continue to market UDENYCA and began paying a mid-single digit royalty to Amgen for five years starting on July 1, 2019.

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

We are a party to certain non-exclusive intellectual property license agreements with certain vendors (pertaining to mammalian cell lines), 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.

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 three approved products: UDENYCA, CIMERLI and YUSIMRY.

Our product candidates are in varying stages of development and will require additional clinical development, management of nonclinical, clinical and manufacturing activities, regulatory approval, adequate manufacturing supplies, commercial organization and significant marketing efforts before we generate any revenue from product sales. For example, YUSIMRY received FDA approval but we still will not launch it until July 2023 due to our settlement agreement with AbbVie, and the FDA has set a PDUFA action date for December 23, 2022 for the toripalimab original BLA. Other than certain PK bridging studies, we have not initiated phase 3 clinical trials for other product candidates in our pipeline. It may be some time before we file for market approval with the relevant regulatory agencies for these product candidates.

We cannot be certain that any of our product candidates will be successful in clinical trials or receive regulatory approval. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials. If we and our existing or future collaboration partners do not receive regulatory approvals for our product candidates, we may not be able to continue our operations.

We, together with our collaboration partners, generally plan to seek regulatory approval to commercialize our product candidates in the United States, the E.U., and additional foreign countries where we or our partners have commercial rights. To obtain regulatory approval, we and our collaboration partners must comply with numerous and varying regulatory requirements of such countries regarding safety, efficacy, chemistry, manufacturing and controls, clinical studies, commercial sales, and pricing and distribution of our product candidates. Even if we and our collaboration partners are successful in obtaining approval in one jurisdiction, we cannot ensure that we will obtain approval in any other jurisdictions. If we and our collaboration partners are unable to obtain approval for our product candidates in multiple jurisdictions, our revenue and results of operations could be negatively affected.

The regulatory approval processes of the FDA, EMA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and the regulatory approval requirements for biosimilars are evolving. If we and our collaboration partners are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The research, development, testing, manufacturing, labeling, packaging, approval, promotion, advertising, storage, marketing, distribution, post-approval monitoring and reporting and export and import of biologic and biosimilar products are subject to extensive regulation by the FDA and other regulatory authorities in the United States, by the EMA and EEA Competent Authorities in the European Economic Area (“EEA”), and by other regulatory authorities in

other countries, where regulations differ from country to country. Neither we nor any existing or future collaboration partners are permitted to market our product candidates in the United States until we and our collaboration partners receive approval from the FDA, or in the EEA until we and our collaboration partners receive EC or EEA Competent Authority approvals.

The time required to develop new products or obtain approval for new products by the FDA and comparable foreign authorities is unpredictable, may take many years following the completion of clinical studies and depends upon numerous factors. Further, applications to the Human Genetic Resources Administration of China (HGRAC) required for any activities, including development activities and data sharing with our partners in China, may result in product development delays. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. For example, in 2020 during FDA's review of Bioeq's Section 351(k) BLA for CIMERLI, the FDA requested that Bioeq submit additional manufacturing data for the equipment in its new location, leading Bioeq to withdraw its Section 351(k) BLA for this candidate in order to provide the requested data and to resubmit the application thereafter. Neither we nor any collaboration partner has obtained regulatory approval for any of our product candidates, other than UDENYCA, which has received approval from the FDA and EMA, YUSIMRY and CIMERLI, which have received approval from the FDA, and toripalimab, which is approved for use in China only, and it is possible that none of our other current or future product candidates will ever obtain additional regulatory approvals.

Applications for our product candidates could fail to receive regulatory approval for many reasons, including but not limited to the following:

- the data collected from clinical studies of our product candidates may not be sufficient to support the submission of an original BLA, an NDA, a Section 351(k) BLA, a biosimilar marketing authorization under Article 6 of Regulation (EC) No. 726/2004 and/or Article 10(4) of Directive 2001/83/EC in the EEA or other submission or to obtain regulatory approval in the United States, the EEA or elsewhere;
- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical studies;
- the FDA may determine that the population studied in the clinical program may not be sufficiently broad or representative to assure safety and efficacy in the full population for which we seek approval, or that conclusions of clinical trials conducted in a single country or region outside the United States may not be generalizable to the patient population in the United States;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from analytical and bioanalytical studies, nonclinical studies or clinical studies;
- we may be unable to demonstrate to the FDA or comparable foreign regulatory authorities that a product candidate's risk-benefit ratio for its proposed indication is acceptable;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications or facilities of our collaborators or third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This approval process, as well as the unpredictability of the results of clinical studies, may result in our failure to obtain regulatory approval to market any of our product candidates, which would significantly harm our business. Any delays in the commencement or completion of clinical testing could significantly impact our product development costs and could result in the need for additional financing.

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

On April 29, 2022, the FDA issued a CRL in response to our original BLA for toripalimab. The letter identified certain issues, including a request for a quality process change. On July 6, 2022, we announced that the FDA accepted the resubmission of the original BLA for toripalimab. The FDA has set a PDUFA action date for December 23, 2022. Even though the FDA accepted our resubmission of the BLA for toripalimab, there is no guarantee that the FDA will conclude that the information in that resubmission will be sufficient to support approval and we may fail to obtain regulatory approval in the United States for toripalimab. Additionally, certain factors beyond our control, such as the COVID-19 pandemic, may impact the timeliness of the regulatory reviews of our submissions or any applications for approval.

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

Our future results of operations depend, to a significant degree, on our ability to obtain regulatory approval for and to commercialize our proposed biosimilar products. To obtain regulatory approval for the commercial sale of these product candidates, we will be required to demonstrate to the satisfaction of regulatory authorities, among other things, that our proposed biosimilar products are highly similar to biological reference products already licensed by the regulatory authority pursuant to marketing applications, notwithstanding minor differences in clinically inactive components, and that they have no clinically meaningful differences as compared to the marketed biological products in terms of the safety, purity and potency of the products. Each individual jurisdiction may apply different criteria to assess biosimilarity, based on a preponderance of the evidence that can be interpreted subjectively in some cases. In the EEA, the similar 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 we and our collaboration partners, 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 institutional review board ("IRB") approval at each clinical study site;
- imposition of a clinical hold by regulatory agencies, after review of an investigational new drug application ("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. For example, we altered the manufacturing processes for CHS-1420 and will need to provide data to the FDA and foreign regulatory authorities demonstrating that the change in manufacturing process has not changed the product candidate. If we are unable to make that demonstration to the FDA or comparable foreign regulatory authorities, we could face significant delays or fail to obtain regulatory approval to market the product, which could significantly harm our business.

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

We and our collaboration partners intend to pursue market authorization globally. In the United States, an abbreviated pathway for approval of biosimilar products was established by the BPCIA, enacted on March 23, 2010, as part of the 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 in the United States, and subject to product approvals and relevant patent and settlement agreement expirations, we intend to market our other biosimilar products in the United States and outside the United States on our own or with future collaboration partners. We entered into a distribution agreement with our

licensee Orox for the commercialization of biosimilar versions of etanercept (Enbrel) (for which we discontinued development), rituximab (Rituxan), adalimumab (Humira) and pegfilgrastim (Neulasta) in certain Caribbean and Latin American countries. We intend to market our biosimilar product candidates in the United States and may seek to partner commercially all biosimilars outside the United States.

In order to market our products in the E.U., the United States and other jurisdictions, we and our collaboration partners must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The EMA is responsible for the centralized 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 average manufacturer price ("AMP") definition under the Medicaid Drug Rebate Program ("MDRP") for drugs that are inhaled, infused, instilled, implanted or injected and not generally distributed through the retail channel; expanded rebate payments under the MDRP to include utilization by individuals enrolled in Medicaid managed care organizations; added a provision to increase the Medicaid rebate for line extension drugs; established annual fees and taxes on manufacturers of certain branded prescription drugs; expanded the entities eligible for discounts under the Public Health Service 340B drug pricing program; and established the Medicare Part D coverage gap discount program, in which manufacturers must agree to offer point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

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

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 the Department of Health and Human Services ("HHS") to implement many of these provisions through guidance, as opposed to regulation, for the initial years. For that and other reasons, it is currently unclear how the IRA will be effectuated, and while the impact of the IRA on our business and the pharmaceutical industry cannot yet be fully determined, it is likely to be significant. In particular, if a product becomes subject to the IRA negotiation provision and related price cap, that may significantly alter the economic rationale for developing and commercializing a biosimilar.

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;
- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or

entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;

- federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- the federal physician "sunshine" requirements under the ACA, which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services information related to payments and other transfers of value made by such manufacturers to physicians (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 that is 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 Average Sales Price ("ASP") information on a quarterly basis. CMS uses this information to compute Medicare Part B payment rates, which consist of ASP plus a specified percentage. If we become aware that our MDRP submissions for a prior period were incorrect or have changed as a result of recalculation of the pricing data, we must resubmit the corrected data for up to three years after those data originally were due. 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 Health Resources and Services Administration ("HRSA") and requires us to agree to charge statutorily defined covered entities no more than the 340B "ceiling price" for our covered 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 addition, legislation may be introduced that, if passed, would further expand the 340B program, such as adding further covered entities or requiring participating manufacturers to agree to provide 340B discounted pricing on drugs when used in an inpatient setting.

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

Individual states continue to consider and have enacted legislation to limit the growth of healthcare costs, including the cost of prescription drugs and combination products. A number of states have either implemented or are considering implementation of drug price transparency legislation 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 $5.60 to $38.10 per share during the period from November 6, 2014 through September 30, 2022 and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include those discussed in the “Risk Factors” section of this Quarterly Report on Form 10-Q and others such as:

- the Covid-19 pandemic and other viral pandemics;
- adverse results or delays in preclinical or clinical studies;
- any inability to obtain additional funding;
- any delay in filing an IND, NDA, BLA, Section 351(k) BLA or other regulatory submission for any of our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory agency’s review of that IND, NDA, BLA, Section 351(k) BLA or other regulatory submission;
- the perception of limited market sizes or pricing for our products and product candidates;
- failure to successfully develop and commercialize our product candidates;
- post-marketing safety issues relating to our product candidates or biosimilars generally;
- failure to maintain our existing strategic collaborations or enter into new collaborations;
- failure by us or our licensors and strategic collaboration partners to prosecute, maintain or enforce our intellectual property rights;
- changes in laws or regulations applicable to our products;
- any inability to obtain adequate product supply for our product candidates or the inability to do so at acceptable prices;
- difficulties in the implementation of the shift in our clinical, commercial, manufacturing, regulatory, marketing and general historical focus on biosimilars to a new strategy to build a leading immuno-oncology franchise funded with cash generated by our commercial biosimilar business;

- adverse regulatory decisions;
- introduction of new products, services or technologies by our competitors;
- failure to meet or exceed financial projections we may provide to the public;
- failure to meet or exceed the financial projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us, our strategic collaboration partners or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key scientific or management personnel;
- lawsuits, including but not limited to complaints initiated by stockholders, customers and collaboration partners, and litigation filed by us or filed against us pertaining to patent infringement or other violations of intellectual property rights;
- the outcomes of any citizen petitions filed by parties seeking to restrict or limit the approval of biosimilar products;
- 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, 2022, our executive officers, directors, five percent stockholders and their affiliates beneficially owned 61.8% of our voting stock (assuming no exercise of outstanding options or conversion of our outstanding convertible notes). These stockholders have the ability to influence us through their ownership positions, which may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may believe are in your best interest as one of our stockholders.

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

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

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

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

This indebtedness could be due sooner upon the triggering of certain covenants in our debt agreements and or upon the occurrence of an event of default. If and when our indebtedness becomes due, if we do not have sufficient cash or access to capital to pay such indebtedness, we will default on our obligations which will adversely harm our business. We also recently entered into a Loan Agreement that contains affirmative and negative covenants that restrict our operations, including, among other restrictions, the requirement to maintain minimum trailing twelve-month net sales in an amount that begins at $200 million in the first quarter of 2022 and increases to $210 million for the quarter ended March 30, 2024 and increases to be as much as $300 million for the quarter ended December 31, 2024. Further, the Loan Agreement includes certain other affirmative covenants and negative covenants, including, covenants and restrictions that among other things, restrict our ability to incur liens, incur additional indebtedness, make investments, engage in certain mergers and acquisitions or asset sales, and declare dividends or redeem or repurchase capital stock.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

If our existing stockholders sell or indicate an intention to sell substantial amounts of our common stock in the public market the market price of our common stock could decline. As of September 30, 2022, there were 77.8 million shares of our common stock outstanding.

In addition, as of September 30, 2022, 30.0 million shares of common stock that are either subject to outstanding options and restricted stock units or reserved for future issuance under our equity incentive plans were eligible or may become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold or if it is perceived that they will be sold in the public market, the market price of our common stock could decline.

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

We have needed and anticipate we will need additional capital in the future to continue our planned operations. To the extent that we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. Similar to prior financing transactions, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders. In addition, if we raise additional funds through licensing arrangements, it may be necessary to grant potentially valuable rights to our product candidates or grant licenses on terms that are not favorable to us.

Pursuant to our 2014 Equity Incentive Award Plan (the "2014 Plan"), our management is authorized to grant stock options and other equity-based awards to our employees, directors and consultants. The number of shares available for future grant under the 2014 Plan will be increased by (i) the number of shares pursuant to outstanding awards under the 2010 Plan that are forfeited or lapse unexercised and which following the effective date are not issued under the 2010 Plan and (ii) an annual increase on the first day of each fiscal year beginning in 2015 and ending in 2024, equal to 4% of the shares of stock outstanding as of the last day of the preceding fiscal year, or such smaller number of shares as determined by our board of directors. Pursuant to our 2014 Employee Stock Purchase Plan ("ESPP"), eligible employees are able to acquire shares of our common stock at a discount to the prevailing market price, and an aggregate of 320,000 shares are initially available for issuance under the ESPP. The number of shares available for issuance under the ESPP will automatically increase on the first day of each fiscal year beginning in 2015 and ending in 2024, equal to 1% of the shares of common stock outstanding on the last day of the immediately preceding fiscal year or such smaller number of shares as determined by our board of directors. If our board of directors elects to increase the number of shares available for future grant under the 2014 Plan or the ESPP, our stockholders may experience additional dilution, which could cause our stock price to fall**.** Pursuant to our 2016 Employment Commencement Incentive Plan (the "2016 Plan"), our management is authorized to grant stock options and other equity-based awards to our new employees. The 2016 Plan is designed to comply with the inducement exemption contained in Nasdaq's Rule 5635(c)(4), which provides for the grant of non-qualified stock options, restricted stock units, restricted stock awards, performance awards, dividend equivalents, deferred stock awards, deferred stock units, stock payment and stock appreciation rights to a person not previously an employee or director, or following a bona fide period of non-employment, as an inducement material to the individual's entering into employment with us. As of September 30, 2022, we reserved for future issuance under the 2016 Plan a total of 0.6 million shares of common stock for new employees. The 2016 Plan does not provide for any annual increases in the number of shares available.

In April 2020, we issued and sold $230.0 million aggregate principal amount of our 1.5% senior convertible notes due April 2026 (the "2026 Convertible Notes"). The holders may convert their 2026 Convertible Notes at their option at any time prior to the close of business on the second scheduled trading day immediately before April 15, 2026. Upon conversion of the 2026 Convertible Notes by a holder, the holder will receive shares of our common stock, together, if applicable, with cash in lieu of any fractional share. The initial conversion rate is 51.9224 shares of common stock per $1,000 principal amount of convertible notes, which is equivalent to an initial conversion price of approximately $19.26 per share, and is subject to adjustment in certain events.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain any future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to any appreciation of their stock.

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

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

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

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

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

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

General Risk Factors

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 in December 2022.

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.

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

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

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

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

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 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 it is approved in December 2022. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time consuming and costly. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain our current levels of such coverage.

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

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

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

our third-party collaborators, consultants, contractors, suppliers, or service providers were to suffer an attack or breach, for example, that resulted in the unauthorized access to or use or disclosure of personal information, including health-related information, we may have to notify individuals, collaborators, government authorities, and the media, and may be subject to investigations, civil penalties, administrative and enforcement actions, and litigation, any of which could harm our business and reputation. Likewise, we rely on our third-party CROs and other third parties to conduct clinical studies, and similar events relating to their computer systems could also have a material adverse effect on our business.

Attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. Further, the COVID-19 pandemic is generally increasing the attack surface available to criminals, as more companies and individuals work online and work remotely, and as such, the risk of a cybersecurity incident potentially occurring, and our investment in risk mitigations against such an incident, is increasing. For example, there has been an increase in phishing and spam emails as well as social engineering attempts from “hackers” hoping to use the recent COVID-19 pandemic to their advantage. Because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence.

To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or systems, or inappropriate or unauthorized access to or disclosure or use of confidential, proprietary, or other sensitive, personal information, including health-related information, we could incur liability and suffer reputational harm, and the development and commercialization of our products could be delayed. Our insurance policies may not be adequate to compensate us for the potential losses arising from such disruptions, failure, or security breach. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and defending a suit, regardless of its merit, could be costly, divert management attention, and harm our reputation.

We face the significant risks associated with our company-wide implementation of an ERP system that may adversely affect our business and results of operations or the effectiveness of our internal controls over financial reporting.

We recently implemented a company-wide ERP system to upgrade certain existing business, operational, and financial processes. Our ERP implementation is a complex, expensive and time-consuming project and our ERP system initially went live in August 2022. Our results of operations could be adversely affected if we experience time delays or cost overruns during the ERP implementation process, or if the ERP system or associated process changes do not give rise to the benefits that we expect. This project has required and may continue to require investment of capital and human resources, the re-engineering of processes of our business, and the attention of many employees who would otherwise be focused on other aspects of our business. Any deficiencies in the design and implementation of the new ERP system could result in potentially higher costs than we had incurred previously and could adversely affect our ability to develop product candidates, launch products, file reports with the SEC in a timely manner, operate our business or otherwise affect our controls environment. Any of these consequences could have a material and adverse effect on our results of operations and financial condition.

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

The global data protection landscape is rapidly evolving, and we are or may become subject to numerous state, federal and foreign laws, requirements and regulations governing the collection, use, disclosure, retention, and security

of personal information, such as information that we may collect in connection with clinical trials in the U.S. and abroad. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on our business. This evolution may create uncertainty in our business, affect our ability to operate in certain jurisdictions or to collect, store, transfer use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. Compliance with these privacy and data security requirements is rigorous and time-intensive and may increase our cost of doing business, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation and reputational harm, which could materially and adversely affect our business, financial condition and results of operations.

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

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

In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same requirements, thus complicating compliance efforts. By way of example, California enacted the California Consumer Privacy Act (the “CCPA”) on June 28, 2018, which went into effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Further, the California Privacy Rights Act (“CPRA”) recently passed in California, which will impose additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. Similar laws have passed in Virginia, Colorado and Utah, and have been proposed in other states and at the federal level, reflecting a trend toward more stringent privacy legislation in the United States. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging.

In addition, the regulatory framework for the receipt, collection, processing, use, safeguarding, sharing and transfer of personal and confidential data is rapidly evolving and is likely to remain uncertain for the foreseeable future as new global privacy rules are being enacted and existing ones are being updated and strengthened. For example, on May 25, 2018, the GDPR took effect. The GDPR is applicable in each EEA member state and applies to companies established in the EEA as well as companies that collect and use personal data to offer goods or services to, or monitor the behavior of, individuals in the EEA, including, for example, through the conduct of clinical trials. GDPR introduces more stringent data protection obligations for processors and controllers of personal data. Among other things, the GDPR requires the establishment of a lawful basis for the processing of data, includes requirements relating to the consent of the individuals to whom the personal data relates, including detailed notices for clinical trial subjects and

investigators, as well as requirements regarding the security of personal data and notification of data processing obligations or security incidents to appropriate data protection authorities or data subjects. Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States; in July 2020, the Court of Justice of the EU ("CJEU") limited how organizations could lawfully transfer personal data from the EU/EEA to the United States by invalidating the Privacy Shield for purposes of international transfers and imposing further restrictions on the use of standard contractual clauses ("SCCs"). The European Commission issued revised SCCs on June 4, 2021 to account for the decision of the CJEU and recommendations made by the European Data Protection Board. The revised SCCs must be used for relevant new data transfers from September 27, 2021; existing standard contractual clauses arrangements must be migrated to the revised clauses by December 27, 2022. The new SCCs apply only to the transfer of personal data outside of the EEA and not the UK. The UK's Information Commissioner's Office has published new data transfer standard contracts for transfers from the UK under the UK GDPR. This new documentation will be mandatory for relevant data transfers from September 21, 2022; existing standard contractual clauses arrangements must be migrated to the new documentation by March 21, 2024. Penalties and fines for failure to comply with GDPR are significant, including fines of up to €20 million or 4% of total worldwide annual turnover, whichever is higher.

The EU has also proposed a Regulation on Privacy and Electronic Communications ("ePrivacy Regulation") which, if adopted, would impose new obligations on the use of personal data in the context of electronic communications, particularly with respect to online tracking technologies and direct marketing. Additionally, the EU adopted the EU Clinical Trials Regulation, which came into effect on January 31, 2022. This regulation imposes new obligations on the use of data generated from clinical trials and enables European patients to have the opportunity to access information about clinical trials.

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

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

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 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.

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

Issuer Purchases of Equity Securities

We did not repurchase any of our equity securities during the third quarter ended September 30, 2022. A total of 32,319 shares were surrendered to Coherus in the third quarter of 2022, 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

Not applicable

ITEM 6. Exhibits

See the Exhibit Index on the page immediately preceding the exhibits for a list of exhibits filed as part of this Quarterly Report on Form 10-Q, which Exhibit Index is incorporated herein by reference.

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	
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
101	The following materials from Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2022 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

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 8, 2022

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

Date: November 8, 2022

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

Date: November 8, 2022

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

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 8, 2022

/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 8, 2022

/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, 2022 (the "Report") fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended, and that information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

Date: November 8, 2022

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

Date: November 8, 2022

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.