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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, 2025

☐ **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 Oncology, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware **(State or Other Jurisdiction of Incorporation or Organization)**	**27-3615821** **(I.R.S. Employer Identification No.)**
333 Twin Dolphin Drive, Suite 600 **Redwood City, California** **(Address of Principal Executive Office)**	**94065** **(Zip Code)**

(650) 649-3530

(Registrant's Telephone Number, Including Area Code)

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

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

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

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

As of October 31, 2025, 120,871,013 shares of the registrant's common stock were outstanding.

COHERUS ONCOLOGY, INC.
FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2025
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CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements regarding future events and our future results that are subject to the safe harbors created under the Securities Act of 1933, as amended (the "Securities Act"), and the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Any statements contained herein that are not statements of historical facts contained in this Quarterly Report on Form 10-Q may be deemed to be forward-looking statements. In some cases, you can identify forward-looking statements by words such as "aim," "anticipate," "assume," "attempt," "believe," "contemplate," "continue," "could," "due," "estimate," "expect," "goal," "intend," "may," "objective," "plan," "predict," "potential," "seek," "should," "strive," "target," "will," "would" and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- *whether our available cash, cash equivalents and marketable securities, product sales, and ATM Offering proceeds received to date will be sufficient to fund our planned expenditures and meet our obligations in the future;*
- *whether we will be able to continue to maintain or increase sales for our product;*
- *our expectations regarding our ability to develop and commercialize our product candidates;*
- *our ability to maintain regulatory approval for our product 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 and product candidates in conformity with regulatory requirements and to scale up manufacturing capacity of our product and product candidates for commercial supply;*
- *our reliance on third-party contract manufacturers to supply our product candidates and product for us;*
- *our expectations regarding the potential market size and the size of the patient populations for our product and product candidates, if approved for commercial use;*
- *our expectations about making required future interest and principal payments as they become due in connection with our debt obligations;*
- *our financial performance, including, but not limited to, projected net revenue, cost of goods sold, research and development expenses, selling and general administrative expense, and interest expense*
- *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 likelihood of us receiving either of the $37.5 million payments we are eligible to receive as part of our divestiture of the UDENYCA franchise, depending on post-closing net sales of UDENYCA;*
- *the scope of protection we are able to establish and maintain for intellectual property rights covering our product and product candidates;*

- *our expectations regarding the scope or enforceability of third-party intellectual property rights, or the applicability of such rights to our product and product candidates;*
- *the cost, timing and outcomes of litigation involving our product 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 and product candidates;*
- *our expectations about potential risks, disruptions and losses from future cyberattacks and security incidents;*
- *the rate and degree of market acceptance of our current or any future product and product candidates;*
- *our ability to compete with companies who currently are producing competitor products or will produce them in the future;*
- *developments and projections relating to our competitors, our market opportunity and our industry; and*
- *the effects of the continuation of the war in Ukraine and conflicts in the Middle East on our business and prospects.*

We have based these forward-looking statements on our current expectations about future events. These statements are not guarantees of future performance and involve risks, uncertainties and assumptions that are difficult to predict. Our actual results may differ materially from those suggested by these forward-looking statements for various reasons, including those identified in Part II, Item 1A Risk Factors and discussed elsewhere in this Quarterly Report on Form 10-Q. Given these risks and uncertainties, you are cautioned not to place undue reliance on forward-looking statements. The forward-looking statements included in this report are made only as of the date hereof. Except as required under federal securities laws and the rules and regulations of the Securities and Exchange Commission ("SEC"), we do not undertake, and specifically decline, any obligation to update any of these statements or to publicly announce the results of any revisions to any forward-looking statements after the distribution of this report, whether as a result of new information, future events, changes in assumptions or otherwise. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures, or investments we may make or enter into, except for the acquisition of Surface to the extent described herein.

This Quarterly Report on Form 10-Q also contains estimates, projections, market opportunity estimates and other information concerning our industry, our business, and the markets for certain diseases, including data regarding the estimated size of those markets, and the incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data, publicly filed reports and similar sources.

PART I. FINANCIAL INFORMATION

ITEM 1. Unaudited Condensed Consolidated Financial Statements

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

	September 30, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 103,352	$ 125,987
Investments in marketable securities	88,311	—
Trade receivables, net	9,245	111,324
TSA receivables, net	241,251	11,010
Inventory	2,048	4,207
Prepaid manufacturing	8,048	6,653
Other prepaids and current assets	8,700	10,222
Assets of discontinued operations, current (Note 6)	—	72,180
Total current assets	460,955	341,583
Property and equipment, net	1,633	2,576
Intangible assets, net	49,484	53,646
Other assets, non-current	4,447	6,485
Assets of discontinued operations, non-current (Note 6)	—	44,243
Total assets	$ 516,519	$ 448,533
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 24,893	$ 28,456
Accrued rebates, fees and reserves	67,010	164,867
TSA payables and accrued liabilities	253,908	11,026
Accrued compensation	13,385	18,344
Accrued and other current liabilities	13,101	60,288
Total current liabilities	372,297	282,981
Term loan, non-current	36,957	36,698
Convertible notes, non-current	—	228,229
Lease liabilities, non-current	1,946	3,286
Other liabilities, non-current	17,545	29,329
Total liabilities	428,745	580,523
Commitments and contingencies (Note 9)		
Stockholders' equity (deficit):		
Preferred stock ($0.0001 par value; shares authorized: 5,000,000; shares issued and outstanding: 0 at September 30, 2025 and December 31, 2024)	—	—
Common stock ($0.0001 par value; shares authorized: 300,000,000; shares issued and outstanding: 116,236,018 and 115,614,548 at September 30, 2025 and December 31, 2024, respectively)	12	12
Additional paid-in capital	1,433,291	1,419,266
Accumulated other comprehensive loss	(203)	(275)
Accumulated deficit	(1,345,326)	(1,550,993)
Total stockholders' equity (deficit)	87,774	(131,990)
Total liabilities and stockholders' equity (deficit)	$ 516,519	$ 448,533

See accompanying notes.

Coherus Oncology, 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,	
	2025	2024	2025	2024
Net revenue	$ 11,571	$ 6,052	$ 29,424	$ 18,656
Costs and expenses:				
Cost of goods sold	3,721	2,729	9,769	5,977
Research and development	27,252	22,052	77,914	71,074
Selling, general and administrative	24,931	28,127	76,995	95,874
Total costs and expenses	55,904	52,908	164,678	172,925
Loss from operations	(44,333)	(46,856)	(135,254)	(154,269)
Interest expense	(2,325)	(2,827)	(6,752)	(8,822)
Loss on debt extinguishment	—	—	—	(12,630)
Other income (expense), net	2,141	2,084	5,229	6,420
Loss from continuing operations before income taxes	(44,517)	(47,599)	(136,777)	(169,301)
Income tax provision	—	—	—	—
Net loss from continuing operations	(44,517)	(47,599)	(136,777)	(169,301)
Net income from discontinued operations, net of tax (Note 6)	8,986	36,848	342,444	248,504
Net income (loss)	$ (35,531)	$ (10,751)	$ 205,667	$ 79,203
Net income (loss) per share:				
Net loss from continuing operations - basic and diluted	$ (0.38)	$ (0.41)	$ (1.18)	$ (1.48)
Net income from discontinued operations - basic and diluted	$ 0.08	$ 0.32	$ 2.95	$ 2.17
Net income (loss) per share - basic and diluted	$ (0.31)	$ (0.09)	$ 1.77	$ 0.69
Weighted-average number of shares used in computing net income (loss) per share:				
Basic and diluted	116,229,170	115,210,091	116,056,247	114,263,256

See accompanying notes.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Net income (loss)	$ (35,531)	$ (10,751)	$ 205,667	$ 79,203
Other comprehensive income (loss):				
Unrealized gain (loss) on available-for-sale securities, net of tax	72	—	72	(24)
Foreign currency translation adjustments, net of tax	—	(3)	—	(3)
Comprehensive income (loss)	$ (35,459)	$ (10,754)	$ 205,739	$ 79,176

See accompanying notes.

Coherus Oncology, 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, 2024	115,614,548	$ 12	$ 1,419,266	$ (275)	$ (1,550,993)	$ (131,990)
Net loss	—	—	—	—	(56,569)	(56,569)
Issuance of common stock upon vesting of restricted stock units ("RSUs")	474,410	—	—	—	—	—
Taxes paid related to net share settlement of RSUs	(181,742)	—	(264)	—	—	(264)
Stock-based compensation expense	—	—	5,353	—	—	5,353
Balances at March 31, 2025	115,907,216	12	1,424,355	(275)	(1,607,562)	(183,470)
Net income	—	—	—	—	297,767	297,767
Issuance of common stock upon vesting of RSUs	44,556	—	—	—	—	—
Taxes paid related to net share settlement of RSUs	(16,519)	—	(16)	—	—	(16)
Issuance of common stock under the employee stock purchase plan ("ESPP")	287,473	—	188	—	—	188
Stock-based compensation expense	—	—	5,358	—	—	5,358
Balances at June 30, 2025	116,222,726	12	1,429,885	(275)	(1,309,795)	119,827
Net loss	—	—	—	—	(35,531)	(35,531)
Issuance of common stock upon exercise of stock options	7,000	—	5	—	—	5
Issuance of common stock upon vesting of RSUs	9,707	—	—	—	—	—
Taxes paid related to net share settlement of RSUs	(3,415)	—	(3)	—	—	(3)
Stock-based compensation expense	—	—	3,404	—	—	3,404
Other comprehensive gain, net of tax	—	—	—	72	—	72
Balances at September 30, 2025	116,236,018	$ 12	$ 1,433,291	$ (203)	$ (1,345,326)	$ 87,774

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

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Loss	Deficit	Deficit
Balances at December 31, 2023	112,215,260	$ 11	$ 1,386,312	$ (248)	$ (1,579,500)	$ (193,425)
Net income	—	—	—	—	102,875	102,875
Issuance of common stock upon exercise of stock options	174,651	—	291	—	—	291
Issuance of common stock upon vesting of RSUs	741,213	—	—	—	—	—
Issuance of common stock under ATM Offering, net of issuance costs	650,005	—	1,507	—	—	1,507
Taxes paid related to net share settlement of RSUs	(284,275)	—	(745)	—	—	(745)
Stock-based compensation expense	—	—	7,677	—	—	7,677
Other comprehensive loss, net of tax	—	—	—	(24)	—	(24)
Balances at March 31, 2024	113,496,854	11	1,395,042	(272)	(1,476,625)	(81,844)
Net loss	—	—	—	—	(12,921)	(12,921)
Issuance of common stock upon vesting of RSUs	21,583	—	—	—	—	—
Issuance of common stock - partial payout of 2023 bonus in RSUs	1,976,750	1	4,407	—	—	4,408
Offering costs associated with ATM Offering	—	—	(52)	—	—	(52)
Taxes paid related to net share settlement of RSUs	(767,971)	—	(1,711)	—	—	(1,711)
Issuance of common stock under the ESPP	471,439	—	685	—	—	685
Stock-based compensation expense	—	—	7,327	—	—	7,327
Balances at June 30, 2024	115,198,655	12	1,405,698	(272)	(1,489,546)	(84,108)
Net loss	—	—	—	—	(10,751)	(10,751)
Issuance of common stock upon vesting of RSUs	22,915	—	—	—	—	—
Taxes paid related to net share settlement of RSUs	(8,163)	—	(10)	—	—	(10)
Stock-based compensation expense	—	—	6,899	—	—	6,899
Other comprehensive loss, net of tax	—	—	—	(3)	—	(3)
Balances at September 30, 2024	115,213,407	$ 12	$ 1,412,587	$ (275)	$ (1,500,297)	$ (87,973)

See accompanying notes.

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

	Nine Months Ended September 30,	
	2025	2024
Operating activities		
Net income	$ 205,667	$ 79,203
Adjustments to reconcile net income to net cash used in operating activities:		
Depreciation and amortization	3,028	4,243
Stock-based compensation expense	14,182	21,418
Impairment of out-license asset and remeasurement of CVR liability, net	1,646	6,772
Loss on debt extinguishment	10,286	12,630
Gain on Sale Transactions, net (Note 6)	(338,680)	(176,646)
Inventory write-downs, net	—	2,481
Change in fair value of derivatives	12,608	625
Other non-cash adjustments, net	(5,352)	(1,130)
Changes in operating assets and liabilities:		
Trade receivables, net	101,895	93,024
Inventory	(15,994)	(25,499)
Prepaid manufacturing	(952)	5,582
Other prepaid, current and non-current assets	2,405	(4,306)
Accounts payable	(14,468)	(10,280)
Accrued rebates, fees and reserves	(89,114)	(7,617)
TSA related operating assets and liabilities, net	12,641	2,396
Accrued compensation	(4,959)	(1,039)
Accrued and other current and non-current liabilities	(13,636)	(50,905)
Net cash used in operating activities	(118,797)	(49,048)
Investing activities		
Purchases of investments in marketable securities	(89,576)	—
Proceeds from maturities of investments in marketable securities	1,650	6,200
Proceeds from sale of investments in marketable securities	—	8,688
Net cash received related to the Sale Transactions (Note 6)	478,681	227,823
Milestone payment to Junshi Biosciences	(12,500)	(12,500)
Other investing activities, net	(330)	652
Net cash provided by investing activities	377,925	230,863
Financing activities		
Proceeds from 2029 Term Loan, net of debt discount and issuance costs	—	36,979
Proceeds from (repayment of) Revenue Purchase and Sale Agreement, net of issuance costs	(47,652)	36,486
Proceeds from issuance of common stock under ATM Offering, net of issuance costs	—	1,455
Proceeds from purchase under the employee stock purchase plan	188	685
Taxes paid related to net share settlement	(283)	(2,466)
Redemption of 2026 Convertible Notes, including transaction costs	(233,185)	—
Repayment of 2027 Term Loans, premiums and make-whole	—	(260,387)
Other financing activities, net	(854)	43
Net cash used in financing activities	(281,786)	(187,205)
Net decrease in cash, cash equivalents and restricted cash	(22,658)	(5,390)
Cash, cash equivalents and restricted cash at beginning of period	126,250	103,343
Cash, cash equivalents and restricted cash at end of period	$ 103,592	$ 97,953
Supplemental disclosures of non-cash activities		
Non-cash employee bonuses settled in common stock	$ —	$ 4,408
Financing issuance costs in accrued and other current liabilities	$ —	$ 859

See accompanying notes.

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

1. Organization and Summary of Significant Accounting Policies

Organization

Coherus Oncology, Inc. (the "Company" or "Coherus") is a fully integrated commercial-stage innovative oncology company with an approved next-generation programmed death receptor-1 ("PD-1") inhibitor, LOQTORZI® (toripalimab-tpzi), and a pipeline that includes two mid-stage clinical candidates targeting liver, lung, head & neck, colorectal and other cancers. The Company's strategy is to grow sales of LOQTORZI in nasopharyngeal carcinoma ("NPC") and advance the development of new indications for LOQTORZI in combination with both its pipeline candidates as well as through its partners, driving sales multiples and synergies from proprietary combinations.

The Company previously owned UDENYCA (pegfilgrastim-cbqv), which was launched commercially in a pre-filled syringe presentation in the United States in January 2019, followed by the launch of UDENYCA in an autoinjector presentation in May 2023 and the launch of UDENYCA ONBODY in February 2024. On December 2, 2024, the Company and Intas Pharmaceuticals Ltd. ("Intas") entered into an asset purchase agreement (the "UDENYCA Purchase Agreement"), pursuant to which the Company agreed to divest the UDENYCA franchise (the "UDENYCA Business") to Intas (the "UDENYCA Sale"). On April 11, 2025 (the "UDENYCA Closing Date"), the Company completed the divestiture of the UDENYCA Business to Intas for upfront, all-cash consideration of $483.4 million, inclusive of $118.4 million for UDENYCA product inventory. Intas has designated Accord BioPharma, Inc., an indirect wholly owned subsidiary of Intas ("Accord" and, together with Intas, the "Intas Parties") to purchase the physical assets, including product inventory. The Company is eligible to receive two additional payments of $37.5 million each (together, the "Earnout Payments"). The first such payment is payable by Intas to the Company if net sales (as defined in the UDENYCA Purchase Agreement, "Net Sales") of UDENYCA for four consecutive fiscal quarters from July 1, 2025 through September 30, 2026 are equal to or greater than $300 million, and the second such payment is payable by Intas to the Company if Net Sales of UDENYCA for four consecutive fiscal quarters from July 1, 2025 through March 31, 2027 are equal to or greater than $350 million. The UDENYCA Sale represented the last and most significant divestiture of the Company's biosimilar businesses, which comprised the UDENYCA, YUSIMRY and CIMERLI franchises; therefore, the strategic shift criteria had been met and discontinued operations presentation has been included in the condensed consolidated financial statements for all periods presented. Refer to Note 6. Discontinued Operations for more information.

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. Accordingly, they do not include all 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, 2024 (the "2024 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 judgments, 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 judgments are inherently uncertain and therefore actual results could differ from these estimates.

Segment Reporting and Geographic Disclosures

The Company has one reportable and operating segment, which is engaged in developing and commercializing human pharmaceutical products. The Company's chief executive officer, as the chief operating decision maker ("CODM"), manages and allocates resources to the operations of the Company on an entity-wide basis. Managing and allocating resources on an entity-wide basis enables the CODM to assess the overall level of resources available and how to best deploy these resources across functions. The CODM assesses operating performance and makes operating decisions primarily based on net income (loss), cash on-hand and investments, and cash flows. All expense categories on the condensed consolidated statements of operations are significant, and there are no other significant segment expenses that would require disclosure. Asset information is not regularly provided to the CODM for assessing performance and allocating resources other than cash, cash equivalents and investments in marketable securities. Primarily, all revenue is generated and all long-lived assets are maintained in the United States.

Restricted Cash

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

Trade Receivables

Trade receivables are recorded net of allowances for chargebacks, cash discounts for prompt payment and credit losses. The Company estimates an allowance for expected credit losses by considering factors such as historical experience, credit quality, the age of the accounts receivable balances, and current economic conditions that may affect a customer's ability to pay. The corresponding expense for the credit loss allowance is reflected in selling, general and administrative expenses. The credit loss allowance was immaterial as of September 30, 2025 and December 31, 2024.

Net Revenues

The Company sells to wholesalers and distributors, (collectively, "Customers"). The Customers then resell to hospitals and clinics (collectively, "Healthcare Providers") pursuant to contracts with the Company. In addition to distribution agreements with Customers and contracts with Healthcare Providers, the Company enters into arrangements with group purchasing organizations that provide for United States government-mandated or privately negotiated rebates, chargebacks and discounts. The Company also enters into rebate arrangements with payers, which consist primarily of commercial insurance companies and government entities, to cover the reimbursement of products to Healthcare Providers. The Company provides co-payment assistance to patients who have commercial insurance and meet certain eligibility requirements. Revenue from product sales is recognized at the point when a Customer obtains control of the product and the Company satisfies its performance obligation, which generally occurs at the time the product is shipped to the Customer. Payment terms differ by jurisdiction and customer, but payment terms typically range from 30 to approximately 80 days from date of shipment.

The Company recognizes revenue from the sales of vaccines to the U.S. federal government for placement into vaccine stockpiles in accordance with SEC Interpretation, Commission Guidance Regarding Accounting for Sales of Vaccines and BioTerror Countermeasures to the Federal Government for Placement into the Pediatric Vaccine Stockpile or the Strategic National Stockpile. This interpretation allows companies to recognize revenue for sales of vaccines into U.S. government stockpiles even though these sales might not meet the criteria for revenue recognition under other accounting guidance.

Transition Service Agreements ("TSAs")

In connection with the Sale Transactions, the Company and each of the buyers in each Sale Transaction entered into a TSA, pursuant to which the Company provides certain business support services on behalf of the buyers including billings, collections, and the remittance of rebates, to ensure business continuity for patients and customers. Since certain contracts with third parties could not immediately be transitioned at the divestiture dates, generally because the contracts did not allow for assignment, the Company remained a legal party to transactions occurring after the closings, often functioning as an agent on behalf of the buyer. Such transactions are presented gross within TSA receivables, net and TSA payables and accrued liabilities in the condensed consolidated balance sheets and do not have a corresponding impact in the condensed consolidated statements of operations.

Discontinued Operations

The Company evaluates all disposal transactions to determine whether they qualify for reporting as discontinued operations. A disposal of a component or a group of components is reported in discontinued operations if the disposal represents a strategic shift that has or will have a major effect on the Company's operations and financial results when the following occurs: (1) a component (or group of components) meets the criteria to be classified as held for sale; (2) the component or group of components is disposed of by sale; or (3) the component or group of components is disposed of other than by sale (for example, by abandonment or in a distribution to owners in a spin-off). The results of discontinued operations, including gains or losses recognized upon disposal, are presented separately from continuing operations in the condensed consolidated statement of operations for all periods presented. The net assets transferred of the biosimilar businesses have been presented as separate line items on the condensed consolidated balance sheet for prior periods.

Reclassifications

Certain amounts in prior years' financial statements have been reclassified to conform with the current period presentation of discontinued operations, including amounts in the condensed consolidated balance sheets, condensed consolidated statements of operations and various footnotes. There were no changes to net income (loss). In addition, certain amounts in the condensed consolidated statements of cash flows have been reclassified to conform with the current period presentation, and these changes have had no impact on the net cash flows in operating, investing or financing activities.

2025 Tax Reform

On July 4, 2025, the One Big Beautiful Bill Act (the "OBBBA") was signed into law in the United States. This comprehensive tax legislation contains a broad range of tax reforms, including provisions that allow for the immediate expensing of domestic research and development expenses, restore and make permanent 100% bonus depreciation for qualifying assets, and ease limitations on the deductibility of interest expense. The legislation has multiple effective dates, with certain provisions taking effect in 2025 and others being implemented through various future years. The enactment of OBBBA in the third quarter of 2025 did not impact the income tax provision because the tax effect was offset by the existing valuation allowance against deferred tax assets.

Recent Accounting Pronouncements

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

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

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

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

2. Revenue

The Company launched LOQTORZI in December 2023. Net revenue for sales of UDENYCA, YUSIMRY and CIMERLI are classified within discontinued operations (refer to Note 6. Discontinued Operations). All LOQTORZI net product revenue was generated in the United States, and the Company's net revenue was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2025	2024	2025	2024
LOQTORZI	$ 11,169	$ 5,832	$ 28,476	$ 11,609
Other revenue	402	220	948	7,047
Total net revenue	$ 11,571	$ 6,052	$ 29,424	$ 18,656

For continuing operations, gross product revenues by significant Customers as a percentage of total gross product revenues were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
McKesson Corporation	44 %	48 %	44 %	43 %
Cencora (previously known as AmeriSource-Bergen Corporation)	31 %	40 %	35 %	42 %
Cardinal Health, Inc.	23 %	12 %	19 %	14 %

Product Sales Discounts and Allowances

The total provision related to sales made in the prior years for the three months ended September 30, 2025 was $(8.7) million favorable and was substantially all reflected in net income from discontinued operations (see Note 6. Discontinued Operations). The total provision related to sales made in the prior years for the three months ended September 30, 2024, was $0.3 million unfavorable. Chargebacks and discounts for prompt payment are recorded as a reduction in trade receivables, and the remaining reserve balances are classified as current liabilities on the condensed consolidated balance sheets.

In connection with the sale of the CIMERLI ophthalmology franchise, the YUSIMRY franchise and the UDENYCA franchise, the Company retained and will continue to be responsible for sales discounts and allowance liabilities incurred prior to March 1, 2024 for CIMERLI, June 26, 2024 for YUSIMRY and April 11, 2025 for UDENYCA. Sales discounts and allowances incurred on behalf of the respective counterparties following the close of the Sale Transactions in accordance with the Company's Transition Services Agreement (the "CIMERLI TSA") with Sandoz Inc. ("Sandoz") for CIMERLI, the Company's Transition Services Agreement (the "YUSIMRY TSA") with Hong Kong King-Friend Industrial Company Ltd. ("HKF") for YUSIMRY and the Company's Transition Services Agreement with Intas (the "UDENYCA TSA" and, together with the CIMERLI TSA and the YUSIMRY TSA, collectively the "TSA" or the "TSAs") for UDENYCA are reflected within TSA receivables, net and TSA payables and accrued liabilities in the condensed consolidated balance sheets and are excluded from the below table (see Note 6. Discontinued Operations).

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

	Nine Months Ended September 30, 2025			
(in thousands)	Chargebacks and Discounts for Prompt Payment	Rebates	Other Fees, Co-pay Assistance and Returns	Total
Balances at December 31, 2024	$ 110,778	$ 123,738	$ 41,129	$ 275,645
Provision related to sales made in:				
Current year	194,158	45,607	31,837	271,602
Prior years - increase (decrease)	(3,439)	(8,908)	(1,530)	(13,877)
Payments and customer credits issued	(298,681)	(106,627)	(58,236)	(463,544)
Balances at September 30, 2025	$ 2,816	$ 53,810	$ 13,200	$ 69,826

	Nine Months Ended September 30, 2024			
(in thousands)	Chargebacks and Discounts for Prompt Payment	Rebates	Other Fees, Co-pay Assistance and Returns	Total
Balances at December 31, 2023	$ 73,953	$ 121,137	$ 49,795	$ 244,885
Provision related to sales made in:				
Current year	727,028	150,820	117,299	995,147
Prior years - increase (decrease)	(969)	6,343	(1,010)	4,364
Payments and customer credits issued	(747,070)	(159,737)	(121,332)	(1,028,139)
Balances at September 30, 2024	$ 52,942	$ 118,563	$ 44,752	$ 216,257

3. Fair Value Measurements

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

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

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

Unrealized gains and losses on available-for-sale debt securities are reported as a component of accumulated comprehensive income (loss), with the exception of unrealized losses believed to be related to credit losses, if any, which are recognized in earnings in the period the impairment occurs. Impairment assessments are made at the individual security level each reporting period. When the fair value of an available-for-sale debt investment is less than its cost at the balance sheet date, a determination is made as to whether the impairment is related to a credit loss and, if it is, the portion of the impairment relating to credit loss is recorded as an allowance through net income. Realized gains and losses, if any, on available-for-sale securities are included in other income (expense), net, in the condensed consolidated statements of operations based on the specific identification method.

In connection with the acquisition of Surface Oncology, Inc. (“Surface”) on September 8, 2023 (the “Surface Acquisition”), the Company recorded contingent consideration liabilities related to contingent value rights (“CVRs”) related to certain acquired out-license assets. The fair value of the CVR liabilities were determined using a Monte Carlo simulation-based model discounted to present value and represents a Level 3 measurement within the fair value hierarchy. Assumptions used in this calculation included estimated revenue, discount rate and various probability factors. During the three months ended September 30, 2025, the CVR liability related to the only remaining out-license, GlaxoSmithKline Intellectual Property No. 4 Limited (“GSK”) (GSK4381562), was written down to zero as a result of receiving notice of the termination of the program (see Note 5. Balance Sheet Components).

The Revenue Participation Right Purchase and Sale Agreement (the “Revenue Purchase and Sale Agreement”), dated as of May 8, 2024 among the Company and Coduet Royalty Holdings, LLC, as administrative agent and each buyer named in an annex thereto (collectively, the “Purchaser Group”) (see Note 8. Financial Liabilities) contained an embedded derivative that met the criteria to be bifurcated and accounted for separately from the Revenue Purchase and Sale Agreement (the "Royalty Fee Derivative Liability"). The Company recorded the initial estimated fair value of the Royalty Fee Derivative Liability of $9.2 million in accrued and other current liabilities on the condensed consolidated balance sheets. To estimate the fair value, the Company uses Monte Carlo simulation models that require the use of Level 3 unobservable inputs, primarily the amount and timing of our expected future revenue, the estimated volatility of these revenues, the discount rate corresponding to the risk of revenue, and the probability of certain events. The Company estimated the total fair value of the Royalty Fee Derivative Liability at September 30, 2025 and December 31, 2024, to be $1.5 million and $13.6 million, respectively. In connection with the UDENYCA Sale, the UDENYCA portion of the Royalty Fee Derivative Liability was derecognized during the three months ended June 30, 2025.

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

	Fair Value Measurements September 30, 2025			
(in thousands)	Level 1	Level 2	Level 3	Total
Financial Assets:				
Cash equivalents[1]	$ 103,228	$ —	$ —	$ 103,228
Marketable debt securities:				
U.S. government agency securities	3,773	—	—	3,773
U.S. treasury securities	45,419	—	—	45,419
Commercial paper and corporate notes	—	39,119	—	39,119
Total	$ 152,420	$ 39,119	$ —	$ 191,539
Financial Liabilities:				
Royalty Fee Derivative Liability	$ —	$ —	$ 1,490	$ 1,490
Contingent consideration	—	—	102	102
Total	$ —	$ —	$ 1,592	$ 1,592

	Fair Value Measurements December 31, 2024			
(in thousands)	Level 1	Level 2	Level 3	Total
Financial Assets:				
Cash equivalents[1]	$ 125,549	$ —	$ —	$ 125,549
Financial Liabilities:				
Royalty Fee Derivative Liability	$ —	$ —	$ 13,620	$ 13,620
Contingent consideration	—	—	632	632
Total	$ —	$ —	$ 14,252	$ 14,252

(1) Cash equivalents may include the following: money market funds, U.S. treasury securities, commercial paper or corporate notes with original maturities of 90 days or less.

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

	September 30, 2025			
(in thousands)	Cost	Unrealized Gain	Unrealized (Loss)	Fair Value
Money market funds	$ 92,289	$ —	$ —	$ 92,289
U.S. government agency securities	6,748	4	—	6,752
U.S. treasury securities	53,347	33	(1)	53,379
Commercial paper and corporate notes	39,083	37	(1)	39,119
Total	$ 191,467	$ 74	$ (2)	$ 191,539

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

The Company held five positions that were in unrealized loss positions as of September 30, 2025. No impairment was recognized in 2025. As of September 30, 2025, the remaining contractual maturities of available-for-sale securities were less than one year, and the average maturity of investments upon acquisition was approximately seven months. The accrued interest receivable on available-for-sale marketable securities was immaterial at September 30, 2025.

4. Inventory and Prepaid Manufacturing

Inventory of $2.0 million and $4.2 million as of September 30, 2025 and December 31, 2024, respectively, consisted entirely of finished goods. 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, 2025 and December 31, 2024, the Company did not have any inventory of continuing operations classified as non-current.

Prepaid manufacturing of $8.0 million as of September 30, 2025 included prepayments to a contract manufacturing organization ("CMO") of $3.8 million for manufacturing services, which the Company expects to be converted into inventory within the next twelve months, and $4.3 million for research and development. Prepaid manufacturing of $6.7 million as of December 31, 2024 included $0.3 million for manufacturing services of the Company's product and $6.4 million for research and development.

5. Balance Sheet Components

Property and Equipment, Net

Property and equipment, net of continuing operations consisted of the following:

(in thousands)	September 30, 2025	December 31, 2024
Machinery and equipment	$ 12,055	$ 13,437
Computer equipment and software	2,158	3,582
Furniture and fixtures	1,005	1,055
Leasehold improvements	5,751	5,751
Total property and equipment	20,969	23,825
Accumulated depreciation and amortization	(19,336)	(20,988)
Property and equipment, net - including discontinued operations	1,633	2,837
Less: Property and equipment, net from discontinued operations	—	(261)
Property and equipment, net	$ 1,633	$ 2,576

Depreciation and amortization expense related to property and equipment, net was $0.3 million and $1.0 million for the three and nine months ended September 30, 2025, respectively, and $0.4 million and $1.5 million for the three and nine months ended September 30, 2024, respectively.

As of September 30, 2025 and December 31, 2024, the net book value of software implementation costs of continuing operations related to hosting arrangements was $0.7 million and $1.7 million, respectively, and the amortization expense was immaterial for all periods presented.

Intangible Assets, Net

Continuing operations intangible assets, net consisted of the following:

(in thousands)	September 30, 2025	December 31, 2024
Finite-lived assets, net of accumulated amortization of $4,375 and $2,719, as of September 30, 2025 and December 31, 2024, respectively	$ 20,625	$ 24,787
Indefinite-lived assets - in-process research and development	28,859	28,859
Total Intangible assets, net	$ 49,484	$ 53,646

Amortization expense related to finite-lived intangible assets was $0.7 million and $2.0 million in the three and nine months ended September 30, 2025, respectively, and $1.1 million and $2.7 million in the three and nine months ended September 30, 2024, respectively.

The exclusive out-license of GSK4381562 to GlaxoSmithKline Intellectual Property No. 4 Limited ("GSK"), acquired as part of the Surface Acquisition, was terminated by GSK with an effective date of December 16, 2025. As a result, during the third quarter of 2025, the Company recognized a net impairment charge of $1.6 million in selling, general and administrative expenses in the condensed consolidated statements of operations relating to the write-off of the net carrying value of the GSK out-license intangible asset of $2.1 million and the final remeasurement of the CVR liability related to GSK4381562 of $0.5 million to its fair value of zero.

The out-licensed partnership program with Novartis Institutes for Biomedical Research, Inc. ("Novartis Institutes") (NZV930), also acquired as part of the Surface Acquisition, was terminated by Novartis Institutes with an effective date of October 2, 2024. As a result, during the first quarter of 2024, the Company recognized a net impairment charge of $6.8 million in selling, general and administrative expenses in the condensed consolidated statements of operations relating to the write-off of the net carrying value of the Novartis Institutes out-license intangible asset of $10.6 million and the final remeasurement of the CVR liability related to NZV930 of $3.8 million to its fair value of zero.

Accrued and Other Current Liabilities

Accrued and other current liabilities of continuing operations consisted of the following:

(in thousands)	September 30, 2025	December 31, 2024
Accrued commercial and research and development manufacturing	$ 4,207	$ 12,449
Accrued co-development costs and milestone payments	—	12,500
Royalty fee derivative liability, current	—	13,620
Accrued other	7,103	20,028
Lease liabilities, current	1,791	1,691
Total Accrued and other current liabilities	$ 13,101	$ 60,288

Other Liabilities, Non-current

Other liabilities, non-current of continuing operations consisted of the following:

(in thousands)	September 30, 2025	December 31, 2024
Contingent consideration, non-current	$ 102	$ 632
Deferred tax liability	1,102	1,102
Revenue participation liability, non-current	13,626	27,595
Royalty fee derivative liability, non-current	1,490	—
Other	1,225	—
Total Other liabilities, non-current	$ 17,545	$ 29,329

6. Discontinued Operations

On December 2, 2024, the Company and Intas entered into the UDENYCA Purchase Agreement. On April 11, 2025, the Company completed the divestiture of the UDENYCA Business to Intas for upfront, all-cash consideration of $483.4 million, inclusive of $118.4 million for UDENYCA product inventory. The Company recognized a net gain on the UDENYCA Sale of $338.7 million, which included the cash receipts less net assets transferred to Accord or otherwise derecognized and transaction expenses of $10.3 million. The Company is eligible to receive two additional Earnout Payments of $37.5 million each. The first such payment is payable by Intas to the Company if Net Sales of UDENYCA for four consecutive

fiscal quarters from July 1, 2025 through September 30, 2026 are equal to or greater than $300 million, and the second such payment is payable by Intas to the Company if Net Sales of UDENYCA for four consecutive fiscal quarters from July 1, 2025 through March 31, 2027 are equal to or greater than $350 million.

On June 26, 2024, the Company completed the sale of its YUSIMRY immunology franchise, which comprised certain assets, including certain YUSIMRY intellectual property, contracts, YUSIMRY inventory, and all activities related to research and development of YUSIMRY for upfront cash consideration of $40.0 million and the assumption of certain liabilities, including $17.0 million of inventory purchase commitments (the "YUSIMRY Sale").

On March 1, 2024, the Company completed the sale of its CIMERLI ophthalmology franchise through the sale of its subsidiary, Coherus Ophthalmology LLC, to Sandoz for upfront, all-cash consideration of $187.8 million, inclusive of $17.8 million for CIMERLI product inventory and prepaid manufacturing assets (the "CIMERLI Sale" and, together with the UDENYCA Sale and the YUSIMRY Sale, the "Sale Transactions").

The UDENYCA Sale represented the last and most significant divestiture of the Company's biosimilar businesses, which comprised the UDENYCA, YUSIMRY and CIMERLI franchises; therefore, the strategic shift criteria had been met and discontinued operations presentation has been included in the condensed consolidated financial statements for all periods presented.

The Company used a portion of the proceeds of the UDENYCA Sale to repay substantially all of the outstanding 2026 Convertible Notes and to buy out the right to receive royalties on net sales of UDENYCA in accordance with the Revenue Purchase and Sale Agreement, and thus the related interest expense and loss on debt extinguishment have been presented within discontinued operations. Interest expense related to the $175.0 million portion of the $250.0 million aggregate principal amount senior secured term loan facility, entered into on January 5, 2022 (as amended, the "2027 Term Loans"), was required to be repaid in April 2024 in connection with the CIMERLI Sale and has also been presented within discontinued operations.

The following table presents a reconciliation of discontinued operations for the periods presented:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2025	2024	2025	2024
Net revenue	$ 10,663	$ 64,722	$ 65,891	$ 194,160
Costs and expenses:				
Cost of goods sold	287	18,012	26,184	77,718
Research and development	564	(376)	726	1,027
Selling, general and administrative	326	6,617	9,809	30,567
Total costs and expenses	1,177	24,253	36,719	109,312
Income from operations	9,486	40,469	29,172	84,848
Interest expense	—	(2,535)	(3,484)	(12,990)
Gain (loss) on Sale Transactions, net	(422)	(1,086)	338,680	176,646
Loss on debt extinguishment	—	—	(10,286)	—
Other income (expense), net	(78)	—	(11,638)	—
Net income from discontinued operations before income taxes	8,986	36,848	342,444	248,504
Income tax provision	—	—	—	—
Net income from discontinued operations, net of tax	$ 8,986	$ 36,848	$ 342,444	$ 248,504

Net revenue from discontinued operations by product was as follows:

(in thousands)	Three Months Ended September 30, 2025	Three Months Ended September 30, 2024	Nine Months Ended September 30, 2025	Nine Months Ended September 30, 2024
UDENYCA	$ 10,663	$ 66,089	$ 65,315	$ 159,673
CIMERLI	—	(1,215)	533	26,979
YUSIMRY	—	(152)	43	7,508
Total net revenue from discontinued operations	$ 10,663	$ 64,722	$ 65,891	$ 194,160

For the three months ended September 30, 2025, net revenue was primarily driven by a favorable settlement, resulting in a non-cash accrual release of $8.7 million.

Assets of discontinued operations were entirely derecognized as of September 30, 2025 and were as follows at December 31, 2024:

(in thousands)	December 31, 2024
Assets of Discontinued Operations	
Inventory	$ 65,887
Prepaid manufacturing	4,983
Other prepaids and current assets	1,310
Total assets of discontinued operations, current	72,180
Property and equipment, net	261
Inventory, non-current	43,776
Other assets, non-current	206
Total assets of discontinued operations, non-current	44,243
Total assets of discontinued operations	$ 116,423

The following table presents the balance sheet classifications of assets and liabilities that were related to discontinued operations but did not transfer to any of the buyers in the Sale Transactions, and thus were not classified as discontinued operations:

(in thousands)	September 30, 2025	December 31, 2024
Assets		
Trade receivables, net [1]	$ (3,050)	$ 102,365
Liabilities		
Accrued rebates, fees and reserves	$ 64,826 [2]	$ 163,771
Liabilities to be paid in connection with UDENYCA Sale		
Accrued and other current liabilities	$ —	$ 14,816
Other liabilities, non-current	$ —	$ 15,667
Convertible notes (Note 8)	$ —	$ 228,229

(1) Chargebacks and discounts for prompt payment are classified as a reduction in trade receivables.

(2) This balance is expected to be settled in a front-weighted fashion over the remainder of 2025 and into 2026.

Cash flows from continuing operations and discontinued operations have been presented together in the condensed consolidated statement of cash flows. During the nine months ended September 30, 2025, operating cash flows of discontinued operations were primarily related to the adjustment for the net gain on UDENYCA Sale of $338.7 million, partially offset by a loss on debt extinguishment of $10.3 million. During the nine months ended September 30, 2024, operating cash flows of discontinued operations were primarily related to the adjustment for the net gain on Sale

Transactions of $176.6 million and an increase in UDENYCA inventory which resulted in a net cash outflow of $22.7 million.

In connection with the Sale Transactions, the Company entered into separate TSAs with each of the buyers pursuant to which the Company is providing certain business support services including billings, collections, and the remittance of rebates, to ensure business continuity for patients and customers for specified periods. Under each of the TSAs, the Company is entitled to be reimbursed for its costs. Such reimbursements were $0.5 million and $1.0 million for the three months ended September 30, 2025 and 2024, respectively, and $2.3 million and $2.1 million for the nine months ended September 30, 2025 and 2024, respectively, and were recorded as a reduction to operating expenses or in other income (expense), net in the condensed consolidated statements of operations based on the nature of the payment.

7. Collaborations and Other Arrangements

In-Licensing Agreement

Junshi Biosciences

In March 2024, the Company entered into an Amendment No. 2 (the "2nd Amendment") to the Exclusive License and Commercialization Agreement (the "Collaboration Agreement") with Junshi Biosciences Co., Ltd. ("Junshi Biosciences") to revise the timing of the $25.0 million milestone payment to Junshi Biosciences that became due in connection with the approval by the U.S. Food and Drug Administration ("FDA") of toripalimab for the treatment of patients with NPC in the first quarter of 2024. Under the terms of the 2nd Amendment, the $25.0 million milestone payment was split into two installments of $12.5 million each, one that was paid in the second quarter of 2024 and one that was paid in January of 2025.

The research and development expense recognized for obligations to Junshi Biosciences for the three and nine months ended September 30, 2025 and the three months ended September 30, 2024 was not material. During the nine months ended September 30, 2024, the Company recognized a reduction in research and development expenses for the release of certain liabilities of $4.8 million pursuant to the 2nd Amendment with Junshi Biosciences. In the condensed consolidated balance sheets as of December 31, 2024, the Company classified $12.5 million in accrued and other current liabilities, as well as $0.4 million in accounts payable related to the co-development, regulatory and technology transfer costs related to these programs.

The accrued royalty obligation to Junshi Biosciences was $2.2 million and $1.5 million as of September 30, 2025 and December 31, 2024, respectively. The additional milestone payments, option fee for the IL-2 cytokine and royalties are contingent upon future events and, therefore, will be recognized when it becomes probable that a milestone will be achieved or when an option fee or royalties are contractually payable.

8. Financial Liabilities

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

	At September 30, 2025				
(in thousands)	Principal Amount	Unamortized Debt Discount and Debt Issuance Costs	Net Carrying Value	Estimated Fair Value	Level
Financial Liabilities:					
2029 Term Loan	$ 38,660	$ (1,703)	$ 36,957	$ 36,957	Level 2*
2026 Convertible Notes	$ 121	$ —	$ 121	$ 119	Level 2**

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

* The principal amounts outstanding are subject to variable interest rates based on three-month SOFR plus fixed percentages. Therefore, the Company believes the carrying amounts of these obligations approximate their fair values.

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

2029 Term Loan

On May 8, 2024, the Company entered into a senior secured term loan facility for up to $38.7 million (the "2029 Term Loan") and received proceeds, net of the original issuance discount, of $37.5 million. The net proceeds were used by the Company as part of the full repayment of the 2027 Term Loans.

The 2029 Term Loan matures on May 8, 2029. The amount borrowed under the 2029 Term Loan accrues interest equal to 8.0%, plus a three-month SOFR rate per annum. The 2029 Term Loan provides for interest-only payments on a quarterly basis until maturity. The loan agreement, by and among the Company, Ankura Trust Company, LLC and the lenders signatory thereto (the "2029 Loan Agreement"), contains certain covenants, and the Company was in full compliance with no events of default as of September 30, 2025.

Interest expense on the 2029 Term Loan was $1.3 million and $3.9 million for the three and nine months ended September 30, 2025, respectively, and $1.4 million and $2.2 million for the three and nine months ended September 30, 2024, respectively, and is classified within continuing operations on the condensed consolidated statements of operations.

Revenue Purchase and Sale Agreement

On May 8, 2024, concurrent with the 2029 Term Loan, the Company entered into the Revenue Purchase and Sale Agreement with the Purchaser Group. Under the terms of the Revenue Purchase and Sale Agreement, the Purchaser Group paid the Company $37.5 million, subject to certain conditions at closing (the "Purchase Price"). In exchange, the Company sold to the Purchaser Group a right to receive 5.0% of U.S. net sales of UDENYCA and LOQTORZI with respect to a specified threshold applicable to UDENYCA net sales and a specified threshold applicable to LOQTORZI net sales during an applicable year and 0.5% of U.S. net sales of UDENYCA and LOQTORZI that exceeded the specified threshold during that year (the "Revenue Payment") for each calendar quarter commencing May 8, 2024. The Purchaser Group's

right to receive the Revenue Payment terminates and the Company no longer has the obligation to pay Revenue Payments once the Purchaser Group receives the amount equal to 2.25 times the Purchase Price allocated to each product. The Company may also buy out the Purchaser Group's rights to receive the Revenue Payments by triggering certain conditions and paying the Purchaser Group the unpaid portion of the 2.25 multiple on the Purchase Price. The proceeds from the Purchase Price were used by the Company as part of the full repayment of the 2027 Term Loans. On April 15, 2025, the Company paid $47.7 million to buy out the Purchaser Group's right to receive the Revenue Payments with respect to UDENYCA in accordance with the Revenue Purchase and Sale Agreement ("UDENYCA Buy-out").

The Revenue Purchase and Sale Agreement contains certain covenants, and the Company was in full compliance with the agreement as of September 30, 2025.

The Revenue Purchase and Sale Agreement contains an embedded derivative that meets the criteria to be bifurcated and accounted for as a freestanding instrument subject to derivative accounting. The allocation of the Purchase Price to the embedded derivative resulted in a $9.2 million discount on the revenue participation liability at inception. Additionally, there was $1.4 million in issuance costs. The discount and issuance costs are amortized to interest expense over the estimated term of the Revenue Purchase and Sale Agreement using the effective interest method. In connection with the UDENYCA Buy-out, the unamortized portion of the discount and issuance costs related to UDENYCA was derecognized. For the three and nine months ended September 30, 2025, there was $1.0 million and $4.8 million, respectively, of interest expense related to the Revenue Purchase and Sale Agreement, of which $1.9 million related to UDENYCA for the nine months ended September 30, 2025 and has been presented within discontinued operations. For the three and nine months ended September 30, 2024, interest expense, inclusive of the amortization of discount and issuance costs, was $2.7 million and $4.4 million, respectively, of which $2.5 million related to UDENYCA and has been presented within discontinued operations for the nine months ended September 30, 2024. For details on the Royalty Fee Derivative Liability, see Note 3. Fair Value Measurements.

A summary of the revenue participation liability is as follows:

(in thousands)	September 30, 2025	December 31, 2024
Revenue participation liability	$ 16,291	$ 37,994
Less: unamortized discount and issuance costs	(2,665)	(9,251)
Net carrying value	$ 13,626	$ 28,743

The following table summarizes the activity within the revenue participation liability:

(in thousands)	
Proceeds from sale of future royalties on May 8, 2024	$ 37,500
Portion of proceeds allocated to the embedded derivative	(9,202)
Issuance costs	(1,391)
Royalty payments	(5,334)
Interest expense recognized	7,170
Revenue participation liability at December 31, 2024	28,743
Royalty payments	(2,675)
Interest expense recognized	4,841
Portion derecognized in connection with the UDENYCA Buy-out	(17,283)
Revenue participation liability at September 30, 2025	$ 13,626

Classification on the condensed consolidated balance sheets is as follows:

(in thousands)	Balance Sheet Classification	September 30, 2025	December 31, 2024
Revenue participation liability, current	Accrued and other current liabilities	$ —	$ 1,148
Revenue participation liability, non-current	Other liabilities, non-current	13,626	27,595
Net carrying value		$ 13,626	$ 28,743

2027 Term Loans

The Company entered into a loan agreement in January 2022 (as amended, the "2027 Loan Agreement") with BioPharma Credit, PLC and the 2027 Lenders that provided for a senior secured term loan facility, of which $250.0 million was funded.

On February 5, 2024, the Company entered into a Consent, Partial Release and Third Amendment to the 2027 Term Loans (the "Consent and Amendment") with the Collateral Agent and the 2027 Lenders. Pursuant to the Consent and Amendment, among other things, the 2027 Lenders and the Collateral Agent required the Company to make a $175.0 million partial prepayment of the principal of the loans outstanding under the 2027 Loan Agreement upon consummation of the transactions contemplated by the CIMERLI Purchase Agreement. As a result of the CIMERLI Sale closing, the Company made the partial prepayment of $175.0 million of the total principal balance of $250.0 million of the 2027 Term Loans on April 1, 2024.

On May 8, 2024, in connection with entering into the 2029 Term Loan and the Revenue Purchase and Sale Agreement, the Company repaid in full all outstanding indebtedness and terminated all commitments under the 2027 Term Loans. The May 8, 2024 payoff amount of $79.6 million included principal repayment in full, accrued interest, a 3.0% prepayment premium fee of the principal amount, a make-whole interest payment and lender fees.

The following table summarizes interest expense for the 2027 Term Loans and the dates when principal was repaid:

	Interest Expense			
(in thousands) Statement of Operations Classification	Three Months Ended September 30, 2024	Nine Months Ended September 30, 2024	Principal Amount Repaid	Date Principal was Repaid
Discontinued Operations	$ —	$ 6,878	$ 175,000	April 1, 2024
Continuing Operations	$ —	$ 4,315	$ 75,000	May 8, 2024

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"). 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 mature on April 15, 2026, unless earlier repurchased or converted.

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). As of September 30, 2025, the Company was in full compliance with these covenants, and there were no events of default under the 2026 Convertible Notes.

On April 15, 2025, the Company paid $170.0 million in cash to repurchase $170.0 million aggregate principal amount of the 2026 Convertible Notes in privately negotiated transactions. On May 15, 2025, pursuant to the Fundamental Change Repurchase Right (as defined in the indenture, dated as of April 17, 2020 (the "Indenture"), between the Company and U.S. Bank Trust Company, National Association (the "Trustee"), as trustee), the Company repurchased $59.9 million aggregate principal amount of the 2026 Convertible Notes, at a cash repurchase price of $59.9

million, which amount was equivalent to 100% of the principal amount of the repurchased notes, together with the accrued and unpaid interest. As of September 30, 2025, the outstanding principal amount of the 2026 Convertible Notes was $0.1 million and consisted of the remaining notes that were not tendered for repurchase. In connection with the repurchases, the Company recorded a $4.7 million loss on debt extinguishment which is classified within discontinued operations in the condensed consolidated statements of operations. The charge in the nine months ended September 30, 2025, included the write-off of the remaining debt discount and debt issuance costs and related transaction fees.

The annual effective interest rate is 2.1% for the 2026 Convertible Notes, and the following table presents the components of interest expense which have been presented within discontinued operations:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2025	2024	2025	2024
Stated coupon interest	$ —	$ 863	$ 1,072	$ 2,588
Amortization of debt discount and debt issuance costs	—	336	423	1,003
Total interest expense	$ —	$ 1,199	$ 1,495	$ 3,591

9. Commitments and Contingencies

Purchase Commitments

The Company entered into agreements with certain vendors to secure certain CMOs to manufacture its supply of product. As of September 30, 2025, the Company's non-cancelable purchase commitments under the terms of its agreements are as follows:

Year ending December 31, (in thousands)	
Remainder of 2025	$ 8,097
2026	5,060
Total obligations	$ 13,157

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 cancelable, with varying provisions regarding termination. If a contract with a specific vendor were to be terminated, the Company would generally only be obligated for products or services that the Company had received as of the effective date of the termination and any applicable cancellation fees.

Guarantees and Indemnifications

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future but have not yet been made. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. However, the Company may record charges in the future as a result of these indemnification obligations. The Company assesses the likelihood of any adverse judgments or related claims, as well as ranges of probable losses. In the cases where the Company believes that a reasonably possible or probable loss exists, it will disclose the facts and circumstances of the claims, including an estimate range, if possible.

Legal Proceedings and Other Claims

The Company is a party to various legal proceedings and claims that arise in the ordinary, routine course of business and that have not been fully resolved. The outcome of such legal proceedings and claims is inherently uncertain. Accruals are recognized for such legal proceedings and claims to the extent that a loss is both probable and reasonably estimable. The best estimate of a loss within a range is accrued; however, if no estimate in the range is better than any other, then the minimum amount in the range is accrued. If it is determined that a material loss is reasonably possible and the loss or range of loss can be estimated, the possible loss is disclosed. Sometimes it is not possible to determine the outcome of these matters or, unless otherwise noted, the outcome (including in excess of any accrual) is not expected to be material, and the maximum potential exposure or the range of possible loss cannot be reasonably estimated. As of September 30, 2025 and December 31, 2024, the Company had an accrual of $6.4 million, related to such matters that was included in accrued rebates, fees and reserves on the condensed consolidated balance sheets.

In late April of 2022, the Company received a demand letter from Zinc Health Services, LLC (“Zinc”) asserting that Zinc was entitled to approximately $14.0 million from the Company for claims related to certain sales of UDENYCA from October 2020 through December 2021. 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 has an accrual established as of September 30, 2025 that represents its estimated liability to resolve the matter. Loss contingencies are inherently unpredictable, the assessment is highly subjective and requires judgments about future events and unfavorable developments or resolutions can occur. The Company regularly reviews litigation matters to determine whether its accrual is adequate. The amount of ultimate loss may differ materially from the amount accrued to date.

Other than the matter in connection with the demand letter described in this Note 9. Commitments and Contingencies, there are no pending legal proceedings, other than ordinary routine litigation incidental to the business, to which the Company or any of its subsidiaries is a party, or that any of the Company or its subsidiaries' property is subject.

10. Stockholders’ Equity (Deficit)

ATM Offering

There were no shares sold under the at-the-market offering (“ATM Offering”) during the three months ended September 30, 2025 and 2024. The following table summarizes information regarding settlements under the ATM Offering for the nine months ended September 30, 2025 and 2024:

	Nine Months Ended September 30,	
(in thousands, except share and per share data)	2025	2024
Number of common stock shares sold during the period	—	650,005
Weighted-average price per share	$ —	$ 2.44
Gross proceeds	$ —	$ 1,589
Less commissions and fees	—	(40)
Net proceeds after commissions and fees	$ —	$ 1,549

As of September 30, 2025, the Company had approximately $64.9 million of its common stock remaining available for sales of common stock from time to time through or to Cowen and Company, LLC (“TD Cowen”) as the Company’s sales agent or principal in the ATM Offering.

Private Placement

On October 21, 2025, the Company sold to certain unaffiliated third-party investors (i) an aggregate of 4,634,995

shares of our common stock (the “Shares”) and (ii) warrants (the “Warrants”) to purchase an aggregate of 463,498 shares of common stock, each for an exercise price of $0.01 per share, for an aggregate purchase price of $8.0 million (collectively, the “Private Placement”). The Warrants may be exercised at any time on or before October 21, 2030. The Warrants are subject to appropriate adjustment in the event of share dividends, stock splits, reorganizations or similar events affecting our common stock.

11. 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 employees and non-employees:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2025	2024	2025	2024
Cost of goods sold [1]	$ 4	$ 282	$ 372	$ 834
Research and development	1,316	2,092	5,157	6,552
Selling, general and administrative	2,069	4,494	8,653	14,032
Stock-based compensation subtotal	3,389	6,868	14,182	21,418
Less: Stock-based compensation from discontinued operations	(67)	(430)	(647)	(1,305)
Total stock-based compensation expense from continuing operations	$ 3,322	$ 6,438	$ 13,535	$ 20,113
Total stock-based compensation expense capitalized into inventory	$ 19	$ 313	$ 305	$ 1,107

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

12. Net Income (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 table sets forth the computation of the basic and diluted net income (loss) per share:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands, except share and per share data)	2025	2024	2025	2024
Net loss from continuing operations	$ (44,517)	$ (47,599)	$ (136,777)	$ (169,301)
Weighted-average common shares outstanding, basic and diluted	116,229,170	115,210,091	116,056,247	114,263,256
Net loss from continuing operations, basic and diluted	$ (0.38)	$ (0.41)	$ (1.18)	$ (1.48)
Net income from discontinued operations, net of tax	$ 8,986	$ 36,848	$ 342,444	$ 248,504
Weighted-average common shares outstanding, basic and diluted	116,229,170	115,210,091	116,056,247	114,263,256
Net income from discontinued operations, basic and diluted	$ 0.08	$ 0.32	$ 2.95	$ 2.17
Net income (loss)	$ (35,531)	$ (10,751)	$ 205,667	$ 79,203
Weighted-average common shares outstanding, basic and diluted	116,229,170	115,210,091	116,056,247	114,263,256
Net income (loss) per share, basic and diluted	$ (0.31)	$ (0.09)	$ 1.77	$ 0.69

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Stock options, performance stock options and shares subject to ESPP	30,696,755	30,097,387	30,489,269	28,714,130
Restricted stock units	210,822	831,936	270,205	936,712
Shares issuable upon conversion of 2026 Convertible Notes	6,283	11,942,152	6,283	11,942,152
Total	30,913,860	42,871,475	30,765,757	41,592,994

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

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, 2024, and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, contained in the 2024 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 fully integrated commercial-stage innovative oncology company with an approved next-generation PD-1 inhibitor, LOQTORZI, growing revenues and a pipeline that includes two mid-stage clinical candidates targeting liver, lung, head & neck, colorectal and other cancers. Our strategy is to grow sales of LOQTORZI in NPC and advance the development of new indications for LOQTORZI in combination with both our pipeline candidates as well as through our partners, driving sales multiples and synergies from proprietary combinations.

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

Product and Product Candidates

Our portfolio includes the following product and product candidates:

Oncology

- LOQTORZI was developed for its ability to block PD-1 interactions with its ligands, PD-L1 and PD-L2, by binding to the FG loop on the PD-1 receptor. We believe blocking PD-1 interactions with PD-L1 and PD-L2 can help to promote the immune system's ability to attack and kill tumor cells. On October 27, 2023, we announced that LOQTORZI was approved by the FDA in combination with cisplatin and gemcitabine for the first-line treatment of adults with metastatic or recurrent locally advanced NPC, and as monotherapy for the treatment of adults with recurrent, unresectable, or metastatic NPC with disease progression on or after platinum-containing chemotherapy. LOQTORZI is an anti-PD-1 antibody that we developed in collaboration with Junshi Biosciences. We announced the launch of LOQTORZI in the U.S. on January 2, 2024.

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

  Further evaluation of LOQTORZI is expected through multiple current and planned clinical studies by us and our partners. We have a post marketing commitment study active and enrolling patients in locations in the U.S. and Canada in order to further evaluate the efficacy of toripalimab in combination with chemotherapy (cisplatin and gemcitabine) in patients with advanced NPC (clinicaltrials.gov identifier# NCT06457503). Junshi Biosciences is currently enrolling in a multiregional Phase 3 clinical study evaluating the treatment of LOQTORZI with its investigational anti-BTLA antibody in LS-SCLC (clinicaltrials.gov identifier# NCT06095583).

INOVIO Pharmaceuticals, Inc. plans a randomized Phase 3 study of INO-3112 and toripalimab in locally advanced, high risk HPV16/18+ oropharyngeal squamous cell carcinoma. Cancer Research Institute is evaluating toripalimab in combination with ENB Therapeutics' investigational agent ENB-003 in its Phase 2 trial titled, "Immunotherapy Platform Study in Platinum Resistant High Grade Serous Ovarian Cancer (IPROC)" (clinicaltrials.gov identifier# NCT04918186) that is being performed in collaboration with Canadian Cancer Trials Group. STORM Therapeutics, Ltd. is evaluating its METTL3 inhibitor STC-15 in combination with LOQTORZI in a Phase 1b/2 study (clinicaltrials.gov identifier# NCT06975293) for the treatment of non-small cell lung cancer and head and neck squamous cell carcinoma ("HNSCC"), and has plans for melanoma and endometrial cancer. On June 27, 2024, we entered into a license Agreement with Apotex, Inc. ("Apotex"), pursuant to which, we granted to Apotex an exclusive license under our rights to toripalimab to commercialize toripalimab within Canada ("Canada License Agreement").

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

- CHS-114 (formerly SRF114), is an investigational human afucosylated IgG1 monoclonal antibody selectively targeting CCR8, a chemokine receptor highly expressed on regulatory T cells ("Treg cells") in the tumor microenvironment. CHS-114 is designed as a cytolytic antibody to cause depletion of intra-tumoral Treg cells, important regulators of immune suppression and tolerance, through ADCC, or ADCP or both. CHS-114 has shown anti-tumor activity as monotherapy or in combination with anti-PD-1 antibodies in preclinical models. We are currently evaluating CHS-114 in combination with toripalimab in a Phase 1b clinical study in second-line HNSCC (clinicaltrials.gov identifier# NCT05635643). We also have an ongoing Phase 1b/2a clinical study of CHS-114 in combination with toripalimab and/or other treatments in participants with advanced solid tumors with the first cohorts evaluating gastric cancer, esophageal squamous cell cancer and microsatellite stable (MSS) colorectal cancer (clinicaltrials.gov identifier# NCT06657144).

License Agreement with Junshi Biosciences

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

Under the terms of the Collaboration Agreement, we paid $150.0 million upfront for exclusive rights to LOQTORZI in the United States and Canada, an option in these territories to Junshi Biosciences' anti-TIGIT antibody CHS-006, an option in these territories to a next-generation engineered IL-2 cytokine, and certain negotiation rights to two undisclosed preclinical immuno-oncology drug candidates. On January 10, 2024, we announced that we had delivered a notice of termination of CHS-006 to Junshi Biosciences. We obtained the right to conduct all commercial activities of LOQTORZI in the United States and Canada. We are obligated to pay Junshi Biosciences up to an aggregate $380.0 million in one-time payments for the achievement of various regulatory and sales milestones, of which we have already paid $25.0 million, and a royalty in the low twenty percent range on net sales of LOQTORZI. On June 27, 2024, we entered into the Canada License Agreement pursuant to which, we granted to Apotex an exclusive license under our rights to toripalimab to commercialize toripalimab within Canada.

Key Business and Other Updates

The following represents a summary of notable business updates and events since the filing of our Quarterly Report on Form 10-Q for the Quarterly Period ended June 30, 2025, including certain items from our press releases and Current Reports on Form 8-K, which readers are encouraged to review in full when they become available on our website at https://www.coherus.com. The content on the referenced website does not constitute a part of and is not incorporated by reference into this Quarterly Report on Form 10-Q.

Regained Nasdaq Compliance

As previously disclosed, on June 30, 2025, we received a deficiency notice from the Listing Qualifications Department (the "Staff") of the Nasdaq Stock Market LLC ("Nasdaq") notifying us that, for 30 consecutive business days, the bid price for our common stock had closed below $1.00 per share, the minimum closing bid price required by the continued listing requirements of Nasdaq. We had a period of 180 calendar days, or until December 29, 2025, to regain compliance with the rule referred to in this paragraph.

On September 5, 2025, we received a letter from Nasdaq notifying us that the Staff had determined that the closing price of our common stock was $1.00 or greater for the requisite period of time, that we had regained compliance with Listing Rule 5550(a)(2) and that the matter was now closed.

Financial Operations Overview

Discontinued Operations

The UDENYCA Sale represented the last and most significant divestiture of the Company's biosimilar businesses, which comprised the UDENYCA, YUSIMRY and CIMERLI franchises; therefore, the strategic shift criteria had been met and discontinued operations presentation has been included in the condensed consolidated financial statements for all periods presented.

Revenue

LOQTORZI was approved in October 2023 and was launched in the United States in December 2023.

Cost of Goods Sold

Cost of goods sold consists primarily of third-party manufacturing, distribution, royalties and certain overhead costs. Cost of goods sold includes a royalty in the low twenty percent range on net sales of LOQTORZI.

Research and Development Expense

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

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

- costs associated with manufacturing process development activities, analytical activities and pre-launch inventory manufactured prior to regulatory approval being obtained or deemed to be probable; and
- upfront and certain milestone payments related to licensing and collaboration agreements.

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

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

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

Selling, General and Administrative Expense

Selling, general and administrative expense consists primarily of personnel costs, allocated facilities costs and other expense for outside professional services, including legal, insurance, human resources, outside marketing, advertising, audit and accounting services, acquisition-related costs, and costs associated with establishing commercial capabilities in support of the commercialization of LOQTORZI. Personnel costs consist of salaries, benefits and stock-based compensation. Reimbursement of expenses from counterparties to the TSAs are recorded as reductions to selling, general and administrative expense.

Interest Expense

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

Other Income (Expense), Net

Other income (expense), net consists primarily of interest earned on our cash and cash equivalents, non-cash accretion of discount on our investments in marketable securities, foreign exchange gains (losses) resulting from currency fluctuations, gains (losses) from financial instruments including the change in fair value of the Royalty Fee

Derivative Liability, gains (losses) from disposal of long-lived assets, and income related to certain services provided under transition service agreements.

Results of Operations

Comparison of Three and Nine Months Ended September 30, 2025 and 2024

Revenue

(in thousands)	Three Months Ended September 30, 2025	2024	Change	Nine Months Ended September 30, 2025	2024	Change
LOQTORZI	$ 11,169	$ 5,832	$ 5,337	$ 28,476	$ 11,609	$ 16,867
Other revenue	402	220	182	948	7,047	(6,099)
Total net revenue	$ 11,571	$ 6,052	$ 5,519	$ 29,424	$ 18,656	$ 10,768

The increase in LOQTORZI net revenue for the three and nine months ended September 30, 2025 compared to the same periods in the prior year was driven primarily by volume growth of LOQTORZI, which launched in December 2023. Other revenue decreased in the nine months ended September 30, 2025 compared to the prior year period primarily driven by the $6.3 million for the outlicensing of rights to commercialize toripalimab within Canada on June 27, 2024.

We expect net revenue from continuing operations in 2025 to be higher than in 2024 because of continued growth of LOQTORZI.

Cost of Goods Sold

(in thousands)	Three Months Ended September 30, 2025	2024	Change	Nine Months Ended September 30, 2025	2024	Change
Cost of goods sold	$ 3,721	$ 2,729	$ 992	$ 9,769	$ 5,977	$ 3,792
Gross margin	68 %	55 %		67 %	68 %	

The increase in cost of goods sold from continuing operations for the three and nine months ended September 30, 2025 compared to the same periods in the prior year was primarily due to volume growth of LOQTORZI, which launched in December 2023.

We expect cost of goods sold from continuing operations for 2025 to be higher than 2024 because of continued growth of LOQTORZI.

Research and Development Expense

(in thousands)	Three Months Ended September 30, 2025	2024	Change	Nine Months Ended September 30, 2025	2024	Change
Research and development	$ 27,252	$ 22,052	$ 5,200	$ 77,914	$ 71,074	$ 6,840

The increase in research and development expense from continuing operations in the three months ended September 30, 2025 compared to the prior period was primarily due to the following:

- an increase of $4.1 million for the development of CH-114; and
- an increase of $2.6 million for the development of casdozokitug.

The increase was partially offset by a decrease of $1.4 million in facilities, supplies and materials and other infrastructure related expenses to support our research and development programs.

The increase in research and development expense from continuing operations in the nine months ended September 30, 2025 compared to the prior period was primarily due to the following:

- an increase of $13.1 million for the development of CHS-114; and
- an increase of $9.4 million for the development of casdozokitug.

The increase was partially offset by the following:

- a decrease of $8.2 million in co-development costs for toripalimab and CHS-006 resulting from reducing the scope of the development plan for toripalimab in the United States and the termination of the TIGIT Program announced in January 2024;
- a decrease of $3.1 million in facilities, supplies and materials and other infrastructure related expenses to support our research and development programs;
- a decrease of $2.1 million in personnel and stock-based compensation expense primarily due to fewer employees; and
- a decrease of $1.7 million for the development of CHS-1000.

We expect our research and development expense in 2025 to be higher than 2024 due to continued investments in our immuno-oncology pipeline.

Selling, General and Administrative Expense

(in thousands)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2025	2024	Change	2025	2024	Change
Selling, general and administrative	$ 24,931	$ 28,127	$ (3,196)	$ 76,995	$ 95,874	$ (18,879)

The decrease in selling, general and administrative expenses from continuing operations in the three months ended September 30, 2025 was primarily due to a lower average headcount which resulted in reductions of $3.3 million in employee-related costs including stock-based compensation and lower professional fees of $1.4 million. These reductions were partially offset by a $1.6 million net impairment charge in the third quarter of 2025 relating to the write-off of the net carrying value of the out-license intangible asset of $2.1 million and the final remeasurement of the CVR liability of $0.5 million related to GSK4381562 to its fair value of zero (see Note 5. Balance Sheet Components).

The decrease in selling, general and administrative expense from continuing operations in the nine months ended September 30, 2025 was primarily due to a lower average headcount resulting in reductions of $8.7 million in employee-related costs including stock-based compensation, the $6.8 million net impairment charge in the first quarter of 2024 relating to the write-off of the net carrying value of the out-license intangible asset of $10.6 million and the final remeasurement of the CVR liability of $3.8 million related to NZV930 to its fair value of zero, lower professional fees of $3.6 million and a reduction of $1.4 million in facilities, supplies and materials and other related expenses to support our commercial infrastructure. These reductions were offset by the $1.6 million net impairment charge in the third quarter of 2025 relating to the write-off of the net carrying value of the out-license intangible asset and the final remeasurement of the CVR liability related to GSK4381562 to its fair value of zero (see Note 5. Balance Sheet Components).

We expect our selling, general and administrative expense from continuing operations for the full year 2025 to be lower than the full year 2024 primarily as a result of decreased operating costs and headcount.

Interest Expense

(in thousands)	Three Months Ended September 30, 2025	2024	Change	Nine Months Ended September 30, 2025	2024	Change
Interest expense	$ 2,325	$ 2,827	$ (502)	$ 6,752	$ 8,822	$ (2,070)

The decrease in interest expense from continuing operations in the nine months ended September 30, 2025 was primarily due to prepaying the remaining $75.0 million of the principal amount due under the 2027 Term Loans on May 8, 2024, partially offset by interest expense on the $38.7 million 2029 Term Loan and the LOQTORZI portion of the Revenue Purchase and Sale Agreement, both of which commenced on May 8, 2024 and incurred nine months of interest during the nine months ended September 30, 2025.

Interest expense from discontinued operations was zero and $2.5 million in the three months ended September 30, 2025 and 2024, respectively, and $3.5 million and $13.0 million in the nine months ended September 30, 2025 and 2024, respectively, and was related to the 2026 Convertible Notes, the UDENYCA portion of the Revenue Purchase and Sale Agreement, and $175.0 million of the $250.0 million principal amount due under the 2027 Term Loans.

We expect interest expense from continuing operations to be lower in 2025 than 2024, primarily as a result of repaying the remaining $75.0 million principal amount of the 2027 Term Loans during the second quarter of 2024.

Loss on Debt Extinguishment

(in thousands)	Three Months Ended September 30, 2025	2024	Change	Nine Months Ended September 30, 2025	2024	Change
Loss on debt extinguishment	$ —	$ —	$ —	$ —	$ 12,630	$ (12,630)

The $12.6 million loss on debt extinguishment in the nine months ended September 30, 2024 resulted from the payoff of the 2027 Term Loans in May 2024, and the charge included the write-off of the remaining debt discount and debt issuance costs, the prepayment premium fee, the make-whole interest payment, and lender fees.

Other Income (Expense), Net

(in thousands)	Three Months Ended September 30, 2025	2024	Change	Nine Months Ended September 30, 2025	2024	Change
Other income (expense), net	$ 2,141	$ 2,084	$ 57	$ 5,229	$ 6,420	$ (1,191)

Other income (expense), net from continuing operations in the three months ended September 30, 2025 was comparable to the same period in the prior year.

Other income (expense), net from continuing operations in the nine months ended September 30, 2025 changed unfavorably compared to the same period in the prior year primarily due to a reduction of certain TSA reimbursements classified in other income of $1.8 million, a decrease in foreign exchange gains of $1.3 million, and the change in fair value of the LOQTORZI Royalty Fee Derivative Liability of $0.8 million, partially offset by an increase in interest and investment income of $2.6 million.

Net Income from Discontinued Operations, net of tax

(in thousands)	Three Months Ended September 30, 2025	2024	Change	Nine Months Ended September 30, 2025	2024	Change
Net income from discontinued operations, net of tax	$ 8,986	$ 36,848	$ (27,862)	$ 342,444	$ 248,504	$ 93,940

The decrease in the three months ended September 30, 2025 was primarily driven by lower net revenue of discontinued products partially offset by lower cost of goods sold. Total net revenues attributable to our divested products, UDENYCA, CIMERLI and YUSIMRY, which are reflected in discontinued operations, were $10.7 million and $64.7 million for the three months ended September 30, 2025 and 2024, respectively, and $65.9 million and $194.2 million during the nine months ended September 30, 2025 and 2024, respectively. For the three months ended September 30, 2025, net revenue was primarily driven by a favorable settlement, resulting in a non-cash accrual release of $8.7 million.

The increase in the nine months ended September 30, 2025 was primarily driven by the $162.0 million favorable change in gain on Sale Transactions (2025 period included the UDENYCA gain and 2024 period included CIMERLI and YUSIMRY gains) and lower cost of goods sold of $51.5 million, partially offset by lower net revenue and an $11.8 million charge in the first quarter of 2025 for the change in fair value of the Royalty Fee Derivative Liability related to UDENYCA.

Liquidity and Capital Resources

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

(in thousands)	September 30, 2025	December 31, 2024
Financial assets		
Total Cash, cash equivalents and marketable securities	$ 191,663	$ 125,987
Financial liabilities[1]:		
2029 Term Loan	$ 36,957	$ 36,698
Revenue Purchase and Sale Agreement	13,626 [2]	28,743
2026 Convertible Notes	121 [2]	228,229
Total Financial liabilities	$ 50,704	$ 293,670

(1) See “Note 8. Financial Liabilities” in the Notes to Condensed Consolidated Financial Statements contained in Part I, Item 1 of this Quarterly Report on Form 10-Q.

(2) We used a portion of the proceeds of the UDENYCA Sale, which closed on April 11, 2025, to repay substantially all of the outstanding 2026 Convertible Notes and to buy out the right to receive royalties on the net sales of UDENYCA in accordance with the Revenue Purchase and Sale Agreement.

As of September 30, 2025, we had cash, cash equivalents and marketable securities of $191.7 million and an accumulated deficit of $1.3 billion. We have generated significant operating losses in all the years since our inception except for certain periods that had gains from divestitures and 2020 and 2019. We currently have one commercial product, LOQTORZI, which generated $11.2 million in net revenues during the three months ended September 30, 2025. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. As of September 30, 2025, our investment in cash, cash equivalents and investments in marketable securities are primarily held in money market accounts, commercial paper and corporate notes, U.S. Treasury securities, and U.S. government agency securities. We have funded our operations primarily through sales of our common stock, issuance and incurrence of debt, the Revenue Purchase and Sale Agreement, the Sale Transactions and sales of our products.

The following is a summary of recent key liquidity events and financing transactions:

- On October 21, 2025, we sold to certain unaffiliated third-party investors (i) an aggregate of 4,634,995 shares of our common stock and (ii) Warrants to purchase an aggregate of 463,498 shares of common stock, each for an exercise price of $0.01 per share, for an aggregate purchase price of $8.0 million. The Warrants may be exercised at any time on or before October 21, 2030. The Warrants are subject to appropriate adjustment in the event of share dividends, stock splits, reorganizations or similar events affecting our common stock.

- During the second quarter of 2025, we used a portion of the proceeds from the UDENYCA Sale to: (1) repay substantially all of the $230 million aggregate principal amount of the outstanding 2026 Convertible Notes, and (2) buy out the royalty rights on the net sales of UDENYCA, in accordance with the Revenue Purchase and Sale Agreement, resulting in a $47.7 million payment.
- On April 11, 2025, we completed the UDENYCA Sale and received $483.4 million in cash, inclusive of $118.4 million for UDENYCA product inventory. We are eligible to receive two additional Earnout Payments of $37.5 million each, provided that certain minimum UDENYCA Net Sales thresholds are met during specified periods after the closing of the UDENYCA Sale.
- On June 27, 2024, we sold to Apotex an exclusive license under our rights to toripalimab to commercialize toripalimab within Canada for $6.3 million.
- On June 26, 2024, we sold our YUSIMRY immunology franchise to HKF for $40.0 million in cash and the assumption of $17.0 million of inventory purchase commitments by HKF.
- On May 8, 2024, we entered into the 2029 Term Loan for the principal amount of $38.7 million, with proceeds of $37.5 million, net of original issuance discount, which was used as part of the full repayment of the 2027 Term Loans. For a summary of the material terms of our 2029 Term Loan, please refer to “Note 8. Financial Liabilities” in the Notes to Condensed Consolidated Financial Statements contained in this Quarterly Report on Form 10-Q.
- On May 8, 2024, we entered into the Revenue Purchase and Sale Agreement, receiving $37.5 million by selling rights to receive future payments based on a percentage of U.S. net sales of UDENYCA and LOQTORZI. The proceeds were used as part of the full repayment of the 2027 Term Loans.
- On April 1, 2024, cash from the CIMERLI Sale was used to repay $175.0 million of the total principal balance of $250.0 million of the 2027 Term Loans.
- On March 1, 2024, we sold our CIMERLI ophthalmology franchise to Sandoz for $187.8 million in cash, inclusive of $17.8 million for CIMERLI product inventory and prepaid manufacturing assets.

We may utilize our ATM Offering from time to time in order to sell our common stock. As of September 30, 2025, we had approximately $64.9 million of our common stock remaining available for sales under the ATM Offering.

We believe that our available cash, cash equivalents and marketable securities, product sales, and ATM Offering proceeds received to date will be sufficient to fund our planned expenditures and meet our obligations for at least the twelve months following our financial statement issuance date.

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

- cash proceeds from product sales;
- the payment of interest, principal and royalties related to our financial liabilities;
- the costs of manufacturing, distributing and marketing our product;

- the cost of manufacturing clinical drug supplies and establishing commercial supplies of our product candidates and product;
- the percentage of customers that continue to purchase our product and that do not switch to products made by our competitors;
- the terms and timing of any other collaborative, licensing and other arrangements that we have established or may establish;
- the timing, receipt and amount of sales, profit sharing or royalties, if any, from any product candidates that are approved in the future;
- the number and characteristics of product candidates that we pursue;
- the scope, rate of progress, results and cost of our clinical trials, preclinical testing and other related activities;
- the costs of manufacturing preclinical study and clinical trial supplies and other materials from CMOs and related costs associated with release and stability testing;
- whether we receive either of the Earnout Payments from the sale of the UDENYCA Business;
- the cost, timing and outcomes of regulatory approvals; and
- the extent to which we divest, acquire or invest in businesses, products or technologies.

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

Contingent Milestones

We have obligations to make future payments to third parties that become due and payable upon the achievement of certain development, regulatory and commercial milestones (such as clinical trial achievements, the filing of a Biologics License Application (“BLA”), approval by the FDA or product launch). These milestone payments and other similar fees are contingent upon future events and therefore are only recorded when it becomes probable that a milestone will be achieved or other applicable criteria will be met. Because the achievement of these milestones had not reached the threshold for recognition as of September 30, 2025, such contingencies were not recorded in our financial statements.

The following presents a summary of our active partnerships and collaborations that have material contingent regulatory and sales milestones as of September 30, 2025:

Counterparty	Description	Remaining Potential Aggregate Milestone Amount
Junshi Biosciences	LOQTORZI	$355.0 million (1)
Adimab LLC	Casdozokitug	$10.5 million
Vaccinex, Inc.	CHS-114	$14.5 million

(1) $65.0 million relates to regulatory milestones for indications that are not currently the subject of our clinical trials and $290.0 million relates to sales milestones.

Contingent Value Rights

As of September 30, 2025, the remaining CVRs in connection with the Surface Acquisition consisted of the CVRs associated with the receipt by us of any upfront payments pursuant to ex-U.S. licensing agreements related to casdozokitug or CHS-114. The potential payments are only due if we first receive upfront payments pursuant to ex-U.S. licensing agreements. Payments to CVR holders can be in the form of cash, stock or a combination of cash and stock.

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, 2025 were $13.2 million, as outlined in Note 9. Commitments and Contingencies in the Notes to Condensed Consolidated Financial Statements contained in Part I, Item 1 of this Quarterly Report on Form 10-Q.

There have been no significant changes to our leases during the nine months ended September 30, 2025, as compared to the disclosure in our 2024 Form 10-K.

Summary Statement of Cash Flows

The following table summarizes our cash flows for discontinued and continuing operations on a combined basis as follows:

	Nine Months Ended September 30,	
(in thousands)	**2025**	**2024**
Net cash used in operating activities	$ (118,797)	$ (49,048)
Net cash provided by investing activities	377,925	230,863
Net cash used in financing activities	(281,786)	(187,205)
Net decrease in cash, cash equivalents and restricted cash	$ (22,658)	$ (5,390)

Net cash used in operating activities

Cash used in operating activities of $118.8 million for the nine months ended September 30, 2025 was primarily due to adjusting net income by the net gain on Sale Transactions of $338.7 million to reflect that transaction as an investing activity, interest payments of $8.2 million and changes in operating assets and liabilities, partially offset by adjustments for non-cash items including stock-based compensation expense of $14.2 million, change in fair value of derivatives of $12.6 million, and loss on debt extinguishment of $10.3 million.

Cash used in operating activities of $49.0 million for the nine months ended September 30, 2024 was primarily due to net income of $79.2 million adjusted for non-cash items including stock-based compensation expense of $21.4 million, loss on debt extinguishment of $12.6 million, impairment of out-license asset net of CVR liability remeasurement of $6.8 million, other non-cash adjustments of $6.2 million and changes in our operating assets and liabilities, partially offset by the net gain on Sale Transactions of $176.6 million and interest payments of $18.8 million.

Net cash provided by investing activities

Cash provided by investing activities of $377.9 million for the nine months ended September 30, 2025 was primarily due to $483.4 million cash received for the UDENYCA Sale, partially offset by $89.6 million in purchases of investments in marketable securities, the second out of two $12.5 million milestone payments to Junshi Biosciences and $4.7 million in retention bonus payments in connection with the CIMERLI Sale.

Cash provided by investing activities of $230.9 million for the nine months ended September 30, 2024 was primarily due to cash proceeds of $187.8 million from the CIMERLI Sale, cash proceeds of $40.0 million from the YUSIMRY Sale, proceeds from sale of investments in marketable securities of $8.7 million, and proceeds from maturities of investments in marketable securities of $6.2 million, partially offset by a $12.5 million milestone payment to Junshi Biosciences.

Net cash used in financing activities

Cash used in financing activities of $281.8 million for the nine months ended September 30, 2025 was due to $233.2 million for repayment of substantially all the 2026 Convertible Notes and $47.7 million for the UDENYCA Buy-out.

Cash used in financing activities of $187.2 million for the nine months ended September 30, 2024 was primarily due to $260.4 million in payments to fully repay the 2027 Term Loans (excluding interest which is presented as an operating activity) and $2.5 million in tax payments related to net share settlement of RSUs. These payments were partially offset by $37.0 million of proceeds from the 2029 Term Loan, net of debt discount and issuance costs, $36.5 million of proceeds from the Revenue Purchase and Sale Agreement, net of issuance costs, and $1.5 million of proceeds from the ATM Offering, net of issuance costs.

Discontinued operations

Cash flows from continuing operations and discontinued operations have been presented together in the condensed consolidated statement of cash flows. During the nine months ended September 30, 2025, operating cash flows of discontinued operations were primarily related to the adjustment for the net gain on UDENYCA Sale of $338.7 million, partially offset by a loss on debt extinguishment of $10.3 million. During the nine months ended September 30, 2024, operating cash flows of discontinued operations were primarily related to the adjustment for the net gain on Sale Transactions of $176.6 million and an increase in UDENYCA inventory which resulted in a net cash outflow of $22.7 million.

Critical Accounting Policies and Significant Judgments and 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, 2025, as compared to the critical accounting estimates described in our 2024 Form 10-K. We believe that the critical accounting estimates discussed in the 2024 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.

Recent Accounting Pronouncements

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

ITEM 3. Quantitative and Qualitative Disclosures About Market Risk

We qualify as a "smaller reporting company", as defined by Rule 12b-2 of the Exchange Act, and as a result we have elected to not provide the information required under this Item 3.

ITEM 4. Controls and Procedures

Evaluation of Effectiveness of Disclosure Controls and Procedures

We carried out an evaluation, under the supervision of our President and Chief Executive Officer and our Chief Financial Officer, and evaluated the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of the end of the period covered by this Quarterly Report on Form 10-Q.

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. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Based on this evaluation, and as a result of the material weakness described below, our President and Chief Executive Officer and our Chief Financial Officer have concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures were not effective at a reasonable assurance level. Notwithstanding this material weakness, management concluded the condensed consolidated financial statements included in this report present fairly, in all material respects, our financial condition, results of operations and cash flows for the periods covered by this report.

Material Weakness in Internal Control over Financial Reporting

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

During the year ended December 31, 2024, we identified a material weakness in the operating effectiveness of our procedures related to documentation and review of certain inventory account reconciliations. The lack of sufficient evidence of the review performed over these accounting records did not allow for the testing and validation that the relevant internal controls operated, and thus it resulted in the material weakness. The material weakness related to documentation and did not result in a misstatement with respect to our financial statements included in the 2024 Form 10-K for the year ended December 31, 2024.

Management's Remediation Measures

We have been taking steps to remediate this material weakness and to strengthen our internal control over financial reporting. The remediation measures include additional training and enhancement of our documentation and retention procedures, particularly as they relate to our inventory account reconciliations. However, the deficient inventory account reconciliations control was decommissioned concurrent with the closing of the UDENYCA Sale on April 11, 2025, leaving no opportunity to formally retest the operating effectiveness of the control during the current period.

Changes in Internal Control Over Financial Reporting.

Except for the material weakness noted above, there has been no change in the Company's internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) that occurred during the quarter ended September 30, 2025 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

ITEM 1. Legal Proceedings

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

Item 1A. *Risk Factors*

Risk Factor Summary

Below is a summary of the principal factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading "Risk Factors" and should be carefully considered, together with other information in this Quarterly Report on Form 10-Q, including our financial statements and related notes thereto, before making investment decisions regarding our common stock.

- We have a limited history of profitability, which we have not maintained and may not achieve again, and only one product that has been approved and marketed and with multiple product candidates that are not approved and still in development.

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

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

- Our product 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, staffing limitations, government shut-downs or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, and conduct inspections of manufacturing facilities, or otherwise prevent new or modified products from being developed, or approved or commercialized in a timely manner or at all, which could negatively impact our business.

- Our product LOQTORZI and product candidates CHS-114 and casdozokitug, if approved, will face significant competition from other immuno-oncology biologics. If we fail to compete effectively, we may not achieve significant market penetration and expansion.

- We 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.

- Healthcare reform measures, including the Inflation Reduction Act of 2022 (the "IRA") and the OBBBA, may increase the difficulty and cost for us to obtain marketing approval for and commercialize our product, 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 and the risks of inaccurately forecasting sales of our product. We also need to make a determination of excess or obsolete inventory that requires judgment and may result in write-downs of inventory, charges related to firm purchase commitments, or both. Any adverse developments affecting the manufacturing operations of our product and product candidates could substantially increase our costs and limit supply for our product and product candidates.

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

- Our product 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 commercial-stage innovative oncology company, including one with a significant international partnership and multiple product candidates in development, is a highly speculative undertaking and involves a substantial degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information in this Quarterly Report on Form 10-Q. If any of the following risks are realized, our business, financial condition, results of operations and prospects could be materially and adversely affected. The risks described below are not the only risks facing us. Risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition, results of operations and/or prospects.

Risks Related to Our Financial Condition and Capital Requirements

We have a limited history of profitability, which we have not maintained and may not achieve again, and only one product that has been approved and marketed, and with multiple product candidates that are not approved and still in development.

We have generated significant operating losses in all the years since our inception except for certain periods that had gains from divestitures and 2020 and 2019. It is uncertain that we will be profitable in future periods, particularly now that the UDENYCA Sale was consummated, as research and development is expensive and risky. The amount of our future net losses or any future net income will depend, in part, on the amount of our future expenditures offset by the amount of future product sales, including sales of our current product or any other products that may receive regulatory approval. Innovative oncology product development is a highly speculative undertaking and involves a substantial degree of risk.

For example, as of September 30, 2025, we had an accumulated deficit of $1.3 billion. The losses and accumulated deficit were primarily due to the substantial investments we made to commercialize our product and identify, develop or acquire our product candidates, including conducting, among other things, analytical characterization, process development and manufacturing, formulation and clinical studies and providing general and administrative support for these operations.

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

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

Our expenses will increase substantially if and as we:

- establish a sales, marketing and distribution infrastructure to commercialize any of our product candidates for which we may obtain marketing approval;
- make upfront, milestone, royalty or other payments under any license agreements;
- continue our nonclinical and clinical development of our product candidates;
- initiate additional nonclinical, clinical or other studies for our product candidates;
- expand the scope of our current clinical studies for our product candidates;
- advance our programs into more expensive clinical studies;
- change or add contract manufacturers, clinical research service providers, testing laboratories, device suppliers, legal service providers or other vendors or suppliers;
- seek regulatory approvals for our product candidates that successfully complete clinical studies;

- seek to identify, assess, acquire and/or develop other product candidates or products that may be complementary to our product;
- 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;
- seek to attract and retain skilled personnel;
- create additional infrastructure to support our operations as a public company and our product development and planned future commercialization efforts; and
- experience any delays or encounter issues with any of the above, including but not limited to failed studies, conflicting results, safety issues, manufacturing delays, litigation or regulatory challenges that may require longer follow-up of existing studies, additional major studies or additional supportive studies or analyses in order to pursue marketing approval.

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

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

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, 2025, our cash, cash equivalents and marketable securities were $191.7 million. We expect that our existing cash and cash equivalents, investments, cash collected from our product sales and cash proceeds from the UDENYCA Sale will be sufficient to fund our current operations for the foreseeable future. We have financed our operations primarily through the sale of equity securities, convertible notes, credit facilities, divestitures, license agreements and through recent product sales of our product.

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 product;
- our ability to maintain continuity for the supply of our product and product candidates;
- 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 and product candidates;
- the number and characteristics of product candidates that we pursue;
- the cost, timing and outcomes of regulatory approvals;
- our ability to receive either of the Earnout Payments in the future;
- 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 repayment in cash, whether due or not, of our long-term debt and the payment of interest, principal and royalties related to our financial liabilities; and
- the cost, timing and outcomes of any litigation that we may file against third parties or that may be filed against us by third parties.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders, and the issuance of additional securities, whether equity or debt, by us or the possibility of such issuance may cause the market price of our shares to decline. The sale of additional equity or convertible securities, such as the sales from time to time through our Sales Agreement with TD Cowen pursuant to which we may issue and sell from time to time up to an additional approximately $64.9 million of our common stock, through or to TD Cowen as our sales agent or principal in an ATM Offering, may dilute the share ownership of our existing stockholders. The incurrence of indebtedness could result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as those contained in the 2029 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 such as a financial covenant which requires us to maintain certain levels of cash and cash equivalents. We could also be required to seek funds through arrangements with collaborative partners or otherwise at an earlier stage or for a lower price than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or for specific strategic considerations.

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

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

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

We are a commercial-stage innovative oncology company with a limited operating history in an emerging regulatory environment of immuno-oncology products. Although we have received upfront payments, milestone and other contingent payments and/or funding for development from some of our collaboration and license agreements, our only approved product is LOQTORZI, which is approved for commercial sale 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 product, and to complete the development of, and obtain the regulatory approvals necessary to commercialize, one or more of our product pipeline candidates, which include:

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

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

- our ability to continue to successfully commercialize LOQTORZI;
- healthcare providers, payers, and patients adopting our product and product candidates once approved and launched;
- obtaining additional regulatory approvals for product candidates for which we complete clinical studies;
- obtaining adequate third-party coverage and reimbursements for our product;
- obtaining market acceptance of our product 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 product 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 product and product candidates, if approved;
- addressing any competing technological and market developments;
- identifying, assessing and developing (or acquiring/in-licensing on favorable terms) new product candidates;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how; and
- defending against any litigation including patent or trade secret infringement lawsuits, which may be filed against us, or achieving successful outcomes lawsuits that we 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 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 immuno-oncology companies (including competition from large pharmaceutical companies possessing large established positions in the immuno-oncology market that may be able to gain advantages in the sale of immuno-oncology products based on brand recognition or existing relationships with customers and payers) and whether we own (or have partnered with companies owning) the

commercial rights for that territory. If the market for our product and product candidates (or our share of that market) is not as significant as we expect, the price of our product is not what we project, the indication approved by regulatory authorities is narrower than we expect or the reasonably accepted population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. If we are unable to successfully complete development and obtain additional regulatory approval for our product, our business may suffer.

The commercial success of our existing product 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 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 product or product candidates, if approved, will depend in part on the medical community, patients and third-party payers accepting our product and product candidates as medically useful, cost-effective and safe. Any product that we bring to the market may not gain market acceptance by physicians, patients, third-party payers and others in the medical community. The degree of market acceptance of our product LOQTORZI, or any of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the safety and efficacy of the product, as demonstrated in clinical studies, and potential advantages over competing treatments;
- the prevalence and severity of any side effects and any limitations or warnings contained in a product's approved labeling;
- the clinical indications for which approval is granted;
- for our product candidates, our ability to compete in a competitive immuno-oncology market;
- inclusion, in either parity or better position, on commonly accepted clinical guidelines or pathways that influence prescribing patterns and/or affect reimbursement;
- 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 product 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 product and product candidates, if approved;
- the price at which we sell our product;
- the potential impact of the IRA on the pharmaceutical industry and the market for our product;
- 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 products and product candidates. Further, continued market acceptance of LOQTORZI, and any future product candidates that may be approved, depend on our efforts to educate the medical community and third-party payers on the benefits of our product and product candidates and will require significant resources from us and we have significantly less resources compared to large, well-funded pharmaceutical companies. Given the resource disparity, our outreach may have little success or may never be successful. If our product or any future product candidates that are approved fail to achieve an adequate level of acceptance by physicians, patients, third-party payers and others in the medical community, we will not be able to generate sufficient revenue to sustain profitability.

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

Pricing, coverage and reimbursement of our product, 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 product and our patient support services must be sufficiently scaled to meet the needs of patients receiving our product. Sales will depend substantially, both domestically and abroad, on the extent to which the costs of our product 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 product 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 product to each payer separately, with no assurance that coverage and adequate reimbursement will be obtained.

If our product 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. 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 product 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 product or any of our product candidates. 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 product 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 product and our product candidates, even if approved, will remain subject to regulatory scrutiny.

Our product 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"), BLA submitted under Section 351(a) of the Public Health Service Act, or marketing authorization application ("MAA"). Accordingly, we and others with whom we work must continue to spend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

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

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 product. 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 the marketing approval that we have obtained and we may not sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

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

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

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, government shut-downs, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs and biologics or modifications to approved drugs and biologics to be reviewed or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. In addition, the current U.S. Presidential administration has issued certain policies and Executive Orders directed towards reducing the employee headcount and costs associated with U.S. administrative agencies, including the FDA, and it remains unclear the degree to which these efforts may limit or otherwise adversely affect the FDA's ability to conduct routine activities.

If a prolonged government shutdown occurs, or if funding shortages, staffing limitations or future global health concerns hinder or prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other such regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Risks Related to Competitive Activity

Our product LOQTORZI and product candidates CHS-114 and casdozokitug, if approved, will face significant competition from other immuno-oncology biologics. If we fail to compete effectively, we may not achieve significant market penetration and expansion.

We operate in highly competitive pharmaceutical markets. Successful competitors in the pharmaceutical market have demonstrated the ability to effectively discover molecules, obtain patents, develop, test and obtain regulatory approvals for products, as well as an ability to effectively commercialize, market and promote approved products. Numerous companies, universities and other research institutions are engaged in developing, patenting, manufacturing and marketing of products competitive with those that we are developing. Many of these potential competitors are large, experienced multinational pharmaceutical and biotechnology companies that enjoy significant competitive advantages, such as substantially greater financial, research and development, legal, governmental affairs, manufacturing, personnel, and marketing resources, with additional benefits of mergers and acquisitions.

LOQTORZI entered a competitive market in the United States where a number of anti-PD-1 or PD-L1 antibody drugs have been approved by the FDA, including the following marketed products from several competitors: Keytruda® (pembrolizumab) from Merck & Company, Inc. (“Merck”), Opdivo® (nivolumab) from Bristol-Myers Squibb Company (“BMS”), Tecentriq® (atezolizumab) from Genentech, Inc. (“Genentech”), Imfinzi® (durvalumab) from AstraZeneca plc (“AstraZeneca”), Bavencio® (avelumab) from EMD Serono Inc. and Pfizer Inc. (“Pfizer”), Libtayo® (cemiplimab-rwlc) from Regeneron Pharmaceuticals, Inc. (“Regeneron”), Jemperli (dostarlimab-gxly) from GlaxoSmithKline plc (“GlaxoSmithKline”) and TEVIMBRA® (tislelizumab-jsgr) from BeiGene, Ltd. Penpulimab-kcqx from Akeso Biopharma Co., Ltd. received approval from the FDA in April 2025 for the treatment of NPC. In addition to LOQTORZI, multiple other competitors are seeking to develop and approve novel anti-PD-1 or PD-L1 antibody drugs in the United States in the coming years, including but not limited to camrelizumab from Elevar Therapeutics, Inc. (in collaboration with Jiangsu Hengrui Pharmaceuticals Co., Ltd.).

Casdozokitug is in development and, although it is the only antagonist antibody in development known to us that is targeting the immune regulatory cytokine IL-27, if approved it faces competition from other immuno-oncology products that are currently approved and that may be approved in the future.

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

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.

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

Many of our competitors have substantially greater financial, technical and other resources, including larger research and development, marketing and manufacturing organizations. Additionally, mergers and acquisitions in the pharmaceutical industry may result in even more resources being concentrated in our competitors. As a result, these companies may obtain regulatory approval more rapidly than we are able to and may be more effective in selling and marketing their products. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis, products that are more effective or less costly than any product candidate

that we may develop; they may also obtain patent protection that could block our product; 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 product, which could adversely affect our results. Biosimilar or immuno-oncology product candidates developed by our competitors may render our potential product candidates uneconomical, less desirable or obsolete, and we may not be successful in marketing our product candidates against competitors.

If other competitors to toripalimab (in indications besides those approved for LOQTORZI), casdozokitug and CHS-114 are approved and successfully commercialized before toripalimab (in indications besides those approved for LOQTORZI), casdozokitug and CHS-114, our business would suffer.

There are a number of companies that currently commercialize PD-1/PD-L1 blocking antibodies or are developing such compounds for commercialization in the United States. If other competitors to toripalimab (in indications besides those approved for LOQTORZI), casdozokitug and CHS-114 are successfully commercialized before toripalimab (in indications besides those approved for LOQTORZI), casdozokitug and CHS-114, we may never achieve meaningful market share for these products, our revenue would be reduced and, as a result, our business, prospects and financial condition could suffer.

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

Our development of novel biologic product candidates, such as casdozokitug and CHS-114, subjects us to additional risks relating to biosimilar competition. In particular, under the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product.

We believe that LOQTORZI does, and any of our product candidates approved under a BLA should, qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, could be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products will depend on a number of marketplace and regulatory factors.

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

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

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

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

We will need to expand and effectively manage our managerial, scientific, operational, financial, commercial and other resources in order to successfully pursue our product development and commercialization efforts. Our success also depends on our continued ability to attract, retain and motivate highly qualified management and technical personnel. We may not be able to attract or retain qualified management and scientific and product development personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses, particularly those located in the San Francisco Bay Area. We also use equity compensation as a part of a comprehensive compensation package for our personnel. The majority of our outstanding options have exercise prices that are above our current stock price. See the tables in Note 12. Stock-Based Compensation and Employee Benefits in the footnotes to our financial statements included in our Annual Report for the Fiscal Year ended December 31, 2024, describing our outstanding stock options as of December 31, 2024. If we are not able to attract, retain and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

We may experience difficulties in managing changes in our number of employees, particularly due to employees departing due to divestitures, reductions in force and turnover, which could disrupt our operations.

As of September 30, 2025, we had 161 full-time and part-time employees, which was equal to approximately 158 full-time equivalents. This represented a decrease of approximately 68 full-time equivalents since December 31, 2024. As our development and commercialization plans and strategies develop and evolve from time to time we face difficulty managing these changes as we experience changes in our number of employees, including due to divestitures, like the employee transfers to Accord in the UDENYCA Sale effective on the UDENYCA Closing Date, reductions in force and turnover. We may not be able to effectively manage during a period of significant change in our number of employees, which may result in weaknesses in our infrastructure, operational mistakes, loss of business opportunities and reduced productivity and morale among remaining employees. If our management is unable to effectively manage the changes in our number of employees, our expenses may increase more than expected and our ability to generate or grow revenue could be reduced. Our future financial performance and our ability to commercialize product candidates and compete effectively will depend, in part, on our ability to effectively manage changes in our number of employees.

Risks Related to Reliance on Third Parties

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

We do not currently have the infrastructure or capability internally to manufacture supplies of our product and product candidates for use in our nonclinical and clinical studies, and we lack the resources and the capability to manufacture any of our product and product candidates on a clinical or commercial scale. We rely on third-party manufacturers to manufacture and supply us with our product and product candidates for our preclinical and clinical studies as well as to maintain commercial supplies of our product. 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 our product, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product or any other product candidates or products that we may develop. Any failure or refusal to supply the components for 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 product 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. We cannot be certain that we will be able to obtain long-term supply arrangements for our product candidates or materials used to produce them on acceptable terms, if at all. If we are unable to arrange for third-party manufacturing, or to do so on commercially reasonable terms, we may not be able to complete development of our product candidates or market them.

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

We have relied upon and plan to continue to rely upon third-party CROs to monitor and manage data for our ongoing nonclinical and clinical programs. We rely on these parties for execution of our nonclinical and clinical studies and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs and other vendors are required to comply with cGMP, Good Clinical Practice (“GCP”), and Good Laboratory Practices, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the EEA and comparable foreign regulatory authorities for all of our product candidates in clinical development. Regulatory authorities enforce these regulations through periodic inspections or remote regulatory assessments (“RRAs”) of study sponsors, principal investigators, study sites and other contractors. If we, any of our CROs, service providers or investigators fail to comply with applicable regulations or GCPs, the data generated in our nonclinical and clinical studies may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional nonclinical and clinical studies

before approving our marketing applications. There can be no assurance that upon inspection or conclusion of an RRA by a given regulatory authority, such regulatory authority will determine that any of our clinical studies comply with GCP regulations. In addition, our clinical studies must be conducted with product generated under cGMP regulations. Failure to comply by any of the participating parties or ourselves with these regulations may require us to repeat clinical studies, which would delay the regulatory approval process. Moreover, our business may be implicated if our CROs or any other participating parties violate federal or state fraud and abuse or false claims laws and regulations or healthcare or data privacy and security laws.

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

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

We are dependent on Junshi Biosciences for the commercialization of our product and the failure to commercialize could have a material adverse effect on our business and operating results.

We have an exclusive license from Junshi Biosciences to develop and commercialize LOQTORZI in the United States and Canada. Junshi Biosciences is responsible for supplying us with drug substance and final drug products.

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

- our existing and potential collaboration partners may fail to provide sufficient amounts of commercial product, 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 product;
- our existing and potential licensees and collaboration partners may incur financial, legal or other difficulties that force them to limit or reduce their participation in our joint projects;
- our existing and potential licensees and collaboration partners may terminate their licenses or collaborations with us, which could make it difficult for us to attract new partners or adversely affect perception of us in the business and financial communities; and
- our existing and potential licensees and collaboration partners may choose to pursue alternative, higher priority programs, which could affect their commitment to us.

Moreover, any disputes with our existing and future licensees and collaboration partners could substantially divert the attention of our senior management from other business activities and may require us to incur substantial costs

associated with litigation or arbitration proceedings. If we cannot maintain successful license and collaboration arrangements, our business, financial condition and operating results may be adversely affected.

Risks Related to Our Future Operations Following the UDENYCA Sale

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

A portion of the aggregate consideration potentially payable to us under the UDENYCA Purchase Agreement is in the form of two Earnout Payments of $37.5 million each. The first such payment is payable by Intas to us if Net Sales of UDENYCA for four consecutive fiscal quarters from July 1, 2025 through September 30, 2026 are equal to or greater than $300 million, and the second such payment is payable by Intas to the Company if Net Sales of UDENYCA for four consecutive fiscal quarters from July 1, 2025 through March 31, 2027 are equal to or greater than $350 million. However, there is no guarantee that we will receive either of the Earnout Payments, and we may not receive more than the consideration that we received at closing of the UDENYCA Sale for selling the UDENYCA Business. If we do not receive the Earnout Payments the total consideration paid to us for the sale of UDENYCA will be significantly lower, which could be harmful to our future financial position.

There are risks and uncertainties associated with the UDENYCA TSA, one or more of which could have a material adverse effect on our business, financial condition, results of operations, cash flows or stock price.

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

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

Risks Related to Manufacturing and Supply Chain

We are subject to a multitude of manufacturing risks and the risks of inaccurately forecasting sales of our product. We also need to make a determination of excess or obsolete inventory that requires judgment and may result in write-downs of inventory, charges related to firm purchase commitments, or both. Any adverse developments affecting the manufacturing operations of our product and product candidates could substantially increase our costs and limit supply for our product and product candidates.

The process of manufacturing our product and 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 ongoing conflicts in Ukraine and the Middle East.

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

Any adverse developments affecting manufacturing operations for our product and product candidates, including due to sudden or long-term changes in weather patterns or conflicts in particular geographic areas, may result in shipment delays, inventory shortages, lot failures, withdrawals or recalls or other interruptions in the supply of our product and product candidates. We also need to make a determination of excess or obsolete inventory that requires judgment and includes consideration of many factors, such as estimates of future product demand, current and future market conditions, product expiration information and potential product obsolescence, among others. Although we believe that the assumptions we use in estimating potential inventory write-downs are reasonable, if actual market conditions are less favorable than projected by us, write-downs of inventory, charges related to firm purchase commitments, or both may be required which would be recorded as cost of goods sold in our consolidated statements of operations. Adverse developments affecting our assumptions of the level and timing of demand for our product include those that are outside of our control such as the actions taken by competitors and customers and other factors.

We may have to take inventory write-downs and incur other charges and expenses, such as charges related to firm purchase commitments, for any product that is 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 fourth quarter of 2023, we recorded a $47.0 million charge for the write-down of slow moving YUSIMRY inventory and the related partial recognition of certain firm purchase commitments. Although we believe that the assumptions that we use in estimating inventory write-downs are reasonable, additional write-downs of inventory may be required in the future if actual market conditions are less favorable than our projections, which could materially and adversely impact our financial results. In addition to such write-downs, we may also have to incur charges and expenses related to firm purchase commitments or for product candidates that fail to meet specifications, undertake costly remediation efforts or seek costlier manufacturing alternatives.

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

For our product 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 this product, such as manufacture of the biological substance present in the product, manufacture of the final filled and finished presentation of this product, as well as laboratory testing, formulation development and clinical testing of this product. Because we currently have engaged a limited number of back-up suppliers or vendors for these single-sourced services, and although we believe that there are alternate sources that could fulfill these activities, we cannot make any assurances that identifying and establishing relationships with alternate suppliers and vendors would not result in significant delay in the development of our product candidates. Additional delays or cost increases could occur due to the direct or indirect effects of the 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 and product candidates, or having to enter into a new agreement with a different third party on less favorable terms than we have with our current suppliers, could have a material adverse impact on our business.

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 BLA, NDA or MAA on a timely basis and must adhere to cGMP regulations enforced by the FDA and other regulatory agencies through their facilities inspection program. Some of our contract manufacturers may have never produced a commercially approved pharmaceutical product and therefore have not obtained the requisite regulatory authority approvals to do so. The facilities and quality systems of some or all of our collaboration partners and third-party contractors must successfully complete a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates or any of our other potential products. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. Although we oversee the contract manufacturers, we cannot control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements. If these facilities do not successfully complete a pre-approval plant inspection, regulatory approval of the products may not be granted or may be substantially delayed until any violations are corrected to the satisfaction of the regulatory authority, if ever.

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

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

Additionally, if a manufacturer cannot meet the supply demand, supply from an alternative manufacturer would require the submission of a BLA/NDA supplement or MAA Variation (or equivalent foreign regulatory filing) which could result in further delay. The regulatory agencies may also require additional studies if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

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.

Risks Related to Adverse Events

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

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

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

Additionally, for our product and for any of our product candidates that may receive marketing approval, if we or others later identify undesirable side effects caused by the product, 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 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 or product candidate, if approved, and could significantly harm our business, results of operations and prospects.

For our product and if we receive approval for our product candidates, regulatory agencies, including the FDA and foreign regulatory agencies, require that we report certain information about adverse medical events if any product 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 product. 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 product or extended delay in approval or clearance of future products.

Adverse events involving another anti-PD-1 or PD-L1 antibody product may negatively affect our business.

In the event that use of another anti-PD-1 or PD-L1 antibody product results in unanticipated side effects or other adverse events, it is likely that our product will be viewed comparably and may become subject to the same scrutiny and regulatory sanctions as the other anti-PD-1 or PD-L1 antibody product, as applicable. Accordingly, we may become subject to regulatory supervisions, clinical holds, product recalls or other regulatory actions for matters outside of our control that affect the other anti-PD-1 or PD-L1 antibody product, as applicable, if and until we are able to demonstrate to the satisfaction of our regulators that our product is not subject to the same issues leading to the regulatory action as the other anti-PD-1 or PD-L1 antibody product, as applicable.

Risks Related to Intellectual Property

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

Our commercial success depends in large part on avoiding infringement of the patents and proprietary rights of third parties. There have been many lawsuits and other proceedings involving patent and other intellectual property rights in the pharmaceutical industry, including patent infringement lawsuits, interferences, oppositions and reexamination proceedings before the 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. Competitors 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 product and our product 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 or unenforceable, and we may not be able to do this. Proving that a patent is invalid or unenforceable is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Also, in proceedings before courts in Europe, the burden of proving invalidity of the patent usually rests on the party alleging invalidity. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on us. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

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

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

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

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. Competitors 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 be issued on our pending applications may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing products similar to ours. Furthermore, our competitors may develop similar or alternative technologies not covered by any patents that may issue to us.

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

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

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

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

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

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

We employ individuals, retain independent contractors and consultants and members on our board of directors or scientific advisory board who were previously employed at universities or other pharmaceutical companies, including our competitors or potential competitors. 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.

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

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

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

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;

- the sublicensing of patents and other rights;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our collaborators; and
- the priority of invention of patented technology.

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

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

We currently have rights to certain intellectual property, through licenses from third parties and under patent applications that we own, to develop and commercialize our product and product candidates. Because we may find that our programs require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights. We may be unable to acquire or in-license compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary for our product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, financial resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment. We may also get into disputes or litigation with third parties from whom we license intellectual property rights necessary for the sale of our product.

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

Risks Related to the Discovery and Development of Our Product Candidates

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

We invest substantial efforts and financial resources to identify, acquire and develop our product candidates. Our future success is dependent on our ability to develop, obtain regulatory approval for, and then commercialize and obtain adequate third-party coverage and reimbursement for one or more of our product candidates. We currently have one approved product: LOQTORZI.

Our product candidates are in varying stages of development and will require additional clinical development, management of nonclinical, clinical and manufacturing activities, regulatory approval, adequate manufacturing supplies, commercial organization and significant marketing efforts before we generate any revenue from product sales. We have not initiated Phase 3 clinical trials for any of the product candidates in our pipeline. It may be some time before we submit an application 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. 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 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 required for any activities, including development activities and data sharing with our partners in China, may result in product development delays. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. Neither we nor any collaboration partner has obtained regulatory approval for any of our product and product candidates, other than LOQTORZI, which has received approval from the FDA and is also approved for use in China, and it is possible that none of our other current or future product candidates will ever obtain additional regulatory approvals.

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

- the data collected from clinical studies of our product candidates may not be sufficient to support the submission of a BLA, an NDA or other submission or to obtain regulatory approval in the United States, the EEA or elsewhere;
- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical studies;
- the FDA may determine that the population studied in the clinical program may not be sufficiently broad or representative to assure safety and efficacy in the full population for which we seek approval, or that conclusions of clinical trials conducted in a single country or region outside the United States may not be generalizable to the patient population in the United States;

- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from analytical and bioanalytical studies, nonclinical studies or clinical studies;
- we may be unable to demonstrate to the FDA or comparable foreign regulatory authorities that a product candidate's risk-benefit ratio for its proposed indication is acceptable;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications or facilities of our collaborators or third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

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

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

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

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical study process. The results of preclinical studies and early and mid-stage 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 or mid-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 oncology 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.

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 approval at each clinical study site;

- imposition of a clinical hold by regulatory agencies, after review of an investigational new drug application or amendment or equivalent application or amendment, or an inspection of our clinical study operations or study sites or as a result of adverse events reported during a clinical trial;
- delays in recruiting suitable patients to participate in our clinical studies sponsored by us or our partners;
- difficulty collaborating with patient groups and investigators;
- failure by our CROs, other third parties or us to adhere to clinical study requirements;
- failure to perform in accordance with the FDA's GCP 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 for use in clinical studies or the inability to do any of the foregoing.

Any inability to successfully complete nonclinical and clinical development could result in additional costs to us or impair our ability to continue to generate revenue. In addition, if we make manufacturing or formulation changes to our product candidates, we may need to conduct additional studies to bridge our modified product candidates to earlier versions.

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

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

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

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

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

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

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

We are marketing LOQTORZI in the United States and may seek to partner commercially our product outside the United States, such as our license agreement with Apotex in Canada for LOQTORZI.

In order to market our product 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 product in any market. Failure to obtain these approvals would materially and adversely affect our business, financial condition and results of operations.

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

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

- we may not be successful in identifying potential product candidates that pass our strict screening criteria;
- we may not be able to overcome technological hurdles to development or a product candidate may not be capable of producing commercial quantities at an acceptable cost or at all;
- we may not be able to assemble sufficient resources to acquire or discover additional product candidates;
- our product candidates may not succeed in nonclinical or clinical testing; and
- competitors may develop alternatives that render our product candidates obsolete or less attractive or the market for a product candidate may change such that a product candidate may not justify further development.

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

Risks Related to Our Compliance with Applicable Laws

Healthcare reform measures, including the IRA and the OBBBA, may increase the difficulty and cost for us to obtain marketing approval for and commercialize our product, 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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, 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; and expanded the entities eligible for discounts under the Public Health Service 340B drug pricing program.

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

Most significantly, on August 16, 2022, the IRA was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new manufacturer discounting program (which began in 2025). The IRA permits the Secretary of the Department of Health and Human Services ("HHS") to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. CMS has published the negotiated prices for the initial ten drugs, which will first be effective in 2026, and the list of the subsequent 15 drugs that will be subject to negotiation, although the Medicare drug price negotiation program is currently subject to legal challenges. For that and other reasons, the impact of the IRA on our business and the pharmaceutical industry cannot yet be fully determined.

Most recently, the OBBBA, which was enacted in July 2025, imposes significant reductions in the funding of the Medicaid program. Such reductions are expected to decrease the number of persons enrolled in Medicaid and reduce

the services covered by Medicaid, which could adversely affect our sales of LOQTORZI or any other product candidate that we may commercialize.

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. The Trump administration is pursuing a strategy to reduce drug costs in the U.S. While it is unclear whether and how the Trump proposals will be implemented, the Trump policies are likely to have a negative impact on the pharmaceutical industry, including sales of LOQTORZI or other product candidates we may commercialize. President Trump has threatened to impose significant tariffs on pharmaceutical manufacturers that do not adopt pricing policies such as most favored nation pricing, which would tie the price for drugs in the U.S. to the lowest price in a group of other countries. In response, multiple manufacturers have reportedly entered into confidential pricing agreements with the federal government. Separately, the Trump administration is pursuing traditional regulatory pathways to impose drug pricing policies, although proposed regulations have not yet been published. Even regulatory proposals or executive actions that are ultimately deemed unlawful could negatively impact the U.S. pharmaceutical sector and our business. In addition, pharmaceutical pricing and marketing has long been the subject of considerable discussion in Congress and among policymakers, and it is possible that Congress could enact additional laws that negatively affect the pharmaceutical industry.

Individual states in the United States have also proposed and enacted legislation and are implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, marketing cost disclosure, drug price reporting and other transparency measures, and, in some cases, measures designed to encourage importation from other countries and bulk purchasing. Some states have enacted legislation creating so-called prescription drug affordability boards, with the goal of imposing price limits on certain drugs in these states. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

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

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

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

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

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

otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information.

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

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

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

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

Federal law requires that any company that participates in the MDRP also participate in the Public Health Service's 340B drug pricing program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B program is administered by the HRSA and requires us to agree to charge statutorily defined covered entities no more than the 340B "ceiling price" for our covered drugs when used in an outpatient setting. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants

from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. The 340B ceiling price is calculated using a statutory formula, which is based on the AMP and rebate amount for the covered outpatient drug as calculated under the MDRP. In general, products subject to Medicaid price reporting and rebate liability are also subject to the 340B ceiling price requirement. We must report 340B ceiling prices to HRSA on a quarterly basis, and HRSA publishes them to 340B covered entities. HRSA has finalized regulations regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities for 340B eligible drugs. HRSA has also finalized an administrative dispute resolution process through which 340B covered entities may pursue claims against participating manufacturers for overcharges.

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

Individual states continue to consider and have enacted legislation to limit the growth of healthcare costs, including the cost of prescription drugs and combination products. A number of states have either implemented or are considering implementation of drug price transparency legislation that may prevent or limit our ability to take price increases at certain rates or frequencies. Requirements under such laws include advance notice of planned price increases, reporting price increase amounts and factors considered in taking such increases, wholesale acquisition cost information disclosure to prescribers, purchasers, and state agencies, and new product notice and reporting. Such legislation could limit the price or payment for certain drugs, and a number of states are authorized to impose civil monetary penalties or pursue other enforcement mechanisms against manufacturers for the untimely, inaccurate, or incomplete reporting of drug pricing information or for otherwise failing to comply with drug price transparency requirements. If we are found to have violated 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 are complex, and are often subject to interpretation by us, governmental or regulatory agencies, and the courts, which can change and evolve over time. Such pricing calculations and reporting, along with any necessary restatements and recalculations, could increase costs for complying with the laws and regulations governing the MDRP and other governmental programs, and under the MDRP could result in an overage or underage in Medicaid rebate liability for past quarters. Price recalculations under the MDRP also may affect the ceiling price at which we are required to offer products under the 340B program. Civil monetary penalties can be applied if we are found to have knowingly submitted any false price or product information to the government, if we are found to have made a misrepresentation in the reporting of ASP, if we fail to submit the required price data on a timely basis, or if we are found to have charged 340B covered entities more than the statutorily mandated ceiling price. CMS could also terminate our Medicaid drug rebate agreement, in which case federal payments may not be available under Medicaid or Medicare Part B for our covered outpatient drugs. We cannot make any assurances that our submissions will not be found by CMS or other governmental agencies to be incomplete or incorrect.

Risks Related to Ownership of Our Common Stock

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

The market price of our common stock has been highly volatile since our Initial Public Offering and the intraday sales price per share has ranged from $0.66 to $38.10 per share during the period from November 6, 2014 through

September 30, 2025 and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include those discussed in the “Risk Factors” section of this Quarterly Report on Form 10-Q and others such as:

- adverse results or delays in preclinical or clinical studies;
- the risk of deterioration in our financial conditions, such as reduced collection of cash and increased costs in the future;
- any inability to obtain additional funding;
- failure to receive either of the Earnout Payments;
- any delay in filing an IND, NDA, 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 or other regulatory submission;
- the perception of limited market sizes or pricing for our product and product candidates;
- failure to successfully develop and commercialize our product candidates;
- post-marketing safety issues relating to our product candidates or product;
- 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 product and product candidates;
- future outbreaks of COVID-19 and other viral pandemics;
- any inability to obtain adequate product supply for our product and product candidates or the inability to do so at acceptable prices;
- adverse regulatory decisions;
- introduction of new products, services or technologies by our competitors;
- failure to meet or exceed financial projections we may provide to the public;
- failure to meet or exceed the financial projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, dispositions, strategic partnerships, joint ventures or capital commitments by us, our strategic collaboration partners or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key scientific or management personnel;
- lawsuits, including but not limited to complaints initiated by stockholders, customers and collaboration partners, and litigation filed by us or filed against us pertaining to patent infringement or other violations of intellectual property rights;
- if securities or industry analysts do not publish research or reports about our business or if they issue an adverse or misleading opinion regarding our company or our stock;
- changes in the market valuations of similar companies;

- general market or macroeconomic conditions, including rising interest rates, increasing tariffs 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; and
- changes in regulatory requirements that could make it more difficult for us to develop our product candidates.

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

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

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

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

Following identification of this material weakness, and as part of our commitment to strengthen our internal control over financial reporting, we continue to implement remedial actions to address this deficiency. The remediation measures include additional training and enhancement of our documentation and retention procedures, particularly as they relate to our inventory account reconciliations. However, the deficient inventory account reconciliations control was decommissioned concurrent with the UDENYCA Sale on April 11, 2025, leaving no opportunity to formally retest the operating effectiveness of the control during the current period.

We will continue to monitor the design and operating effectiveness of these and other processes, procedures and controls and make any further changes management determines are appropriate. We can give no assurance that additional material weaknesses will not be identified in the future. The effectiveness of our internal control over financial reporting is subject to various inherent limitations, including judgments used in decision making, assumptions about the likelihood of future events, the possibility of human error and the risk of fraud. If we are unable to remediate the material weakness, our ability to maintain compliance with the covenants contained in our 2029 Loan Agreement, record, process and report financial information accurately, and to prepare the consolidated financial statements within the time periods

specified by the rules and regulations of the SEC, could be adversely affected which, in turn, may adversely affect our reputation and business and the trading price of our common stock.

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

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

As of September 30, 2025, our executive officers, directors, five percent stockholders and their affiliates beneficially owned a significant amount of our voting stock. These stockholders have the ability to influence us through their ownership positions, which may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may believe are in your best interest as one of our stockholders.

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

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

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

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

This indebtedness could be due sooner upon the triggering of certain covenants in our debt agreements and or upon the occurrence of an event of default. If and when our indebtedness becomes due, if we do not have sufficient cash or access to capital to pay such indebtedness, we will default on our obligations which will adversely harm our business. We entered into the 2029 Loan Agreement that contains affirmative and negative covenants that restrict our operations, including, among other restrictions, the requirement to maintain certain levels of cash and cash equivalents. Further, the 2029 Loan Agreement includes certain other affirmative covenants and negative covenants, including, covenants and restrictions that among other things, restrict our ability to incur liens, incur additional indebtedness, make investments, engage in certain mergers and acquisitions or asset sales, and declare dividends or redeem or repurchase

capital stock. We may need to request waivers from time to time with respect to the 2029 Loan Agreement and if we are unable to obtain a waiver that we need it could materially impact our business and financial results.

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

If our existing stockholders sell or indicate an intention to sell substantial amounts of our common stock in the public market the market price of our common stock could decline. In addition, we may authorize our sales agent to sell our common stock from time to time as part of the ATM Offering. As of September 30, 2025, there were 116,236,018 shares of common stock outstanding.

In addition, as of September 30, 2025, approximately 36.6 million shares of common stock that are either subject to outstanding options and restricted stock units or reserved for future issuance under our equity incentive plans were eligible or may become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold or if it is perceived that they will be sold in the public market, the market price of our common stock could decline.

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

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

Pursuant to our Amended and Restated 2014 Equity Incentive Award Plan (the “2014 Plan”), our management is authorized to grant stock options and other equity-based awards to our employees, directors and consultants. Any increase in the number of shares available for future grant under the 2014 Plan must be approved by our stockholders. Pursuant to our 2014 Employee Stock Purchase Plan (“ESPP”), eligible employees are able to acquire shares of our common stock at a discount to the prevailing market price. Pursuant to our 2016 Employment Commencement Incentive Plan (the “2016 Plan”), our management was authorized to grant stock options and other equity-based awards to our new employees, however in connection with the approval of the 2014 Plan in 2024, we agreed that we would not make any new awards under the 2016 Plan after the effective date of the 2014 Plan.

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

Our cash and cash equivalents are deposited or invested with several banks and other financial institutions. Actual events involving reduced or limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds, have in the past and may in the future lead to market-wide liquidity problems. For example, in March 2023, Silicon Valley Bank was closed and taken over by the Federal Deposit Insurance Corporation and subsequently had all of its customer deposits and other liabilities and substantially all loans and other assets acquired by First-Citizens Bank & Trust Company. We had approximately $191.7 million of cash, cash equivalents and marketable securities as of September 30, 2025 with the majority held by custodians or in money market mutual

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

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

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

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

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

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

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

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

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

General Risk Factors

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

We sell our product to wholesalers and distributors and the wholesalers and distributors then resell to hospitals and clinics pursuant to contracts with us. The majority of our revenue comes from a limited number of wholesalers. In the third quarter of 2025, three wholesalers individually comprised approximately 44%, 31%, and 23%, respectively, of our total gross product revenue from continuing operations. We expect that revenue from a limited number of wholesalers will continue to account for a large portion of our revenue in the future. The loss by us of any of these wholesalers, or a material reduction in their purchases or their market pricing, could harm our business, results of operations, financial condition and prospects. In addition, if any of these wholesalers were to fail to pay us in a timely manner, it could harm our cash flow.

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

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

- multiple, conflicting and changing laws and regulations such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses, including those that affect our work with a collaboration partner in China;
- failure by us or our collaboration partners to obtain and maintain regulatory approvals for the use of our product in various countries;
- additional potentially relevant third-party patent rights;
- foreign CMOs may be subject to U.S. legislation, sanctions, trade restrictions, new or increasing tariffs, retaliatory trade actions due to recent or future trade tension and other regulatory requirements which could increase the cost or reduce the supply of material available to us, delay the procurement or supply of such material or have an adverse effect on our ability to secure commitments from governments to purchase our product;
- 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 product and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, tariffs and retaliatory tariffs, 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 the war between Russia and Ukraine; and
- regulatory and compliance risks that relate to maintaining accurate information and control over sales and activities that may fall within the purview of the United States Foreign Corrupt Practices Act, its books and records provisions or its anti-bribery provisions.

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

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

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

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

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

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

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

The issuance of one or more submarine patents may harm our business by causing substantial delays in our ability to introduce a product 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 product.

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 product or pipeline molecules. We may incorrectly determine that our product is 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 a 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 product.

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

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

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

The patent positions of oncology 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.

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

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

Because competitors may be able to develop their own proprietary technologies, it is uncertain whether any of our issued patents or pending patent applications would cover the products of any competitors. The product and patent landscape is highly uncertain and we cannot predict whether our patent filings will afford us a competitive advantage against third parties or if our product will avoid infringement of third-party patents.

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 product 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 and product candidates, we may not be able to compete effectively in our markets.

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

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

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

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

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

The continuation of the war in Ukraine and conflicts in the Middle East may exacerbate certain risks we face.

The war between Russia and Ukraine and the global response, including the imposition of sanctions by the United States and other countries, could create or exacerbate risks facing our business. Conflicts in the Middle East may also increase the risks facing our business. We have evaluated our operations and partner contracts, and we currently do not expect either conflict to directly have a significant effect on our financial condition or results of operations. However, if the war between Russia and Ukraine or conflicts in the Middle East escalate or expand, risks that we have identified in this Quarterly Report on Form 10-Q may be materially increased. For example, if our supply arrangements or clinical operations are disrupted due to expanded sanctions or involvement of, and adverse impacts on, countries where we

have operations or relationships, our business could be materially disrupted. Further, the use of cyberattacks could expand as part of the ongoing conflicts, which could adversely affect our ability to maintain or enhance our cybersecurity measures. These and other risks are described more fully in this “Risk Factors” section.

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

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

We are subject to Section 404 of The Sarbanes-Oxley Act of 2002 (“Section 404”), and the related rules of the SEC, which generally require our management and independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting. During the course of our review and testing, we may identify deficiencies and be unable to remediate them before we must provide the required reports. Furthermore, if we have a material weakness in our internal controls over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. We or our independent registered public accounting firm may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could harm our operating results, cause investors to lose confidence in our reported financial information and cause the trading price of our stock to fall. For example, as described in our 2024 Form 10-K, our management concluded that our internal control over financial reporting was not effective as of December 31, 2024 due to a material weakness in the operating effectiveness of our procedures related to our documentation and review of certain inventory account reconciliations. We are taking steps to remediate this material weakness and to strengthen our internal control over financial reporting, which include additional training and enhancement of our documentation and retention procedures, particularly as they relate to our inventory account reconciliations. However, the deficient inventory account reconciliations control was decommissioned concurrent with the UDENYCA Sale that closed on April 11, 2025, leaving no opportunity to formally retest the operating effectiveness of the control during the current period.

In addition, as a public company we are required to file accurate and timely quarterly and annual reports with the SEC under the Exchange Act. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from The Nasdaq Global Market or other adverse consequences that would materially harm our business.

Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may also lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time consuming and costly. For example, we expect these rules and regulations to make it more difficult and more

expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain our current levels of such coverage.

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

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

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

We and certain of our service providers are from time to time subject to cyberattacks and security incidents. While we do not believe that we have experienced any significant system failure, accident or security breach to date, if we or our third-party collaborators, consultants, contractors, suppliers, or service providers were to suffer an attack or breach, for example, that resulted in the unauthorized access to or use or disclosure of Confidential Information, we may have to notify individuals, collaborators, government authorities, and the media, and may be subject to investigations, civil penalties, administrative and enforcement actions, and litigation, any of which could harm our business and reputation. Likewise, we rely on our third-party CROs and other third parties to conduct clinical studies, and similar events relating to their computer systems could also have a material adverse effect on our business. There can also be no assurance that our and our service providers' cybersecurity risk management program and processes, including policies, controls or procedures, will be fully implemented, complied with or effective in protecting our systems, networks and Confidential Information.

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

To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or systems, or inappropriate or unauthorized access to or disclosure or use of Confidential Information, we could incur liability and suffer reputational harm, and the development and commercialization of our product and product candidates could be delayed. Federal, state and international laws and regulations can expose us to enforcement actions and investigations by regulatory authorities, and potentially result in regulatory penalties, fines and significant legal liability, if our information technology security efforts fail. We may also be exposed to a risk of loss or litigation and potential liability, which could materially and adversely affect our business, results of operations or financial condition. Our insurance policies may not be adequate to compensate us for the potential losses arising from such disruptions, failure, or security breach. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and defending a suit, regardless of its merit, could be costly, divert management attention, and harm our reputation.

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

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

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

Even when HIPAA does not apply, according to the Federal Trade Commission (“FTC”), failing to take appropriate steps to keep consumers’ personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act. The FTC expects a company’s data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. The FTC has authority to initiate enforcement actions against entities that make deceptive statements about privacy and data sharing in privacy policies, fail to limit third-party use of personal health information, fail to implement policies to protect personal health information or engage in other unfair practices that harm customers or that may violate Section 5(a) of

the FTC Act. Additionally, federal and state consumer protection laws are increasingly being applied by the FTC and states' attorneys general to regulate the collection, use, storage, and disclosure of personal information, through websites or otherwise, and to regulate the presentation of website content.

In addition, state laws govern the privacy and security of personal information in certain circumstances, many of which differ from each other in significant ways and may not have the same requirements, thus complicating compliance efforts. By way of example, California enacted the California Consumer Privacy Act as amended by the California Privacy Rights Act (collectively, the "CCPA"), which requires covered businesses that process the personal information of California residents to, among other things: (i) provide certain disclosures to California residents regarding the business's collection, use, and disclosure of their personal information; (ii) receive and respond to requests from California residents to access, delete, and correct their personal information, or to opt out of certain disclosures of their personal information; and (iii) enter into specific contractual provisions with service providers that process California resident personal information on the business's behalf. Similar laws have passed in other states and are continuing to be proposed at the state and federal level, reflecting a trend toward more stringent privacy legislation in the United States. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging. In the event that we are subject to or affected by HIPAA, the CCPA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our business and financial condition.

In addition, the regulatory framework for the receipt, collection, processing, use, safeguarding, sharing and transfer of personal data is rapidly evolving and is likely to remain uncertain for the foreseeable future as new global privacy rules are being enacted and existing ones are being updated and strengthened. For example, on May 25, 2018, the General Data Protection Regulation ("GDPR") took effect. The GDPR is applicable in each EEA member state and applies to companies established in the EEA as well as companies that collect and use personal data to offer goods or services to, or monitor the behavior of, individuals in the EEA, including, for example, through the conduct of clinical trials. GDPR introduces more stringent data protection obligations for processors and controllers of personal data. Among other things, the GDPR requires the establishment of a lawful basis for the processing of data, includes requirements relating to the consent of the individuals to whom the personal data relates, including detailed notices for clinical trial subjects and investigators, as well as requirements regarding the security of personal data and notification of data processing obligations or security incidents to appropriate data protection authorities or data subjects. The GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States; and the efficacy and longevity of current transfer mechanisms between the EEA and the United States remains uncertain. Case law from the Court of Justice of the European Union states that reliance on the standard contractual clauses - a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism - alone may not necessarily be sufficient in all circumstances and that transfers must be assessed on a case-by-case basis. On July 10, 2023, the European Commission adopted its Adequacy Decision in relation to the new EU-US Data Privacy Framework ("DPF") rendering the DPF effective as a GDPR transfer mechanism to U.S. entities self-certified under the DPF. We expect the existing legal complexity and uncertainty regarding international personal data transfers to continue. In particular, we expect the DPF Adequacy Decision to be challenged and international transfers to the United States and to other jurisdictions more generally to continue to be subject to enhanced scrutiny by regulators. As a result, we may have to make certain operational changes and we will have to implement revised standard contractual clauses and other relevant documentation for existing data transfers within required time frames. Penalties and fines for failure to comply with GDPR are significant, including fines of up to €20 million or 4% of the total worldwide annual turnover of a non-compliant undertaking, whichever is higher. In addition to fines, a breach of the GDPR may result in regulatory investigations, reputational damage, orders to cease/ change our data processing activities, enforcement notices, assessment notices (for a compulsory audit) and/ or civil claims (including class actions).

Further, since the beginning of 2021, we have also been subject to the United Kingdom General Data Protection Regulation and Data Protection Act 2018, which collectively imposes separate but similar obligations to those under the GDPR and comparable penalties, including fines of up to £17.5 million or 4% of a noncompliant undertaking's global

annual revenue for the preceding financial year, whichever is greater. On October 12, 2023, the U.K. Extension to the DPF came into effect (as approved by the U.K. government), as a data transfer mechanism from the U.K. to U.S. entities self-certified under the DPF. Other foreign jurisdictions are increasingly implementing or developing their own privacy regimes with complex and onerous compliance obligations and robust regulatory enforcement powers. As we continue to expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business.

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

We may be negatively impacted by continued inflation.

We may be adversely impacted by continued increases in inflation. Current and future inflation may be driven by the following factors: supply chain disruptions, increased tariffs and retaliatory tariffs, 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 product, our costs for labor and materials and the size of any margins we are able to realize on our revenues. This would have a material and adverse impact on our business, financial position, results of operations and cash flows. Inflation may also result in higher interest rates, which in turn would result in higher interest expense related to our variable rate indebtedness.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

Our research and development activities and our third-party manufacturers' and suppliers' activities involve the controlled storage, use and disposal of hazardous materials, including the components of our product candidates and other hazardous compounds. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly cleanup and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by us and our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. We do not currently carry biological or hazardous waste insurance coverage.

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

Issuer Purchases of Equity Securities

We did not repurchase any of our equity securities during the third quarter ended September 30, 2025. A total of 3,415 shares were surrendered to us in the third quarter of 2025, to satisfy minimum tax withholding obligations in connection with the vesting or exercise of stock-based awards.

ITEM 3. Defaults Upon Senior Securities

Not applicable

ITEM 4. Mine Safety Disclosures

Not applicable

ITEM 5. Other Information

(a) Issuance and Sale of Unregistered Equity Securities.

On October 21, 2025, we sold to certain unaffiliated third-party investors (i) an aggregate of 4,634,995 shares of our common stock and (ii) Warrants to purchase an aggregate of 463,498 shares of common stock, each for an exercise price of $0.01 per share, for an aggregate purchase price of $8.0 million. The Warrants may be exercised at any time on or before October 21, 2030. The Warrants are subject to appropriate adjustment in the event of share dividends, stock splits, reorganizations or similar events affecting our common stock.

The Private Placement was conducted pursuant to an exemption from registration under the Securities Act under Section 4(a)(2) of the Securities Act. The Shares, Warrants and shares issuable upon exercise of the Warrants were not registered under the Securities Act or any state securities laws and may not be reoffered or resold in the United States absent registration with the SEC or an applicable exemption from the registration requirements.

(b) None.

(c) During the three months ended September 30, 2025, no director or officer of the Company adopted or terminated a “Rule 10b5-1 trading arrangement” or “non-Rule 10b5-1 trading arrangement,” as each such term is defined in Item 408(a) of Regulation S-K.

ITEM 6. Exhibits

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

INDEX TO EXHIBITS

Exhibit Number	Description	Incorporated by Reference			Filed Herewith
		Form	Exhibit	Date Filed	
3.1	Amended and Restated Certificate of Incorporation.	8-K	3.1	11/13/2014	
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Coherus BioSciences, Inc. (the previous name of Coherus Oncology, Inc.), effective as of May 29, 2025	8-K	3.1	5/30/2025	
3.3	Second Amended and Restated Bylaws of Coherus Oncology, Inc., effective as of May 29, 2025.	8-K	3.2	5/30/2025	
4.1	Reference is made to exhibits 3.1, 3.2 and 3.3.				
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	4.1	4/17/2020	
4.5	Notice of Successor Trustee to Indenture dated February 7, 2022.	10-Q	4.5	5/5/2022	
4.6	First Supplemental Indenture, dated March 31, 2025, between Coherus BioSciences, Inc. and U.S. Bank Trust Company, National Association, as trustee.	8-K	4.1	4/1/2025	
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, 2025 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 Income (Loss), (iv) Condensed Consolidated Statements of Stockholders' 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 ONCOLOGY, INC.

Date: November 6, 2025

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

Date: November 6, 2025

/s/ Bryan McMichael
Bryan McMichael
Chief Financial Officer
(Principal Financial Officer and 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 Oncology, Inc.;

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

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

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

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

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

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

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

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 6, 2025

/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, Bryan McMichael, certify that:

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

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

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

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

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

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

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

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

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 6, 2025

/s/ Bryan McMichael
Bryan McMichael
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 Oncology, Inc. (the "Registrant") certify that the Quarterly Report of Coherus Oncology, Inc. on Form 10-Q for the quarterly period ended September 30, 2025 (the "Report") fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended, and that information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

Date: November 6, 2025

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

Date: November 6, 2025

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