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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2025

OR

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

For the transition period from ____ to ____

Commission file number: 001-42706

CARIS LIFE SCIENCES, INC.
(Exact name of registrant as specified in its charter)

Texas	**85-2077369**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**

750 W. John Carpenter Freeway
Suite 800
Irving, TX 75039
(Address of principal executive offices, including ZIP code)

Registrant's telephone number, including area code: (866) 771-8946

Not applicable
(Former name or former address, if changed since last report)

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, $0.001 par value	CAI	The Nasdaq Stock Market LLC

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 November 3, 2025, the registrant had 282,146,923 shares of common stock, par value $0.001 par per share, outstanding.

CARIS LIFE SCIENCES, INC.
FORM 10-Q

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Special Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q (this "Quarterly Report") contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this Quarterly Report, including statements regarding our expectations of future results of operations and financial condition, business strategy, solutions, technology, R&D costs, regulatory approvals, potential market opportunity, anticipated trends in our business, timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. These statements involve known and unknown risks, uncertainties, and other important factors that are in some cases beyond our control and may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by the forward-looking statements.

The words "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," or "would," or the negative of these terms or other similar expressions, are intended to identify forward looking statements. Forward-looking statements contained in this Quarterly Report include, but are not limited to, statements about:

- developments in the precision oncology industry, including our biopharma partners' use of molecular information and the market size for molecular information services;
- our expectations as to our addressable U.S. market in oncology, future financial performance, results of operations, or other operational results or metrics;
- the ability of the Caris platform to help our biopharma partners and physicians improve the efficiency and success of their therapeutic development, and clinical programs;
- our ability to scale the Caris platform and develop new solutions or enhancements to existing solutions;
- our ability to capture, aggregate, analyze, or otherwise utilize molecular information in novel ways;
- our ability to compete with companies that are currently in, or may in the future enter, the industry in which we operate;
- third-party payer reimbursement and coverage decisions;
- our ability to establish, maintain, protect, and enforce our intellectual property rights of our solutions;
- federal, state, and foreign regulatory requirements, including FDA regulation of our solutions;
- the timing, likelihood, or conditions of regulatory filings and approvals;
- our ability to hire and retain key personnel;
- our anticipated cash needs and our estimates regarding our capital requirements;
- our estimates regarding our expenses, future revenue, and capital requirements; and
- remediating the material weakness in our internal control over financial reporting.

These forward-looking statements are subject to a number of risks, uncertainties, and assumptions, including those described in the section titled "Risk Factors" and elsewhere in this Quarterly Report and in other filings we make with the Securities and Exchange Commission from time to time. Moreover, we operate in a competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties, and assumptions, the forward-looking events and circumstances discussed in this Quarterly Report may not occur, and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

Although we believe that the expectations reflected in our forward-looking statements are reasonable based on the information available to us when they are made, we cannot guarantee that the future results, advancements, discoveries, levels of activity, performance, or events and circumstances reflected in the forward-looking statements will be achieved or occur. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Quarterly Report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and you are cautioned not to unduly rely upon these forward-looking statements. We undertake no obligation to update any forward-looking statements, which speak only as the date they are made, for any reason after the date of this Quarterly Report.

Part I - Financial Information

Item 1. Condensed Consolidated Financial Statements (Unaudited)

CARIS LIFE SCIENCES, INC
CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)

(amounts in thousands, except share data)	As of September 30, 2025	As of December 31, 2024
Assets		
Current assets:		
Cash, cash equivalents, and restricted cash	$ 754,739	$ 65,442
Short-term marketable securities	2,272	2,201
Accounts receivable	26,697	88,244
Supplies	49,303	39,572
Prepaid expenses and other current assets	21,234	20,270
Total current assets	854,245	215,729
Property and equipment, net	63,997	67,817
Goodwill	19,344	19,344
Other assets	46,985	40,844
Total assets	**$ 984,571**	**$ 343,734**
Liabilities, Redeemable Convertible Preferred Stock, and Shareholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 28,999	$ 27,791
Accrued expenses and other current liabilities	56,867	77,542
Current portion of indebtedness	164	60,090
Total current liabilities	86,030	165,423
Long-term indebtedness, net of debt discounts	376,296	319,438
Warrant liabilities	—	91,642
Other long-term liabilities	43,881	44,418
Total liabilities	506,207	620,921
Commitments and contingencies (see note 9)		
Redeemable convertible preferred stock:		
Series A preferred stock, par value $0.001: no and 490,000,000 shares authorized as of September 30, 2025 and December 31, 2024; no and 485,795,293 shares issued and outstanding as of September 30, 2025 and December 31, 2024; and $296,335 aggregate liquidation preference as of December 31, 2024	—	709,261
Series B preferred stock, par value $0.001: no and 30,000,000 shares authorized as of September 30, 2025 and December 31, 2024; no and 29,629,630 shares issued and outstanding as of September 30, 2025 and December 31, 2024; and $16,000 aggregate liquidation preference as of December 31, 2024	—	42,963
Series C preferred stock, par value $0.001: no and 142,000,000 shares authorized as of September 30, 2025 and December 31, 2024; no and 116,200,835 shares issued and outstanding as of September 30, 2025 and December 31, 2024; and $408,715 aggregate liquidation preference as of December 31, 2024	—	408,715
Series D preferred stock, par value $0.001: no and 102,600,000 shares authorized as of September 30, 2025 and December 31, 2024; no and 102,516,283 shares issued and outstanding as of September 30, 2025 and December 31, 2024; and $1,060,712 aggregate liquidation preference as of December 31, 2024	—	1,060,712
Redeemable convertible preferred stock	—	2,221,651
Shareholders' equity (deficit):		
Preferred stock, $0.001 par value per share; 100,000,000 and no shares authorized as of September 30, 2025 and December 31, 2024, respectively; no shares issued and outstanding as of September 30, 2025 and December 31, 2024	—	—
Common stock $0.001 par value; 2,800,000,000 and 1,150,000,000 shares authorized as of September 30, 2025 and December 31, 2024, respectively; 283,723,897 and 36,686,819 shares issued as of September 30, 2025 and December 31, 2024, respectively; 282,103,259 and 36,504,319 shares outstanding as of September 30, 2025 and December 31, 2024, respectively; shares issued and outstanding include 23,446 and 662,000 unvested shares subject to repurchase as of September 30, 2025 and December 31, 2024, respectively	283	38
Treasury stock at cost, 1,620,638 and 182,500 shares of common stock as of September 30, 2025 and December 31, 2024, respectively	(16,917)	(330)
Additional paid-in capital	3,124,943	—
Related party promissory note receivable (see note 7)	—	(26,456)
Accumulated deficit	(2,630,693)	(2,472,300)
Accumulated other comprehensive income	748	210
Total shareholders' equity (deficit)	478,364	(2,498,838)
Total liabilities, redeemable convertible preferred stock, and shareholders' equity (deficit)	**$ 984,571**	**$ 343,734**

The accompanying notes are an integral part of these condensed consolidated financial statements

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS) (UNAUDITED)

(amounts in thousands, except share and per share data)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Revenue:				
Molecular profiling services	$ 207,587	$ 93,803	$ 484,593	$ 254,692
Pharma research and development services	9,246	7,817	34,554	27,653
Total revenue	**216,833**	**101,620**	**519,147**	**282,345**
Costs and operating expenses:				
Cost of Services - Molecular profiling services	66,980	54,810	193,195	167,134
Cost of Services - Pharma research and development services	2,347	2,398	7,698	7,130
Selling and marketing expense	41,267	36,758	123,355	115,077
General and administrative expense (see note 10)	51,973	40,852	168,458	126,273
Research and development expense	21,624	27,644	69,739	86,807
Total costs and operating expenses	**184,191**	**162,462**	**562,445**	**502,421**
Income (Loss) from operations	**32,642**	**(60,842)**	**(43,298)**	**(220,076)**
Other expense, net:				
Interest income	7,360	1,744	9,482	6,152
Interest expense	(13,507)	(13,799)	(45,497)	(36,763)
Changes in fair value of financial instruments	(2,081)	5,131	(52,285)	6,067
Other income (expense), net	(89)	37	(18,447)	(323)
Total other expense, net	**(8,317)**	**(6,887)**	**(106,747)**	**(24,867)**
Income (Loss) before income taxes and provision for income taxes	**24,325**	**(67,729)**	**(150,045)**	**(244,943)**
Provision for income taxes	—	—	—	—
Net income (loss)	**24,325**	**(67,729)**	**(150,045)**	**(244,943)**
Other comprehensive income, net of tax:				
Unrealized gain on available-for-sale securities	—	—	—	7
Foreign currency translation adjustments	79	(120)	538	(20)
Comprehensive income (loss)	**24,404**	**(67,849)**	**(149,507)**	**(244,956)**
Net income (loss) attributable to common shareholders:				
Net income (loss)	24,325	(67,729)	(150,045)	(244,943)
Deemed dividend from Series D redeemable convertible preferred stock (see note 6)	—	—	(384,436)	—
Adjustments of redeemable convertible preferred stock to redemption value	—	(24,661)	(85,433)	(71,368)
Net income (loss) attributable to common shareholders	**$ 24,325**	**$ (92,390)**	**$ (619,914)**	**$ (316,311)**
Net income (loss) per share attributable to common shareholders:				
Basic	$ 0.09	$ (2.59)	$ (4.83)	$ (8.92)
Diluted	$ 0.08	$ (2.59)	$ (4.83)	$ (8.92)
Weighted-average shares used in computing net income (loss) per share attributable to common shareholders:				
Basic	282,099,073	35,643,589	128,447,673	35,442,927
Diluted	297,211,838	35,643,589	128,447,673	35,442,927

The accompanying notes are an integral part of these condensed consolidated financial statements

CONDENSED CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND SHAREHOLDERS' EQUITY (DEFICIT) (UNAUDITED)

	Three Months Ended September 30, 2025										
	Redeemable Convertible Preferred Stock		Common Stock		Treasury Stock						
(amounts in thousands, except share data)	Shares	Amount	Shares	Amount	Shares	Amount	Additional Paid-In Capital	Related Party Promissory Note Receivable	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Shareholders' Equity
Balances at June 30, 2025	—	$ —	281,090,538	$ 282	1,620,638	$(16,917)	$3,123,888	$ —	$(2,655,018)	$ 669	$ 452,904
Issuance of Series E Preferred Stock, net of issuance costs	—	(276)	—	—	—	—	—	—	—	—	—
Issuance of Series F Preferred Stock, net of issuance costs	—	(104)	—	—	—	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	13,655	—	—	—	13,655
Issuance of common stock upon exercise of stock options	—	—	600,133	1	—	—	1,152	—	—	—	1,153
Shares withheld for taxes related to net exercise of options	—	—	(220,273)	—	—	—	(16,152)	—	—	—	(16,152)
Vesting of shares from early exercised stock options	—	—	—	—	—	—	327	—	—	—	327
RSU's vested upon IPO, settled in August 2025	—	—	1,048,250	—	—	—	—	—	—	—	—
Shares withheld for taxes related to settled RSUs	—	—	(415,389)	—	—	—	—	—	—	—	—
Conversion of preferred stock to common stock	—	380	—	—	—	—	(380)	—	—	—	(380)
Net exercise of the 2025 Warrants in connection with initial public offering	—	—	—	—	—	—	(573)	—	—	—	(573)
Conversion of the 2025 Convertible Note	—	—	—	—	—	—	3,034	—	—	—	3,034
Other comprehensive income	—	—	—	—	—	—	(8)	—	—	79	71
Net loss	—	—	—	—	—	—	—	—	24,325	—	24,325
Balances at September 30, 2025	—	$ —	282,103,259	$ 283	1,620,638	$(16,917)	$3,124,943	$ —	$(2,630,693)	$ 748	$ 478,364

	Three Months Ended September 30, 2024										
	Redeemable Convertible Preferred Stock		Common Stock		Treasury Stock						
(amounts in thousands, except share data)	Shares	Amount	Shares	Amount	Shares	Amount	Additional Paid-In Capital	Related Party Promissory Note Receivable	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Shareholders' Deficit
Balances at June 30, 2024	734,142,041	$2,171,991	35,418,384	$ 38	182,500	$ (330)	$ —	$ (26,073)	$(2,333,550)	$ 325	$ (2,359,590)
Stock-based compensation	—	—	—	—	—	—	4,723	—	—	—	4,723
Issuance of common stock upon exercise of stock options	—	—	91,435	—	—	—	657	—	—	—	657
Interest income from related party promissory notes	—	—	—	—	—	—	—	(189)	—	—	(189)
Vesting of shares from early exercised stock options	—	—	306,000	—	—	—	4,956	—	—	—	4,956
Adjustment of preferred stock to redemption value	—	24,661	—	—	—	—	(10,336)	—	(14,325)	—	(24,661)
Other comprehensive income	—	—	—	—	—	—	—	—	—	(120)	(120)
Net loss	—	—	—	—	—	—	—	—	(67,729)	—	(67,729)
Balances at September 30, 2024	734,142,041	$2,196,652	35,815,819	$ 38	182,500	$ (330)	$ —	$ (26,262)	$(2,415,604)	$ 205	$ (2,441,953)

	Nine Months Ended September 30, 2025										
	Redeemable Convertible Preferred Stock		Common Stock		Treasury Stock						
(amounts in thousands, except share data)	Shares	Amount	Shares	Amount	Shares	Amount	Additional Paid-In Capital	Related Party Promissory Note Receivable	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Shareholders' Equity (Deficit)
Balances at December 31, 2024	734,142,041	$2,221,651	35,842,319	$ 38	182,500	$ (330)	$ —	$ (26,456)	$(2,472,299)	$ 210	$ (2,498,837)
Issuance of Series E Preferred Stock, net of issuance costs	12,345,674	57,217	—	—	—	—	—	—	—	—	—
Issuance of Series F Preferred Stock, net of issuance costs	4,657,401	21,617	—	—	—	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	56,639	—	—	—	56,639
Issuance of common stock upon exercise of stock options	—	—	1,948,254	1	—	—	3,775	—	—	—	3,776
Shares withheld for taxes related to net exercise of options	—	—	(355,232)	—	—	—	(18,218)	—	—	—	(18,218)
Vesting of shares from early exercised stock options	—	—	—	—	—	—	327	—	—	—	327
RSU's vested upon IPO, settled in August 2025	—	—	1,048,250	—	—	—	—	—	—	—	—
Shares withheld for taxes related to settled RSUs	—	—	(415,389)	—	—	—	—	—	—	—	—
Interest income from related party promissory notes	—	—	—	—	—	—	—	(128)	—	—	(128)
Payment of related party promissory notes	—	—	—	—	—	—	—	26,584	—	—	26,584
Repurchases of common stock	—	—	(1,438,138)	—	1,438,138	(16,587)	—	—	—	—	(16,587)
Adjustment of preferred stock to redemption value	—	85,433	—	—	—	—	(77,084)	—	(8,349)	—	(85,433)
Conversion of preferred stock to common stock, including the derecognition of associated embedded derivatives of $60,086	(751,145,116)	(2,385,918)	211,378,638	211	—	—	2,445,793	—	—	—	2,446,004
Issuance of common stock in connection with initial public offering, net of offering costs, underwriting discounts and											

commissions	—	—	27,058,823	27	—	—	519,425	—	—	—	519,452
Net exercise of the 2018 and 2020 Warrants in connection with initial public offering	—	—	4,174,907	4	—	—	131,742	—	—	—	131,746
Net exercise of the 2025 Warrants in connection with initial public offering	—	—	784,231	—	—	—	15,926	—	—	—	15,926
Conversion of the 2025 Convertible Note, including the derecognition of associated embedded derivatives of $13,082	—	—	2,076,596	2	—	—	46,640	—	—	—	46,642
Other comprehensive income	—	—	—	—	—	—	(22)	—	—	538	516
Net loss	—	—	—	—	—	—	—	—	(150,045)	—	(150,045)
Balances at September 30, 2025	—	$ —	282,103,259	$ 283	1,620,638	$(16,917)	$3,124,943	$ —	$(2,630,693)	$ 748	$ 478,364

	Nine Months Ended September 30, 2024										
	Redeemable Convertible Preferred Stock		Common Stock		Treasury Stock						
(amounts in thousands, except share data)	Shares	Amount	Shares	Amount	Shares	Amount	Additional Paid-In Capital	Related Party Promissory Note Receivable	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Shareholders' Deficit
Balances at December 31, 2023	734,142,041	$2,125,284	35,297,278	$ 38	182,500	$ (330)	$ —	$ (25,701)	$(2,119,175)	$ 218	$ (2,144,950)
Stock-based compensation	—	—	—	—	—	—	13,666	—	—	—	13,666
Issuance of common stock upon exercise of stock options	—	—	212,541	—	—	—	1,260	—	—	—	1,260
Interest income from related party promissory notes	—	—	—	—	—	—	—	(561)	—	—	(561)
Vesting of shares from early exercised stock options	—	—	306,000	—	—	—	4,956	—	—	—	4,956
Adjustment of preferred stock to redemption value	—	71,368	—	—	—	—	(19,882)	—	(51,486)	—	(71,368)
Other comprehensive income	—	—	—	—	—	—	—	—	—	(13)	(13)
Net loss	—	—	—	—	—	—	—	—	(244,943)	—	(244,943)
Balances at September 30, 2024	734,142,041	$2,196,652	35,815,819	$ 38	182,500	$ (330)	$ —	$ (26,262)	$(2,415,604)	$ 205	$ (2,441,953)

The accompanying notes are an integral part of these condensed consolidated financial statements

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

(amounts in thousands)	Nine Months Ended September 30,	
	2025	2024
Cash flows from operating activities		
Net loss	$ (150,045)	$ (244,943)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	18,324	39,847
Stock-based compensation expense	56,639	13,666
Non-cash operating lease expense	4,323	4,224
Amortization of debt discounts	12,163	5,148
Changes in fair value of financial instruments	52,284	(6,068)
Loss on debt extinguishment	17,930	—
Other	788	3,947
Changes in operating assets and liabilities:		
Accounts receivable	61,232	(15,009)
Supplies	(11,144)	4,211
Prepaid expenses and other current assets	(4,805)	(2,176)
Other assets	(326)	(158)
Accounts payable	(1,196)	5,054
Accrued expenses and other liabilities	(17,792)	(14,021)
Net cash provided by (used in) operating activities	38,375	(206,278)
Cash flows from investing activities		
Maturities of marketable securities	—	61,376
Purchases of property and equipment	(11,170)	(6,154)
Net cash provided by (used in) investing activities	(11,170)	55,222
Cash flows from financing activities		
Payments made on finance lease obligations	(67)	(136)
Proceeds from exercise of stock options	3,775	1,258
Payment of taxes withheld from net settlement of exercised options and vested RSUs	(18,218)	—
Payment of deferred offering costs	(7,710)	(1,034)
Proceeds from the 2023 term loan, net of issuance costs	—	199,978
Purchase of treasury stock	(22)	—
Issuance of Series E Preferred Stock, net of issuance costs	87,637	—
Issuance of Series F Preferred Stock, net of issuance costs	33,601	—
Issuance of the 2025 Convertible Notes, net of issuance costs	27,865	—
Issuance of the 2025 Warrants	10,270	—
Payments of 2023 term loan amendment fee	(4,000)	—
Proceeds from initial public offering, net of underwriting discounts and commissions	528,459	—
Net cash provided by financing activities	661,590	200,066
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	159	(3)
Net increase in cash, cash equivalents, and restricted cash	688,954	49,007
Cash, cash equivalents, and restricted cash at beginning of period	68,028	60,007
Cash, cash equivalents, and restricted cash at end of period	$ 756,982	$ 109,014

The accompanying notes are an integral part of these condensed consolidated financial statements

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Note 1. Nature of the Business

Caris Life Sciences, Inc. (the "Company" or "Caris") is a patient-centric, next-generation artificial intelligence ("AI") TechBio company and precision medicine pioneer. The Company commercializes and develops innovative solutions to transform healthcare through the use of comprehensive molecular information, AI, and machine learning ("ML") algorithms.

The Company's current molecular profiling services portfolio is focused on oncology and consists of MI Profile, a tissue-based molecular profiling solution, and Caris Assure, a novel, universal blood-based molecular profiling solution, with the aim to address the entire continuum of cancer treatment.

The Company also collaborates with biopharmaceutical companies to provide commercial services and prospective and retrospective testing, along with data and bioinformatics collaborations and novel target identification and discovery solutions.

The Company was incorporated under the laws of the Cayman Islands in November 2011 (Caris Life Sciences, Ltd.) and re-domiciled to be incorporated in Texas in July 2020 (Caris Life Sciences, Inc.) and is headquartered in Irving, Texas. The Company also has locations in Phoenix, Arizona; New York, New York; Cambridge, Massachusetts; Basel, Switzerland; and Tokyo, Japan.

Note 2. Summary of Significant Accounting Policies and Estimates

Basis of Financial Statement Presentation

The condensed consolidated financial statements include the accounts of Caris and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

The Company's condensed consolidated financial statements have been prepared in conformity with generally accepted accounting principles in the United States ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASUs") of the Financial Accounting Standards Board ("FASB").

Unaudited Interim Consolidated Financial Information

The unaudited condensed consolidated financial statements have been prepared on the same basis as the annual consolidated financial statements and reflect, in the opinion of management, all adjustments of a normal and recurring nature that are necessary for the fair statement of the Company's financial position as of September 30, 2025, its results of operations for the three and nine months ended September 30, 2025 and 2024, and cash flows for the nine months ended September 30, 2025 and 2024. The results of operations for the nine months ended September 30, 2025 are not necessarily indicative of the results to be expected for the year ending December 31, 2025, or for any other future annual or interim period. The condensed consolidated balance sheet as of December 31, 2024 included herein was derived from the audited financial statements as of that date and should be read in conjunction with the audited annual consolidated financial statements. Certain information and footnote disclosures normally included in consolidated financial statements prepared in accordance with GAAP have been condensed or omitted from these unaudited condensed consolidated financial statements.

Pre-IPO Financing

On April 1, 2025, the Company closed a private financing in which we issued a combination of senior convertible notes (the "2025 Convertible Notes") with warrants (the "2025 Warrants") to acquire shares of common stock, Series E redeemable convertible preferred stock ("Series E Preferred Stock") and Series F redeemable convertible preferred stock ("Series F Preferred Stock"), for an aggregate of $167.7 million. Investors in the private financing generally participated in each of the instruments. The 2025 Convertible Notes had an aggregate principal amount of $30.0 million. The 2025 Convertible Notes accrued interest at a rate of 8% per annum, payable quarterly in cash, and were scheduled to mature on January 1, 2026. The 2025 Warrants were not initially exercisable for any shares of common stock, but such warrants became exercisable for a specified dollar value of shares on a monthly basis commencing on June 1, 2025 if we had not completed an IPO by such date. The Series E Preferred Stock and Series F Preferred Stock both were issued at an original issue price of $8.10 per share for gross proceeds of approximately $137.7 million. Additionally, the gross proceeds of

$167.7 million, less issuance costs of $8.3 million, were allocated as follows: $27.9 million to the 2025 Convertible Notes, $10.3 million to the 2025 Warrants, $87.6 million to the Series E Preferred Stock, and $33.6 million to the Series F Preferred Stock.

Upon the closing of the IPO, the 2025 Convertible Notes (plus accrued interest), Series E Preferred Stock and Series F Preferred Stock (plus an 8% accrued dividend in connection with the preferred stock) converted into common stock at a price equal to 70% of the initial public offering price per share. Although structured and referred to as a legal-form conversion, this feature effectively functions as a share-settled redemption provision for accounting purposes.

Reverse Stock Split

Effective June 1, 2025, the Company's Board approved a one-for-four reverse stock split of the Company's common stock. This also resulted in an adjustment to the conversion price for each series of the Company's convertible preferred stock, to the underlying number of shares outstanding with respect to the restricted stock units, and to the exercise prices and number of shares of common stock underlying the outstanding stock options and warrants. Accordingly, all share and per share information relating to common stock for all periods presented in the accompanying consolidated financial statements and notes thereto have been retroactively adjusted. The shares of common stock retain a par value of $0.001 per share. Accordingly, an amount equal to the excess was reclassified from common stock to additional paid-in capital or, in the absence of additional paid-in-capital, accumulated deficit.

Initial Public Offering

On June 20, 2025, the Company completed its IPO of common stock, in which the Company issued and sold 23,529,412 shares of its common stock at an IPO price of $21.00 per share, which resulted in net proceeds of $459.5 million after deducting underwriting discounts and commissions of $39.8 million and before deducting offering costs of $9.0 million. Additionally, on June 25, 2025, the underwriters exercised in full their over-allotment option and purchased from the Company an additional 3,529,411 shares of common stock at the IPO price, which resulted in net proceeds to the Company of $68.9 million after deducting discounts and commissions.

An amended and restated certificate of formation, which authorized 2,800,000,000 shares of common stock and 100,000,000 shares of preferred stock, became effective on June 20, 2025 in connection with the closing of the Company's initial public offering ("IPO"). As of September 30, 2025, no shares of preferred stock are outstanding.

In connection with the IPO, all outstanding shares of the Company's then-outstanding redeemable convertible preferred stock, inclusive of accrued dividends, automatically converted into 211,378,638 shares of common stock. Refer to Note 6 for additional information. Additionally, all of the Company's then-outstanding 2025 Convertible Notes converted into an aggregate of 2,076,596 shares of common stock upon the IPO. As the IPO was not completed by June 1, 2025, 784,231 shares of common stock were issued on June 20, 2025 at an exercise price of $0.04 per share in connection with the automatic net exercise of the warrants issued in connection with the 2025 Convertible Notes. Lastly, the 2018 and 2020 warrants were net exercised into 4,174,907 shares of common stock as outlined in the terms of the applicable warrant agreements.

In connection with the IPO, the Company recognized $19.5 million of stock-based compensation expense due to vesting of previously-granted restricted stock units. The vesting of such restricted stock units was contingent upon the Company completing either an IPO of its common stock or through a change of control. The vested restricted stock units were settled in August 2025. Refer to Note 7 for additional information.

Prior to the IPO, deferred offering costs, which consisted of accounting, legal and other fees directly related to the IPO, were capitalized as prepaid expenses and other current assets on the condensed consolidated balance sheets. In connection with the IPO, $9.0 million of deferred offering costs were reclassified to additional paid-in capital as a reduction of the net proceeds received from the IPO.

Use of Estimates

The preparation of the condensed consolidated financial statements in conformity with GAAP in the United States requires the use of estimates and assumptions about future events that affect the amounts reported in the Company's condensed consolidated financial statements and related notes, including the amounts of assets and liabilities, the disclosure of contingent liabilities at the date of the condensed consolidated financial statements, and the reported amounts of revenues and expenses during the periods reported.

Significant estimates and assumptions are used for, but not limited to:

- revenue recognition
- fair value of stock-based awards and common stock
- fair value of financial assets and liabilities

Future events and their effects cannot be predicted with certainty. Accordingly, the accounting estimates require the exercise of judgment. These estimates and assumptions are based on current facts, historical experience and various other factors believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the recording of expenses that are not readily apparent from other sources. The accounting estimates used in the preparation of the Company's condensed consolidated financial statements may change as new events occur, additional information is obtained, and the operating environment changes. The Company will evaluate and update the assumptions and estimates on an ongoing basis and may employ outside experts to assist in its evaluation, as considered necessary. Actual results could materially differ from those estimates.

Cash, Cash Equivalents, and Restricted Cash

The Company considers all highly liquid investments with original maturities of three months or less from date of acquisition to be cash equivalents. Refer to Note 4 for information on the Company's restricted cash.

Revenue Recognition

The Company recognizes revenue under ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 606"). Revenue is recognized when control of goods and services are transferred to customers, in an amount that reflects the consideration the Company expects to be entitled to in exchange for those services.

ASC 606 provides for a five-step model that includes:

Step 1: Identify the contract(s) with a customer.
Step 2: Identify performance obligations in the contract.
Step 3: Determine the transaction price.
Step 4: Allocate the transaction price to the performance obligations in the contract.
Step 5: Recognize revenue when (or as) the entity satisfies a performance obligation.

The Company derives revenue from two distinct channels:

- Molecular profiling services involving the provision of precision oncology solutions utilizing MI Profile and Caris Assure
- Pharma research and development services involving delivery of laboratory, strategic data, and research services to biopharmaceutical customers

Molecular Profiling Services

For the majority of its molecular profiling services, the Company recognizes revenue from the sale of its precision oncology solutions, provided to customers, including certain hospitals, institutions and patients, at the point in time when the results of the profiling services are delivered to ordering physicians. Most cases requested on behalf of customers are provided without a written agreement; however, the Company determines that an implied contract exists with its customers for whom a physician orders the case. Results from molecular profiling services are delivered via fax, electronically, or in hard copy. Shipping and handling activities are considered fulfillment activities and as such, amounts incurred are recorded within Cost of Services - Molecular profiling services on the condensed consolidated statements of operations and comprehensive loss. The Company identifies each sale of the Company's profiling service as a distinct performance obligation. Payment terms are a function of a patient's existing insurance benefits and applicable reimbursement contracts established between the Company and payers. Collection of consideration the Company expects to receive typically occurs within 90 to 120 days of billing. Occasionally, payers may recoup or we may refund consideration, mainly as a result of claim processing.

The total consideration to which the Company expects to be entitled in exchange for the Company's services may be fixed or variable. Consideration includes reimbursement from patients, hospitals, and third-party commercial and governmental payers, such as insurance companies, adjusted for variable consideration related to implicit price concessions that the Company may grant. The Company estimates the variable consideration under a portfolio approach

for third-party payers, hospitals and patients with similar reimbursement characteristics. This includes analysis of an average reimbursement per case per portfolio and a percentage of cases reimbursed by considering the historical reimbursement data (including any refunds and recoupments) from such third-party payers, hospitals and patients. Specifically, the Company calculates the historical average reimbursement rates for each portfolio and applies an estimated reimbursement rate, based on historical trends, to the number of cases delivered each period. The period for which historical data is drawn upon is determined on a by- portfolio basis for each payer group, taking into consideration the average collection period. Additionally, the estimate also considers current contractual and statutory requirements, patient insurance eligibility and payer reimbursement contracts, and any known current or anticipated reimbursement trends not reflected in the historical data and only recognizes revenue for variable consideration that the Company determines is probable will not result in a significant reversal in the future. The Company monitors the estimated amount to be collected at each reporting period based on actual cash collections in order to assess whether a revision to the estimate is required. Subsequent changes to the estimate of the transaction price are recorded as adjustments to molecular profiling services revenue in the period where such changes occur. Both the estimate and any subsequent revision are uncertain and require the use of management's judgment in the estimation of the variable consideration and application of the constraint for such variable consideration.

Pharma Research and Development Services

The Company collaborates with biopharmaceutical companies to provide commercial services and prospective and retrospective testing, along with data and bioinformatics collaborations and novel target identification and discovery solutions.

Contracts with biopharmaceutical customers may include multiple distinct performance obligations, such as molecular profiling services, pharma research and development services, and strategic data services. The Company evaluates the terms and conditions included within its contracts with biopharmaceutical customers for proper revenue recognition, including whether services are capable of being distinct and considered distinct within the context of the contract. The performance obligations for biopharmaceutical customers vary by contract. Such contracts may include a performance obligation to provide molecular profiling services, to facilitate the development and regulatory approval of drugs, or to provide target discovery services. Under those contracts, the Company receives payments upon the achievement of milestones, as well as provision of on-going support. The transaction price of the development services contracts may include variable consideration, due to the uncertainty associated with the achievement of the milestones. In making the assessment of whether variable consideration should be included in the transaction price, the Company considers its historical experience with similar milestones, the degree of complexity and uncertainty associated with each milestone, and whether achievement of the milestone is dependent on parties other than the Company. The Company recognizes pharma research and development services revenue over the period in which biopharmaceutical research and development services are provided. Depending on the nature of the service, the Company recognizes revenue using either the output or input method to measure progress, whichever provides a more faithful depiction of the transfer of goods or services. Use of an output method or input method to depict the transfer of services generally does not result in a material difference with respect to the timing of revenue recognition because most services commence and end within the same reporting period. A constraint for variable consideration is applied such that it is probable a significant reversal of revenue will not occur when the uncertainty associated with the contingency is resolved. Application of the constraint for variable consideration is updated at each reporting period as a revision to the estimated transaction price.

Standalone Selling Price

The Company determines standalone selling prices by considering the historical selling prices of its performance obligations in similar transactions, where applicable, as well as other factors, including, but not limited to, the price that customers in the market would be willing to pay, competitive pricing from other vendors, industry publications, current pricing practices and management estimates.

Contract Balances

The timing of revenue recognition may differ from the timing of invoicing to customers. Accounts receivable are recorded at the invoiced amount, net of an allowance for credit losses. A receivable is recognized in the period the Company delivers goods or provides services, or when the right to consideration is unconditional. In situations where revenue recognition occurs before invoicing, an unbilled receivable is created, which represents a contract asset. As of September 30, 2025 and December 31, 2024, the unbilled receivable balance was $9.9 million and $4.6 million, respectively, which is included in accounts receivable on the condensed consolidated balance sheets.

The Company recognizes contract liabilities primarily related to payments received in advance of satisfaction of performance obligations from contracts with customers. Contract liabilities are relieved as the Company fulfills its obligations under the contract and revenue is recognized. As of September 30, 2025 and December 31, 2024, the contract liability balance was $2.8 million and $7.5 million, respectively, which is included in accrued expenses and other current liabilities on the condensed consolidated balance sheets.

The following table shows the changes in the contract liabilities during the period:

	(amounts in thousands)
Balance at December 31, 2024	$ 7,470
Increase in contract liabilities	7,903
Revenue recognized during the period that was included in deferred revenues at the beginning of the period	(7,093)
Revenue recognized from performance obligations satisfied within the same period	(5,489)
Balance at September 30, 2025	$ 2,791

The amount of revenue recognized during the nine months ended September 30, 2024 pertaining to amounts deferred as of December 31, 2023 was $5.2 million.

Transaction Price Allocated to Remaining Performance Obligations

The transaction price allocated to remaining performance obligations represents contracted revenue that has not yet been recognized, which includes contract liabilities and non-cancelable amounts that will be invoiced and recognized as revenue in future periods and excludes performance obligations that are subject to cancellation terms. The Company has elected not to disclose information regarding the transaction price allocated to the remaining performance obligations for which the original expected duration of the contract is one year or less. The amount of transaction price allocated to the remaining performance obligations for contracts with original expected duration over one year as of September 30, 2025 was $9.1 million. The Company expects to recognize the amount within twelve months from the respective balance sheet dates.

Additionally, for the three months ended September 30, 2025 and 2024, the Company recorded $38.3 million and $6.8 million, respectively, of adjustments to revenue related to services delivered in prior periods, which is based on variability that was subsequently resolved. For the nine months ended September 30, 2025 and 2024, the Company recorded $23.4 million and $2.9 million, respectively, of adjustments to revenue related to services delivered in prior periods, which is based on variability that was subsequently resolved.

Practical Expedients and Contract Costs

Payment terms and conditions vary by contract and customer. In instances where the timing of the Company's revenue recognition differs from the timing of its invoicing, the Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the customer and the transfer of the promised services to the customer will be one year or less.

As a practical expedient, the Company recognizes the incremental costs of obtaining contracts, such as sales commissions, as expenses when incurred, if the amortization period of the asset that the Company otherwise would have recognized for the capitalized costs is one year or less. Sales commissions are recorded within selling and marketing expense on the condensed consolidated statements of operations and comprehensive loss. The Company did not capitalize any sales commissions or contract fulfillment costs as of September 30, 2025 and December 31, 2024.

Collaboration Agreements

The Company is party to various collaboration and licensing agreements under which the Company out-licenses certain know-how and molecular data. The collaboration arrangements are intended to solidify the Company's third-party partnerships to align oncology capabilities and create industry-leading molecular oncology research platforms to accelerate drug development and novel research. Under these collaboration arrangements, the Company generally receives a split of fees from its collaborative partners that are earned pursuant to statements of work ("SOWs") executed with end users of the Company's licensed molecular data.

The Company's collaboration and licensing agreements are within the scope of ASC Topic 808, Collaborative Arrangements ("ASC 808") and ASC 606 because the counterparty to these agreements meets the definition of a customer. As such, the Company recognizes revenue earned from the licenses of molecular data granted to the Company's collaborative partners in accordance with ASC 606. Each license of molecular data granted by the Company to a collaborative partner represents a distinct performance obligation in the contract. The transaction price for a given arrangement is entirely variable and depends on the SOWs executed by the counterparty with end users. The amount of revenue allocated to each license is equal to the amount of revenue to which the Company expects to be entitled. The Company recognizes revenue at the point in time that it delivers the molecular data to the third-party collaborative partner. For the three months ended September 30, 2025 and 2024, the Company recognized collaboration revenue of $— million and $2.5 million, respectively, and $6.9 million and $9.1 million for the nine months ended September 30, 2025 and 2024, respectively, which is included in revenue from pharma research and development services on the condensed consolidated statements of operations and comprehensive loss.

Cost of Services - Molecular profiling services

Cost of services for molecular profiling services generally consists of cost of materials, direct labor including bonus and stock-based compensation, and equipment maintenance and depreciation expenses associated with processing cases (including accessioning, sequencing, quality control analyses and shipping charges to transport tissue samples), freight and profile results for ordering physicians. Costs associated with completing the molecular profiling services are recorded as the service is performed, regardless of when revenue is recognized with respect to the service.

Cost of Services - Pharma research and development services

Cost of services for pharma research and development services generally consists of cost incurred for the performance of the services requested by the Company's biopharmaceutical customers related to the delivery of laboratory, strategic data and research services, and will vary depending on the nature, timing, and scope of customer projects. Costs associated with delivering pharma research and development services are recorded as incurred.

Concentration of Credit Risk

Financial instruments that potentially expose the Company to concentration of credit risk consist primarily of cash, cash equivalents, marketable securities, and accounts receivable. The Company maintains its cash primarily with domestic financial institutions of high credit quality, with balances that exceed amounts insured by the Federal Deposit Insurance Corporation as of September 30, 2025 and December 31, 2024, respectively.

The Company invests in treasury bills issued by the U.S. Government. U.S. treasury bills with original maturities of three months or less are classified within cash equivalents. Short-term marketable securities are comprised of U.S. treasury bills with original maturities between three and twelve months. The Company believes it is not exposed to any significant credit risk on cash, cash equivalents, and marketable securities and performs periodic evaluations of the credit standing of such institutions. The goal of the Company's investment policy is to ensure safety and preservation of the principal balance, and diversification of risk over cash balances held on deposit.

The Company is subject to credit risk from its accounts receivable. The Company's accounts receivable arise from the provision of molecular profiling services and pharma research and development services, primarily with biopharmaceutical companies, all of which have high credit ratings. The Company has not experienced any material losses related to receivables from individual customers, or groups of customers. The Company does not require collateral. Accounts receivable are recorded net of allowance for credit losses, if any. Concentrations of credit risk are limited due to the number of payers and their dispersion across multiple geographic regions.

For the three and nine months ended September 30, 2025 and 2024, the Company's revenues were primarily derived from the sale of Caris molecular profiling services. As discussed above, payment terms of the services are a function of a patient's existing insurance benefits and applicable reimbursement contracts established between the Company and payers. Revenue associated with each payer, including its affiliated entities, as a percentage of the Company's total revenue for the respective period, and accounts receivable balance attributable to each payer, including its affiliated entities, as a percentage of the Company's total accounts receivable balance at the respective condensed consolidated balance sheet date, are as follows:

Major Payer	% Revenue for the three months ended September 30,		% Revenue for the nine months ended September 30,		% Accounts receivable as of	
	2025	2024	2025	2024	September 30, 2025	December 31, 2024
Payer 1	37.7%	35.6%	43.3%	35.8%	50.8%	16.1%
Payer 2	21.2%	17.3%	17.2%	14.9%	*	19.3%
Payer 3	12.9%	*	10.9%	*	*	*

*Represents major payers below 10.0%.

Accounts Receivable

Accounts receivable includes billed and unbilled receivables, net of an allowance for expected credit losses. Accounts receivable primarily represent receivables from biopharmaceutical customers and third-party payers. Accounts receivable for pharmaceutical services are established based on the amounts outstanding per the contractual arrangements with biopharmaceutical customers. The Company applies the current expected credit loss standard in ASC Subtopic 326-20, *Financial Instruments—Credit Losses* ("ASC 326-20") and reserves a portion of the accounts receivable based on assessment of the collectability of customer accounts at the time of revenue recognition. The Company regularly reviews the reserve 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.

Receivables deemed to be uncollectible are written-off against the allowance for credit losses at the time such receivables are deemed to be uncollectible under a specific identification or estimated method. Recoveries of accounts receivable previously written off are recorded when received. As of September 30, 2025 and December 31, 2024, the Company had an immaterial allowance for credit losses related to its accounts receivable.

Supplies

Supplies consist primarily of laboratory items and reagents used by the Company in providing services. All supplies are raw materials and are stated at the lower of cost or net realizable value on a first-in, first-out basis. The Company periodically reviews its supplies for excess or obsolescence and writes down obsolete or otherwise unmarketable supplies to their estimated net realizable value. As of September 30, 2025 and December 31, 2024, the amount of write downs associated with the Company's supplies was immaterial.

Deferred Offering Costs

Deferred offering costs consist primarily of accounting, legal, and other fees related to the Company's proposed IPO. The Company had $4.5 million of deferred offering costs as of December 31, 2024. Prior to the IPO, deferred offering costs were capitalized on the consolidated balance sheet. Upon the consummation of the IPO, $9.0 million of deferred offering costs were reclassified into additional paid-in capital as an offset against IPO proceeds.

Property and Equipment, Net

The Company reports property and equipment at cost, net of accumulated depreciation, amortization, and any asset impairments. The cost of properties held under finance leases is equal to the present value of lease payments not yet paid, adjusted for initial direct costs, prepaid lease payments and lease incentives received. Major improvements which add to productive capacity or extend the life of an asset are capitalized. Normal repairs and maintenance are expensed as incurred. When assets are retired or otherwise disposed of, the cost and related accumulated depreciation and amortization are removed from the accounts, and any resulting gain or loss is reflected in the accompanying condensed consolidated statements of operations and comprehensive loss for the period.

Depreciation and amortization expenses are calculated on a straight-line basis and applied to asset classes based upon the Company's estimate of the asset class's useful life, as summarized below:

	Estimated Useful Life
Laboratory equipment	3 years
Computer equipment and software	3 years
Furniture and fixtures	5 years
Aircraft	15 years
Leasehold improvements/leased buildings	Lesser of remaining lease term or useful life
Leased equipment	Lesser of initial lease term or 5 years

Computer equipment and software includes the purchases of hardware, software and capitalized labor costs associated with internally developed software.

The Company capitalizes purchased software which is ready-for-service and capitalizes qualifying internal software development costs incurred on significant projects. Capitalization of costs begins when two criteria are met: (1) the preliminary project stage is completed, management with relevant authority authorizes and commits to funding the software project, and (2) it is probable that the software will be completed and used for its intended function. Capitalization ceases when the software is substantially complete and ready for its intended use, including the completion of all significant testing. Costs related to preliminary project activities and post-implementation operating activities are expensed as incurred.

Research and development costs and other computer software maintenance costs related to software development are expensed as incurred.

Capitalized software costs are included in property and equipment, net. These costs are amortized using the straight-line method over the estimated useful life of the underlying software, which is three years.

Fair Value Measurements

Fair value is defined as the exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions market participants would use in pricing an asset or liability.

The basis for these assumptions establishes a three-level fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

- *Level 1* - Observable inputs such as quoted prices in active markets for identical assets and liabilities;
- *Level 2* - Inputs, other than quoted prices in active markets, that are observable either directly or indirectly; and
- *Level 3* - Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

Assets and liabilities measured at fair value are based on one or more of three valuation techniques. The three valuation techniques are as follows:

- *Market approach* – Prices and other relevant information generated by market transactions involving identical or comparable assets or liabilities;
- *Cost approach* – Amount that would be required to replace the service capacity of an asset (i.e., replacement cost); and
- *Income approach* – Techniques to convert future amounts to a single present amount based on market expectations (including present value techniques, option-pricing models, and lattice models).

Financial instruments consist of cash, cash equivalents, restricted cash, short-term marketable securities, accounts receivable, prepaid expenses and other current assets, accounts payable, accrued expenses and other current liabilities, debt, warrants, and derivative instruments.

As of September 30, 2025 and December 31, 2024, the carrying amounts of the Company's cash equivalents, restricted cash, accounts receivable, prepaid expenses and other current assets, accounts payable, accrued expenses and

other current liabilities approximate their fair value based on the short-term nature of these items. There were no transfers between Levels 1, 2 or 3 for the periods ended September 30, 2025 and December 31, 2024.

The Company's financial assets and liabilities subject to fair value measurements on a recurring basis and the level of inputs used in such measurements were as follows:

	As of September 30, 2025			
	Fair Value	Level 1	Level 2	Level 3
Financial assets		(amounts in thousands)		
Short-term marketable securities	$ 2,272	$ 2,272	$ —	$ —

	As of December 31, 2024			
	Fair Value	Level 1	Level 2	Level 3
Financial assets		(amounts in thousands)		
Short-term marketable securities	$ 2,201	$ 2,201	$ —	$ —
Financial liabilities				
Warrant liability	$ 91,642	$ —	$ —	$ 91,642
Derivative liability	$ 6,058	$ —	$ —	$ 6,058

2018 and 2020 Warrant Liability

The Company utilized a probability-weighted scenario approach factoring in various exit strategies and the related timing of such to estimate the fair value of its warrant liability. For each scenario, the Company utilized a Black-Scholes option pricing model with the following assumptions:

- *Fair value per share of the underlying stock*—The fair value of the underlying stock represents the fair value of the Company's Series C preferred stock that the warrants are convertible into.
- *Volatility*—The volatility is derived from historical volatilities of several unrelated publicly-listed peer companies, since the Company has no trading history. When making the selections of industry peer companies to be used in the volatility calculation, the Company considers the size, operational and economic similarities to the Company's principal business operations.
- *Risk-free interest rate*—The risk-free interest rate is based on U.S. treasury yield as of the measurement dates interpolated to match the maturity equal to the respective term to exit.
- *Dividend yield*—The expected dividend assumption is based on the Company's current expectations about the Company's anticipated dividend policy.
- *Expected term (years)*—Based on expected term under various exit strategies.

The below table summarizes the significant unobservable inputs used in the fair value measurement of the 2018 and 2020 warrant liabilities as of December 31, 2024. The warrants were reclassified from liability to equity upon the IPO as they were exercised into Series C preferred stock, which was converted to common stock. The difference between the fair value of the warrants immediately prior to the reclassification and its prior fair value was recorded in the condensed consolidated statement of operations and comprehensive loss as changes in fair value of financial instruments. The fair

value immediately prior to the reclassification is based on the total number of common stock issued upon exercise and conversion, multiplied by the public offering price of $21.00 per share.

	As of December 31, 2024	
	2018 Warrants	2020 Warrants
Fair value per share of the underlying stock	$3.66 - $5.65	$3.66 - $5.65
Expected volatility	47.6% - 63.0%	61.2% - 63.0%
Risk-free interest rate	4.2% - 4.3%	4.3%
Expected dividend yield	—%	—%
Expected term (years)	0.29 - 0.75	0.29 - 2.25

2025 Warrant Liability - Pre-IPO Financing

The Company utilized a probability-weighted scenario approach factoring in various exit scenarios and the related timing of such to estimate the fair value of its warrants that were issued in conjunction with the 2025 Convertible Notes. Upon issuance as of April 1, 2025, the fair value of these warrants was $10.3 million. Immediately prior to the IPO, the fair value of these warrants was $16.5 million.

Derivative Liability - 2023 Term Loan

On January 18, 2023, the Company entered into a credit agreement (the "New Term Loan Agreement") under which the Company issued senior, secured promissory notes (the "2023 Term Loan") by which the New Term Loan lenders agreed to lend the Company up to an aggregate principal amount of $400.0 million, $200.0 million of which was received by the Company upon issuance, and $200.0 million of which was drawn down in March 2024. The Company identified certain embedded features in the 2023 Term Loan, including various contingent prepayment, compensatory payment, and default interest rate features, that are required to be bifurcated from the 2023 Term Loan and separately accounted for in the condensed consolidated financial statements as a compound derivative liability.

Fair value of the derivative liability as of December 31, 2024 was estimated using the discounted cash flow method under the income approach. This approach involves significant Level 3 inputs and assumptions including an estimated probability and timing of certain contingent events, such as events of default, change of control, sale of assets, etc. The analysis also required the selection of a discount rate representative of the Company's credit risk. The discount rate used for the initial fair value was calibrated to the transaction. The value of the derivative liability in connection with the 2023 Term Loan reduced to zero upon the IPO, as the contingent prepayment is no longer required.

Refer to Note 8 for additional information about the compound embedded derivative liability.

Derivative Liability - Pre-IPO Financing

In estimating the fair value of the bifurcated derivatives related to the Series E Preferred Stock, Series F Preferred Stock and the 2025 Convertible Notes, the Company applied the with-and-without methodology as of April 1, 2025. This approach calculates the value of the bifurcated embedded derivative as the difference between the value of each instrument including the derivative and the value of each instrument excluding the derivative. Upon issuance on April 1, 2025, the fair values of the bifurcated embedded derivatives relating to the Series E Preferred Stock, Series F Preferred Stock, and 2025 Convertible Notes were $30.1 million, $11.9 million, and $21.2 million, respectively. Immediately prior to the IPO, the fair values of these bifurcated derivatives were $43.6 million, $16.5 million, and $13.1 million, respectively, determined as the excess of each instrument's fair value immediately prior to the IPO over the sum of its original proceeds and any accrued interest or dividends. Upon the IPO, the derivative liabilities were derecognized in conjunction with the conversion of the 2025 Convertible Notes, Series E Preferred Stock, and Series F Preferred Stock, and the issuance of the associated shares was recorded in common stock and additional paid-in capital.

Debt - 2023 Term Loan

As of September 30, 2025, the estimated fair value of the 2023 Term Loan, was $380.7 million, compared to a carrying value of $375.9 million. As of December 31, 2024, the estimated fair value of the 2023 Term Loan, excluding the bifurcated embedded derivative, was $380.9 million, compared to a carrying value of $373.1 million. The Company

estimated the fair value of the 2023 Term Loan as of September 30, 2025 based on a discounted cash flow analysis, and an income approach, which represented the use of Level 3 inputs in the fair value hierarchy.

2025 Convertible Notes, Series E Preferred Stock, and Series F Preferred Stock - Pre-IPO Financing

The Company calculated the fair value of the 2025 Convertible Notes, as well as the Series E Preferred Stock, Series F Preferred Stock, and warrants as of April 1, 2025 using a calibrated approach that aligned the total fair value of the instruments with the cash proceeds received. Upon issuance as of April 1, 2025, the fair value of the 2025 Convertible Notes, the Series E Preferred Stock and the Series F Preferred Stock were $29.4 million, $92.5 million, and $35.5 million respectively. Immediately prior to the IPO, the fair value of the 2025 Convertible Notes was $43.6 million, based on the total number of common stock issued upon conversion, multiplied by the initial public offering price of $21.00 per share.

Goodwill

Goodwill represents the excess of the purchase price over the fair value of net identifiable assets and liabilities acquired through a business combination. The Company evaluates goodwill for impairment in accordance with ASC Topic 350, *Intangibles – Goodwill and Other* on an annual basis on October 1, or more frequently if events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. The Company first assesses qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount, or the Company may determine to proceed directly to the quantitative impairment test.

If the Company assesses qualitative factors and concludes that it is more likely than not that the fair value of a reporting unit is less than its carrying amount or if the Company determines not to use the qualitative assessment, then a quantitative impairment test is performed. The factors utilized in the qualitative assessment include macroeconomic conditions, industry and market considerations, cost factors, overall financial performance, and Company-specific events. The quantitative impairment test requires comparing the fair value of the reporting unit to its carrying value, including goodwill. The fair value of the reporting unit is determined based on the present value of estimated cash flows using available information regarding expected cash flows of each reporting unit, discount rates, and the expected long-term cash flow growth rates.

The Company has identified that its business operates as a single operating segment which is also a single reporting unit for purposes of testing goodwill for impairment. An impairment exists if the fair value of the reporting unit is lower than its carrying value. If the fair value of the reporting unit is lower than its carrying value, the Company would record an impairment loss equal to the excess of the reporting unit's carrying value over its fair value.

There were no impairment losses for the three and nine months ended September 30, 2025 and 2024.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development expenses consist of costs incurred in performing research and development activities. The costs include direct costs for salaries and benefits, materials, contract services and other outside costs, and costs to acquire in-process research and development projects and technologies that have no alternative future use.

Advertising

The Company expenses advertising costs as incurred. The Company incurred advertising costs of $0.3 million and $0.4 million for the three months ended September 30, 2025 and 2024, respectively, and $0.5 million and $0.9 million for the nine months ended September 30, 2025 and 2024, respectively.

Self-Insurance

The Company offers medical insurance coverage to eligible employees under a self-insured program managed by a third-party administrator, leveraging stop-loss insurance policies to mitigate risk. The Company records an estimate of its liability for medical claims, which includes the incurred claims amount plus an estimate of incurred, but not reported claims. Self-insurance liability of $2.2 million and $1.9 million as of September 30, 2025 and December 31, 2024, respectively, is included within accrued expenses and other current liabilities on the condensed consolidated balance sheets.

Net Income (Loss) per Share Attributable to Common Shareholders

The Company calculates its basic and diluted net income (loss) per share attributable to common shareholders in conformity with the two-class method required for companies with participating securities. Each series of the Company's redeemable convertible preferred stock is considered to be a participating security because the preferred shareholders have a right to receive dividends on a pari passu basis with the Company's common shareholders. The two-class method determines net income (loss) per share for each class of common stock and participating security according to dividends declared or accumulated and participating rights in undistributed earnings. The two-class method requires income (loss) available to common shareholders for the period to be allocated between common and participating securities based upon the respective rights of each to share in earnings as if all income (loss) for the period had been distributed. The participating securities are not required to participate in the losses of the Company, and therefore during periods of loss there is no allocation required under the two-class method between common and participating securities.

Income Taxes

The Company accounts for income taxes under the asset and liability method as set forth in ASC 740 "*Income Taxes*" ("ASC 740"). Under this method, deferred tax assets and liabilities are determined based on the differences between the financial statement and tax bases of assets and liabilities by using enacted tax rates in effect for the year in which the differences are expected to reverse. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

The calculation of the Company's tax liabilities involves dealing with uncertainties in the application of complex tax laws and regulations in a multitude of jurisdictions across its global operations. The Company records uncertain tax positions in accordance with ASC 740 on the basis of a two-step process in which (1) we determine whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (2) for those tax positions that meet the more-likely-than-not recognition threshold, we recognize the largest amount of tax benefit that is more than 50% likely to be realized upon ultimate settlement with the related taxing authority. For tax positions not meeting the more-likely-than-not test, no tax benefit is recorded.

At September 30, 2025 and December 31, 2024, the Company has accumulated net operating loss carryforwards in both the U.S. and foreign jurisdictions, and no provision for income taxes is required. The Company's deferred tax assets are subject to a full valuation allowance.

Recently Issued Accounting Pronouncements Not Yet Adopted

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* which requires presentation of specific categories of reconciling items, as well as reconciling items that meet a quantitative threshold, in the reconciliation between the income tax provision and the income tax provision using statutory tax rates. The standard also requires disclosure of income taxes paid disaggregated by jurisdiction with separate disclosure of income taxes paid to individual jurisdictions that meet a quantitative threshold. For public business entities, the ASU is effective for annual periods beginning after December 15, 2024, with early adoption permitted. For entities other than public business entities, the ASU is effective for annual periods beginning after December 15, 2025. The amendments of the ASU should be applied on a prospective basis; however, entities have the option to apply retrospectively for each period presented. The Company does not expect the adoption of this new standard in 2025 to have an impact on its condensed consolidated financial position, results of operations, or cash flow.

In November 2024, the FASB issued ASU No. 2024-03, *Income Statement- Reporting Comprehensive Income-Expense disaggregation disclosures (Subtopic 220-40) Disaggregation of Income Statement Expenses*. This ASU requires disclosure of specified information about certain costs and expenses in the notes to financial statements. This ASU is effective for annual periods beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027. Adoption of this ASU should be applied on a prospective basis. Early adoption is permitted. We are currently evaluating the impact that this guidance will have on the disclosures within our financial statements, and expect to adopt this ASU for the fiscal year beginning January 1, 2027.

In September 2025, the FASB issued ASU No. 2025-06, *Intangibles - Goodwill and Other - Internal-Use Software*. This ASU removes all references to prescriptive and sequential software development stages throughout Subtopic 350-40. This will require an entity to change how it starts capitalizing software costs, along with updating how entities evaluate the probable-to-complete recognition threshold. For all entities, the ASU is effective for annual reporting periods beginning after December 15, 2027, with early adoption permitted. The amendments of this ASU can be applied using any of the following three approaches: prospective transition approach; modified transition approach that is based

on the status of the project and whether software costs were capitalized before the date of adoption; and retrospective transition approach. We are currently evaluating the impact that this guidance will have, and expect to adopt this ASU for the year ending December 31, 2028.

Note 3. Condensed Consolidated Balance Sheet and Statement of Operations and Comprehensive Loss Components

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

	As of September 30, 2025	As of December 31, 2024
	(amounts in thousands)	
Prepaid expenses	$ 18,657	$ 13,562
Other current assets	2,577	6,708
Total prepaid expenses and other current assets	$ 21,234	$ 20,270

Property and Equipment, Net

Property and equipment, net consist of the following:

	As of September 30, 2025	As of December 31, 2024
	(amounts in thousands)	
Computer equipment and software	$ 75,814	$ 73,312
Capitalized software	27,097	25,921
Laboratory equipment	108,476	103,795
Furniture and fixtures	8,305	9,110
Leasehold improvements/Leased buildings	63,502	63,039
Aircraft and leased equipment	21,255	21,249
Total property and equipment	304,449	296,426
Less: accumulated depreciation and amortization	(240,452)	(228,609)
Property and equipment, net	$ 63,997	$ 67,817

Total depreciation and amortization expense was $4.9 million and $10.5 million for the three months ended September 30, 2025 and 2024, respectively, and $18.3 million and $39.8 million for the nine months ended September 30, 2025 and 2024, respectively.

Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following:

	As of September 30, 2025	As of December 31, 2024
	(amounts in thousands)	
Trade accruals	$ 5,635	$ 7,131
Accrued payroll and employee medical	14,270	17,882
Accrued bonus	20,905	25,736
Current portion of early exercise stock option liability	327	4,957
Contract liability	2,791	7,470
Current portion of operating lease liabilities	6,450	6,080
Other accrued expenses	6,489	8,286
Total accrued expenses and other current liabilities	$ 56,867	$ 77,542

Other Long-Term Liabilities

Other long-term liabilities consist of the following:

	As of September 30, 2025	As of December 31, 2024
	(amounts in thousands)	
Long-term operating lease liabilities, net of current portion	$ 43,828	$ 38,651
Long-term portion of early exercise stock option liability	53	5,767
Total other long-term liabilities	$ 43,881	$ 44,418

Other Income (Expense), Net

Other income (expense), net, consists of the following:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
	(amounts in thousands)			
Loss on debt extinguishment	$ —	$ —	$ (17,930)	$ —
Other	(89)	37	(517)	(323)
Total other income (expense), net	$ (89)	$ 37	$ (18,447)	$ (323)

Note 4. Restricted Cash

The Company entered into a lease agreement with KCP NNN II Leasehold 4, LLC on July 25, 2019 to lease 114,500 square feet of space in Irving, Texas. As part of the lease agreement, the Company delivered an unconditional, irrevocable letter of credit for $3.4 million from a nationally recognized bank. The Company obtained this letter of credit and placed $3.4 million in a security deposit account. As of September 30, 2025 and December 31, 2024, amounts outstanding are $2.1 million and $2.7 million, respectively, and are included within cash, cash equivalents, and restricted cash and other assets on the condensed consolidated balance sheets.

The remaining restricted cash amounts are not material individually.

The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported within the condensed consolidated balance sheet that sum to the total of the amounts shown in the condensed consolidated statements of cash flows. Restricted cash is presented within cash, cash equivalents, and restricted cash and other assets on the condensed consolidated balance sheets.

	Condensed consolidated balance sheet line item	As of September 30, 2025	As of December 31, 2024
		(amounts in thousands)	
Cash and cash equivalents	Cash, cash equivalents, and restricted cash	$ 753,221	$ 63,950
Restricted cash - short-term	Cash, cash equivalents, and restricted cash	1,518	1,492
Restricted cash - long-term	Other assets	2,243	2,586
Total		$ 756,982	$ 68,028

Note 5. Income Taxes

The Company is subject to tax liabilities imposed by multiple jurisdictions. The Company determines our best estimate of the annual effective tax rate at each interim period using expected annual pre-tax earnings, statutory tax rates, and available tax planning opportunities. Certain significant or unusual items are separately recognized in the quarter in which they occur, which can cause variability in the effective tax rate from quarter to quarter. The Company recognizes interest and penalties related to uncertain tax positions, if any, as an income tax expense. The effective tax rate on income for the nine months ended September 30, 2025 and 2024 is shown in the table below. For the nine

months ended September 30, 2025 and 2024, the tax rates differed from the U.S. federal statutory rate of 21.0% primarily due to the impact of net operating losses and valuation allowances.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
	(amounts in thousands)			
Income (loss) before provision for income taxes	$ 24,325	$ (67,729)	$ (150,045)	$ (244,943)
Provision for income taxes	—	—	—	—
Effective tax rate	— %	— %	— %	— %

The Company is subject to taxation in the United States and various states and foreign jurisdictions. As of September 30, 2025, all loss years remain open to examination by the taxing authorities.

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for temporary differences between the financial reporting bases and tax bases of assets and liabilities based on enacted tax rates expected to be in effect when such amounts are realized or settled. However, deferred tax assets are recognized only to the extent that it is more likely than not that they will be realized based upon consideration of available evidence, including future reversals of existing taxable temporary differences, future projected taxable income, the length of the tax asset carryforward periods and tax planning strategies. The effects of remeasurement of deferred tax assets and liabilities resulting from changes in tax rates are recognized in income in the period of enactment.

On July 4, 2025, H.R. 1, known as the One Big Beautiful Bill Act (the "OBBBA"), was signed into law. The OBBBA includes a broad range of tax reform provisions, including extending and modifying certain key provisions from the 2017 Tax Cuts & Jobs Act (both domestic and international). The Company is currently evaluating the potential impacts of the OBBBA on its consolidated financial statements.

Note 6. Redeemable Convertible Preferred Stock

As of September 30, 2025, there were no shares of redeemable convertible preferred stock outstanding.

On April 1, 2025, the Company entered into a preferred stock purchase agreement with certain investors pursuant to which it issued a total of 12,345,674 and 4,657,401 shares of Series E Preferred Stock and Series F Preferred Stock, respectively, at $8.10 per share for gross proceeds of approximately $137.7 million. Allocated issuance costs paid in connection with the Series E Preferred Stock and Series F Preferred Stock were approximately $6.8 million.

The Company has previously issued shares of Series A, Series B, Series C, and Series D convertible preferred stocks. Upon the closing of the IPO on June 20, 2025, all outstanding shares of the Company's redeemable convertible preferred stock, including Series E and F, converted into an aggregate of 211,378,638 shares of common stock.

The following table summarizes the redeemable convertible preferred stock outstanding immediately prior to their conversion into common stock (excluding the 2018 and 2020 warrants that, prior to our IPO, were exercisable for Series C convertible preferred stock), and the rights and preferences of the Company's respective series preceding the Company's IPO in June 2025:

(amounts in thousands, except share and per share amounts)	As of June 20, 2025				
	Shares Authorized	Shares Issued and Outstanding	Original Issue Price Per Share	Aggregate Liquidation Preference	Net Carrying Value
Series A Preferred Stock	490,000,000	485,795,293	$ 0.61	$ 296,335	$ 709,261
Series B Preferred Stock	30,000,000	29,629,630	$ 0.54	16,000	42,963
Series C Preferred Stock	142,000,000	116,200,835	$ 2.76	415,616	415,616
Series D Preferred Stock	102,600,000	102,516,283	$ 8.10	1,078,273	1,078,273
Series E Preferred Stock	12,345,678	12,345,674	$ 8.10	101,786	145,412
Series F Preferred Stock	10,493,827	4,657,401	$ 8.10	38,399	54,857
Total redeemable convertible preferred stock	787,439,505	751,145,116		$ 1,946,409	$ 2,446,382

As of December 31, 2024, redeemable convertible preferred stock consisted of the following:

(amounts in thousands, except share and per share amounts)	As of December 31, 2024				
	Shares Authorized	Shares Issued and Outstanding	Original Issue Price Per Share	Aggregate Liquidation Preference	Net Carrying Value
Series A Preferred Stock	490,000,000	485,795,293	$ 0.61	$ 296,335	$ 709,261
Series B Preferred Stock	30,000,000	29,629,630	$ 0.54	16,000	42,963
Series C Preferred Stock	142,000,000	116,200,835	$ 2.76	408,715	408,715
Series D Preferred Stock	102,600,000	102,516,283	$ 8.10	1,060,712	1,060,712
Total redeemable convertible preferred stock	764,600,000	734,142,041		$ 1,781,762	$ 2,221,651

The redeemable convertible preferred stock is classified as mezzanine equity pursuant to the guidance in ASC 480. The rights, preferences, and privileges of the redeemable convertible preferred stock were as follows:

Voting Rights

On any matter presented to the shareholders of the Company for their action or consideration at any meeting of shareholders of the Company (or by written consent of shareholders in lieu of meeting), each holder of outstanding shares of preferred stock will be entitled to cast the number of votes equal to the number of whole shares of common stock into which the shares of preferred stock held by such holder are convertible as of the record date for determining shareholders entitled to vote on such matter.

Dividends

All classes of preferred stock are entitled to receive dividends out of any assets legally available only when, as, and if declared by the Company's board of directors, prior to and in preference to any declaration or payment of any dividend on the common stock.

Liquidation Preference

In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company, the holders of shares of Series C, Series D and Series E preferred stock then outstanding will be entitled to be paid out of the assets of the Company available for distribution to its shareholders at an amount per share equal to the greater of (i) the Series C, Series D and Series E original issue price, plus (A) any dividends declared but unpaid thereon and (B) a 7.0% cumulative accruing dividend, compounding annually from the date of issuance of such share of Series C, Series D and Series E preferred stock, (ii) the amount that the holder of a share of Series C, Series D and Series E preferred stock would have received upon conversion to common stock, or (iii) solely with respect to the Series D preferred stock, 1.2 times the Series D original issue price.

The Series F Preferred Stock then outstanding will then be entitled to be paid out of the assets of the Company available for distribution to its shareholders at an amount per share equal to the greater of (i) the Series F Preferred Stock original issue price, plus (A) any dividends declared but unpaid thereon and (B) a 8.0% cumulative accruing dividend, compounding annually from the date of issuance of such share of Series F Preferred Stock, (ii) 1.5 times the Series F Preferred Stock original issue price, or (iii) the amount that the holder of a share of Series F Preferred Stock would have received upon conversion to common stock.

The Series A and Series B preferred stock are then paid on a pro rata, pari passu basis an amount equal to the greater of (i) the respective original issue price plus any dividends declared but unpaid thereon, and (ii) the amount that the holder of a share of Series A or Series B preferred stock, respectively, would receive upon conversion to common stock. The remaining proceeds will be distributed to the holders of common stock.

Conversion Rights

The holders of the Company's Series A, Series B, Series C, Series D, Series E and Series F preferred stock have the right to convert their shares into a number of fully paid and nonassessable shares of common stock as determined by dividing the respective Series A, Series B, Series C, Series D, Series E and Series F preferred stock original issue price by the conversion price in effect at the time. The initial conversion price of the Series A, Series B, Series C, Series D, Series E and Series F preferred stock was $0.61, $0.54, $2.76, $8.10, $8.10, and $8.10, respectively, and is subject to adjustment in accordance with anti-dilution provisions provided for in the Company's Certificate of Formation. In connection with and shortly before the closing of the Pre-IPO Financing, the Company amended and restated its Certificate of Formation. Under this amended and restated Certificate of Formation, and solely for purposes of calculating the conversion of the Series C preferred stock in connection with an initial public offering, both the original issue price and the initial conversion price of the Series C preferred stock were revised from $2.76 to $4.58.

Upon the closing of the IPO, the Series E and Series F Preferred Stock will convert into common stock at a price equal to 70% of the initial public offering price per share. This legal-form conversion upon an initial public offering effectively functions as a share-settled redemption provision for accounting purposes and is accounted for as a bifurcated derivative liability in accordance with ASC 815.

As a result of the IPO, the aforementioned conversion price adjustment for Series D preferred stock was triggered due to the IPO price being less than 1.11111 times the then-current conversion price. Consequently, the Company recorded a deemed dividend, which increased net loss attributable to common shareholders by $384.4 million. The deemed dividend equals the fair value of incremental shares of common stock resulting the triggering of this feature.

Redemption Rights

At any time on or after March 2026 with respect to our Series C preferred stock, and May 2026 in respect of our Series D and Series E preferred stock, upon written notice from the applicable shareholders, the Series C, Series D and Series E shares shall be redeemed by the Company at a price per share equal to the greater of (i) the original issue price plus (a) all declared by unpaid dividends thereon and (b) a 7.0% cumulative accruing dividend, compounding annually, or (ii) the fair market value as determined by an independent appraiser.

Anti-dilution

Subject to certain exceptions, the conversion price of the Series A, Series B, Series D, Series E and Series F preferred stock is subject to broad-based weighted average adjustment to prevent dilution in the event that the Company issues additional shares at a purchase price less than the then-applicable conversion price. Subject to certain exceptions, in the event the Company sells additional shares of stock at a price per share less than the Series C original issue price, the conversion price of the Series C preferred stock is adjusted to the lower price that the Company sells shares in such offering. In the event the Company sells shares in an initial public offering for less than 1.11111 times the applicable Series C conversion price, then the Series C conversion price will be reduced (but never increased), concurrently with such issuance to 90.0% of the purchase price in such initial public offering. In the event the Company sells shares in an initial public offering for less than 110.0% of the applicable Series D conversion price, then the Series D conversion price will be reduced (but never increased), concurrently with such issuance to 90.0% of the purchase price in such initial public offering.

Note 7. Shareholders' Equity and Equity Compensation

Preferred Stock

In connection with the IPO, the Company's amended and restated certificate of formation became effective, which authorized the issuance of 100,000,000 shares of preferred stock with a par value of $0.001 per share. As of September 30, 2025, there were no shares of preferred stock issued and outstanding.

Common Stock

As of September 30, 2025 and December 31, 2024, 2,800,000,000 and 1,150,000,000 shares of common stock with a $0.001 par value were authorized, respectively. There were 282,103,259 and 35,842,319 shares outstanding at September 30, 2025 and December 31, 2024, respectively.

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's shareholders. Common shareholders are entitled to receive dividends if and when declared by the Company's board of directors, subject to the preferential dividend rights of any preferred stock then outstanding and compliance with our contractual obligations. No dividends have been declared or paid by the Company since its inception.

Treasury Stock

During the nine months ended September 30, 2025, the Company repurchased 1,438,138 shares of common stock for an amount of $16.6 million, mainly associated with previously early-exercised options. Refer to below under "Option Activity — Modifications to Stock Options" for further details. No common shares were repurchased during the year ended December 31, 2024. Repurchased common stock is shown on the condensed consolidated balance sheets and condensed consolidated statements of redeemable convertible preferred stock and shareholders' deficit as treasury stock. The Company had 1,620,638 and 182,500 shares of treasury stock as of September 30, 2025 and December 31, 2024, respectively. These shares have not been retired. The Company has not issued any shares of treasury stock as of September 30, 2025 and December 31, 2024.

2020 Incentive Plan

Pursuant to the 2020 Incentive Plan (the "2020 Plan"), the Company may grant awards of options, restricted awards, performance awards or share appreciation rights to employees, consultants, and directors of the Company. A total of 22,906,854 shares of common stock are reserved for issuance upon the exercise of all awards granted or available to be granted under the 2020 Plan as of September 30, 2025. In June 2025, in connection with the IPO and the adoption of the 2025 Plan (as defined below), the Company will not make any additional grants under the 2020 Plan. Any outstanding awards granted under the 2020 Plan remain subject to the terms of the 2020 Plan, and any shares underlying outstanding awards under the 2020 Plan that expire or are repurchased, forfeited, canceled, or withheld will become available for issuance under the 2025 Plan.

To the extent permitted by applicable laws or any exchange rule, any shares of common stock issued under this Plan that are issued (a) in connection with the Company's acquisition of an unaffiliated business entity, (b) to the employees of such entity, and (c) in substitution of equity incentive awards previously issued to such employees by such entity shall not reduce the number of shares of common stock available for issuance under the Plan.

2025 Incentive Plan

Effective May 23, 2025, the Company's Board of Directors adopted, and the shareholders approved, the 2025 Incentive Plan (the "2025 Plan"). The 2025 Plan provides for the grant of incentive stock options ("ISOs"), nonstatutory stock options ("NSOs"), share appreciation rights, restricted awards, performance awards, and other awards. As of September 30, 2025, a total of 4,132,565 shares of common stock were reserved for issuance in settlement of awards granted under the 2025 Plan. The material terms of the 2025 Plan are substantially similar to the 2020 Plan, except with respect to the number of authorized shares, which initially equaled 15,125,002 shares, plus the number of shares that would return to the share reserve of the 2020 Plan following the pricing of the Company's initial public offering.

The 2025 Plan's share reserve will increase on January 1 of each calendar year during the term of the 2025 Plan, beginning in 2026, by a number of shares as determined by the administrator of the 2025 Plan and in consultation with the Company, provided, that such increase (if any) will be no greater than the amount by which (y) 4% of the aggregate number of outstanding shares of our common stock as of the last day of the immediately preceding fiscal year exceeds (z)

the aggregate number of shares remaining available for grant under the 2025 Plan on the last day of the immediately preceding fiscal year.

Employee Stock Purchase Plan

The Company's Board of Directors has adopted, and the shareholders approved, the 2025 Employee Stock Purchase Plan (the "ESPP"), which became effective in connection with the IPO. The ESPP enables eligible employees to purchase shares of the Company's common stock with payroll deductions. A total of 2,571,250 shares of the Company's common stock were initially reserved for issuance under the ESPP.

The number of shares reserved for issuance and sale under the ESPP will increase automatically on January 1 of each calendar year during the term of this Plan beginning in 2026, by a number of Shares equal to 1% of the Common Stock outstanding on the last day of the immediately preceding fiscal year, unless the ESPP administrator should decide to increase the number of shares available under the ESPP by a lesser amount.

The purchase price designated by the ESPP administrator will be no less than the lower of 85% of the closing trading price per share of our common stock on the first trading date of an offering period in which a participant is enrolled or 85% of the closing trading price per share on the purchase date, which will occur on the last trading day of each purchase period within an offering period.

The initial enrollment and offering periods have not begun as of September 30, 2025.

Option Activity

Under the Plan, the Company has granted incentive stock options and non-qualified stock options to its employees and other service providers (non-employees). Most of the Company's stock options vest incrementally over five years, subject to the grantee's continuous employment with the Company ("time-vesting options"). The Company recognizes compensation cost on a straight-line basis over the requisite service period for its time-vesting options. In addition to its time-vesting options, the Company has also granted stock options to certain non-employees for which vesting is tied to the grantee's performance ("performance-vesting options"). The Company evaluates whether it is probable that the performance metric will be achieved for its performance-vesting options and recognizes compensation cost on a straight-line basis over the implied service period if achievement of the performance metric is deemed probable. No option shall be exercisable after the expiration of 10 years from the date it was granted. The exercise price of each option shall be not less than 100.0% of the fair market value of the common stock subject to the option on the date the option is granted.

The following tables summarize the Company's stock option activity during the nine months ended September 30, 2025:

	Options Outstanding			
	Number of Options	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contract Term (in years)	Aggregate Intrinsic Value (in thousands)
Total outstanding as of December 31, 2024:	21,770,225	$ 9.06	5.40	$ 226,117
Granted	3,085,295	18.79		
Exercised	(1,287,294)	6.13		
Forfeited or expired	(897,662)	13.49		
Total outstanding as of September 30, 2025	22,670,564	$ 10.38	5.21	$ 450,463
Total exercisable as of September 30, 2025	16,656,509	$ 7.74	4.21	$ 374,980
Total vested or expected to vest as of September 30, 2025	21,841,290	$ 10.09	5.10	$ 440,333

Aggregate intrinsic value represents the difference between the estimated fair value of the underlying common stock and the exercise price of outstanding, in-the-money options.

The total intrinsic value of options exercised was $8.7 million and $1.1 million during the three months ended September 30, 2025 and 2024, respectively, and was $13.5 million and $2.6 million during the nine months ended September 30, 2025 and 2024, respectively. As of September 30, 2025, there was approximately $58.6 million of total unrecognized stock-based compensation cost related to the unvested options under the Plan, which is expected to be recognized over a weighted-average period of 3.09 years.

Modification to stock options

On November 9, 2021 and February 23, 2022, the Company granted stock options to certain executives that are exercisable upon vesting for 331,250 shares and 2,000,000 shares of the Company's common stock, respectively (the "Prior Stock Options"). The Prior Stock Options vested over five years. On August 11, 2022, the Company's Compensation Committee approved a modification to the Prior Stock Options, which was communicated to holders of the Prior Stock Options on September 1, 2022. The modification reduced the exercise price to $16.20 and modified the vesting conditions such that 20.0% vest upon grant, while the remainder vest over the following four years. The total number of grantees affected by this modification was twelve. The modification was not mandatory, but rather could be elected by holders of the Prior Stock Options on an individual holder basis. If the holder elected to participate, the holder's Prior Stock Options were immediately canceled, and the Company issued the holder an equivalent number of new stock options in exchange (the "New Stock Options") which could be early exercised prior to vesting. All of the holders elected to participate in the modification and exchanged their Prior Stock Options for New Stock Options. In addition, as an alternative to paying cash, holders of the New Stock Options that elected to exercise their options were able to pay for the exercise price by executing a full recourse promissory note with the Company that is secured by the holder's restricted shares that are issued upon early exercise. Five grantees elected to early exercise 1,530,000 options utilizing the promissory note.

The principal of each note was equal to the exercise price of the New Stock Options. Interest on the unpaid balance compounded annually and accrued at a fixed rate per annum equal to the mid-term applicable federal rate in effect on the issuance of the note. The maturity date of the notes was the earlier of (1) December 31, 2030 or (2) the occurrence of a change in control event, unless an acceleration event occurs sooner. An acceleration event would generally occur if required to ensure compliance with Section 402 of the Sarbanes-Oxley Act of 2022, the termination of the holder's employment, the insolvency of the holder or the breach of any warranty of the holder. The holder may elect to prepay the outstanding principal and accrued interest balance of the promissory note at any time without penalty.

In addition to the outstanding balance of the note becoming due and payable immediately, upon the occurrence of an acceleration event, if the holder defaults on payment of the note, then interest would accrue at the maximum rate permitted by applicable law. The Company would have full recourse against the holder for failure to pay the note as and when due. Such promissory notes were secured by the restricted shares issued to the holder that were underlying the note. If the note is not repaid upon an event of default or acceleration event, the Company had the right to repurchase the restricted shares issued upon the exercise of the note for fair market value, which proceeds will apply to repayment of the note (with any remaining balance remaining due).

The Company accounted for the modification as a Type I (Probable to Probable) modification under ASC 718 that does not change the classification of the award (i.e., the New Stock Options continue to be classified within equity). The Company calculated the fair value of the Prior Stock Options and New Stock Options immediately prior to and after the modification using the Black-Scholes option pricing model. The incremental fair value was added to the original unrecognized compensation cost to arrive at the new unrecognized compensation cost, to be recognized over the remaining requisite service period.

Unvested stock received from early exercises of the New Stock Options are subject to a right of repurchase at the lesser of (i) original issuance price or (ii) then-current fair market value in the event of the employee's termination, either voluntary, or involuntary. The Company's repurchase right with respect to these shares typically lapse over four years as the shares become vested. Early exercises of stock options are not deemed to be substantive exercises for accounting purposes and accordingly, consideration received for exercises of unvested stock options is initially recorded as a liability and subsequently reclassified into shareholders' deficit as the related shares vest. As of September 30, 2025 and December 31, 2024, 23,446 and 662,000 shares from options exercised to date were subject to repurchase at a price of $16.20 per share. Of the amount subject to repurchase as of September 30, 2025 and December 31, 2024, $0.3 million and $5.0 million was recorded within other accrued expenses and current liabilities, respectively, and $0.1 million and $5.8 million was recorded within other long-term liabilities on the condensed consolidated balance sheets, respectively. In addition, as the early exercise was performed via issuance of a promissory note, a corresponding debt amount, plus related interest income was recorded as contra-equity. The total amount presented as contra-equity as of December 31,

2024 was $26.5 million, which includes interest income and the impact from exercises of both the vested portion of the New Stock Options and early exercises.

On March 3, 2025, the Company repurchased 1,429,213 common stock shares issued upon early exercise of stock options at $18.60 per share and proceeds were used to pay off the promissory notes and accrued interests. Repurchased common stock shares included 810,816 and 618,397 common stock shares, respectively, that were for options vested and unvested at the time of the repurchase, respectively. On the same day, the Company granted 1,530,000 new stock options to the same employees. New options were issued at an exercise price of $18.60 per share, have the same vesting status as cancelled options and are not early exercisable. The other terms of the new options are substantially the same as the original options.

The Company accounted for the repurchase of the shares and grant of the new options as a Type I (Probable to Probable) modification under ASC 718. The Company calculated the fair value of the original options and new options immediately prior to and after the modification using the Black-Scholes option pricing model based on the following assumptions: risk-free interest rate of 3.93% - 3.99%; dividend yield of 0.00%; stock price volatility of 68.96% - 69.48%; and an expected life of 5.0 - 5.3 years. The total incremental fair value was $15.1 million, of which $8.6 million corresponding to the vested options was immediately recognized as compensation expense, with the remaining $6.5 million and the original unrecognized compensation cost of $5.7 million being recognized over the remaining requisite service period.

Restricted Awards Activity

The Company grants restricted stock units that will be settled in shares of the Company's common stock upon vesting to its employees, consultants and non-employee directors.

Vesting of the restricted stock units granted prior to the IPO was generally contingent upon the Company completing either an initial public offering of its common stock or a change of control. In connection with the IPO, the Company settled an aggregate of 1,048,250 fully vested RSUs (“IPO Settled RSUs”) in August 2025. The Company withheld 415,389 shares of common stock issuable upon settlement of the IPO Settled RSUs and recorded a tax withholding liability of $12.4 million, all of which were subsequently remitted as taxes paid. Vesting of restricted stock units granted after the IPO generally occurs incrementally over four years, subject to the grantee's continuous service with the Company.

The following table summarizes the Company's restricted stock unit activity for the nine months ended September 30, 2025:

	Number of Restricted Stock Units	Weighted Average Grant Date Fair Value
Unvested as of December 31, 2024	762,500	$ 18.19
Granted	4,743,247	$ 20.94
Vested	(1,048,250)	$ 18.23
Cancelled/forfeited	(88,642)	$ 22.13
Unvested as of September 30, 2025	4,368,855	$ 21.09

As of September 30, 2025, there was approximately $85.3 million of total unrecognized stock-based compensation cost related to unvested RSUs, which is expected to be recognized over a weighted-average period of 3.52 years.

Stock-Based Compensation Expense

The Company recorded stock-based compensation expense in the condensed consolidated statements of operations and comprehensive loss as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
	(amounts in thousands)			
Cost of services - Molecular profiling services	$ 1,104	$ 411	$ 2,452	$ 1,237
Cost of services - Pharma research and development services	17	3	20	6
Selling and marketing expense	3,322	1,092	6,554	3,177
General and administrative expense	6,410	2,148	39,438	6,147
Research and development expense	2,802	1,069	8,175	3,099
Total	$ 13,655	$ 4,723	$ 56,639	$ 13,666

There was no tax benefit associated with the above stock-based compensation expense.

Valuation of Stock-Based Awards

The Company records stock-based compensation expense for stock-based awards based on the estimated fair value of the awards on the date of the grant.

The Company estimates the fair value of stock options using a Black-Scholes option pricing model. Prior to the IPO, the absence of a public market for the Company's common stock required the Company's Board of Directors to estimate the fair value of its common stock for purposes of granting options and for determining stock-based compensation expense by considering several objective and subjective factors, including contemporaneous third-party valuations, actual and forecasted operating and financial results, market conditions and performance of comparable publicly traded companies, developments and milestones in the Company, the rights and preferences of common and convertible preferred stock, transactions involving the Company's common stock, and assumptions for a discount for lack of marketability. The fair value of the Company's common stock was determined in accordance with the applicable elements of the American Institute of Certified Public Accountants Accounting and Valuations Guide, *Valuation of Privately Held Company Equity Securities Issued as Compensation*.

The key assumptions used in determining the fair value of options granted and a summary of the methodology applied to develop each assumption are as follows:

	Three Months Ended September 30,	Nine Months Ended September 30,	
	2024	2025	2024
Expected volatility	68.2% - 68.4%	68.3% - 69.5%	62.5% - 68.4%
Risk-free interest rate	3.7%	3.9% - 4.2%	3.7% - 4.6%
Expected term (years)	6.34 - 6.57	5.00 - 6.55	5.97 - 6.57
Expected dividend rate	—%	—%	—%
Expected forfeiture rate	8.4%	0.0% - 8.5%	8.4% - 8.5%

For the three months ended September 30, 2025, there were no options granted.

Expected volatility. This is a measure of the amount by which the share price has fluctuated or is expected to fluctuate. An increase in the expected price volatility will increase the fair value of the option granted and the related compensation expense. As the Company was not publicly traded prior to June 2025, the expected price volatility for the Company's options was determined by using an average of historical volatilities of selected industry peers deemed to be comparable to the business corresponding to the expected term of the awards.

Risk-free interest rate. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant for U.S. Treasury notes with maturities corresponding to the expected term of the awards.

Expected term. This is the period of time over which the options granted are expected to remain outstanding and is based on the Company's estimate, taking into consideration vesting term, contractual term and historical actual lives. Options granted have a maximum term of ten years. An increase in the expected life will increase the fair value of the option granted and the related compensation expense. Due to the lack of historical share option exercise data, the Company utilizes the simplified method for determining the expected term.

Dividend rate. The Company has not made any dividend payments, nor does it have plans to pay dividends in the foreseeable future. Therefore, an expected dividend yield of zero is utilized.

Forfeitures. Forfeitures are estimated at the time of grant and reduce compensation expense ratably over the vesting period. This estimate is adjusted periodically based on the extent to which actual forfeitures differ, or are expected to differ, from the previous estimate.

Note 8. Long-Term Debt

The carrying value of debt presented within current portion of notes payable and long-term indebtedness, net of debt discounts on the condensed consolidated balance sheets as of September 30, 2025 and December 31, 2024 includes the following components:

	As of September 30, 2025	As of December 31, 2024
	(amounts in thousands)	
Term loan Initial Draw - January 18, 2023	$ 200,000	$ 200,000
Exit fee on term loan - January 18, 2023	2,000	2,000
Term loan Subsequent Draw - March 5, 2024	200,000	200,000
Exit fee on term loan - March 5, 2024	2,000	2,000
Less: Amortized debt discounts and financing costs [1]	(28,120)	(30,863)
Net debt	$ 375,880	$ 373,137
Compound bifurcated derivative liability	$ —	$ 6,058

[1] Includes debt discounts of $28.3 million associated with the initial carrying value of compound bifurcated derivative liability.

Maturities of the Company's debt are expected to be as follows as of September 30, 2025:

	Amount
Years Ending December 31,	
Remainder of 2025	$ —
2026	—
2027	—
2028	400,000
2029	—

Term Loan

On January 18, 2023, the Company entered into the New Term Loan Agreement with OrbiMed Royalty & Credit Opportunities III, LP, OrbiMed Royalty & Credit Opportunities IV, LP (collectively, "OrbiMed"), and Braidwell Transaction Holdings LLC ("Braidwell", and collectively with OrbiMed, the "New Term Loan Lenders"). Pursuant to the New Term Loan Agreement, the Company issued senior, secured promissory notes by which the New Term Loan Lenders agree to lend the Company up to an aggregate principal amount of $400.0 million (the "2023 Term Loan"), $200.0 million of which was

received by the Company upon issuance (the "Initial Draw"), and the remaining $200.0 million was received by the Company in March 2024 (the "Delayed Draw").

Until the earlier of December 31, 2024 or the date on which the 2023 Term Loan amount was fully drawn, which occurred on March 5, 2024, the undrawn balance of the New Term Loan Commitment was subject to a fee of 0.5% per annum. The outstanding principal amount of the 2023 Term Loan is due and payable on January 18, 2028. If an event of default occurs and is continuing, the New Term Loan Lenders may declare all amounts outstanding under the New Term Loan Agreement to be immediately due and payable. A final payment exit fee equal to 1.0% of the amount funded under the New Term Loan Agreement is due upon prepayment or maturity. Amounts borrowed pursuant to the New Term Loan Agreement may be prepaid at any time. Upon prepayment, the Company is subject to a prepayment penalty based on the timing of repayment.

The 2023 Term Loan bears interest at a rate per annum equal to a fixed margin of 6.5% plus the greater of (a) forward-looking three-month secured overnight financing rate ("SOFR") and (b) 2.5%. In the event of default, the fixed margin shall increase by 3.0% per annum. As of September 30, 2025, the interest rate was 10.8%. Regular quarterly payments are interest-only for the 60-month term of the New Term Loan Agreement, with the principal due at maturity. The effective interest rate for the Initial Draw of the 2023 Term Loan is 17.0%, and the effective interest rate for the Delayed Draw of the 2023 Term Loan is 12.0%.

The Company's obligations under the New Term Loan Agreement are secured by a first lien security interest in substantially all of the assets of the Company and its subsidiaries. The New Term Loan Agreement contains certain customary representations and warranties, affirmative and negative covenants, financial covenants, and events of default applicable to the Company and its subsidiaries. Additional covenants include those restricting dispositions, fundamental changes to its business, mergers or acquisitions, indebtedness, encumbrances, distributions, investments, transactions with affiliates and subordinated debt. At September 30, 2025, the Company is in compliance with all covenants.

On April 1, 2025, the Company entered into an amendment of the 2023 Term Loan agreement. The amendment allowed for various consents from the lenders of the 2023 Term Loan as it relates to the 2025 Convertible Note, issued as part of the Pre-IPO financing. As part of the amendment, the Company paid an amendment fee of 1%, or $4.0 million. The Company evaluated the transaction and accounted for the amendment as a debt modification.

The Company identified multiple embedded derivatives that require bifurcation from the 2023 Term Loan. They are separately accounted for in the condensed consolidated financial statements as one compound derivative liability. Those embedded features include various contingent prepayment and compensatory payment features as well as interest rate increases upon an event of default.

Interest Expense

The components of interest expense associated with the Company's long-term indebtedness and the 2025 Convertible Note, excluding finance leases, are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
	(amounts in thousands)			
Debt discount amortization	$ 2,463	$ 1,827	$ 12,163	$ 5,148
Interest expense	11,036	11,963	33,311	31,587
Interest expense on long-term indebtedness, excluding finance leases	$ 13,499	$ 13,790	$ 45,474	$ 36,735

2018 and 2020 Warrant Liability

On September 21, 2018, the Company entered into a secured term loan agreement (the "Original Term Loan Agreement") with Sixth Street Specialty Lending, Inc. and Barnett Debt Holdings, LLC. As part of the Original Term Loan Agreement, the Company issued a warrant to purchase 13,694,623 shares of Series C preferred stock (the "2018 Warrants"). In connection with the amendment to the Original Term Loan Agreement in 2020, the Company issued an additional warrant to purchase 11,399,814 shares of Series C preferred stock (the "2020 Warrants") and amended the 2018 Warrants. Furthermore, these amendments also permitted the exercise of both the 2018 Warrants and 2020

Warrants into Series C preferred stock or common stock at the option of the holder. The 2018 Warrants are exercisable into Series C preferred stock at a price of $1.61 and into common stock at a price of $6.44. The 2020 Warrants are exercisable into Series C preferred stock at a price of $1.93 and into common stock at a price of $7.73. As a result of the amendment to permit exercise of the warrants into redeemable preferred stock, the warrants are classified as a liability pursuant to the guidance in ASC 480. Therefore, the warrants were reported at fair value within warrant liabilities on the condensed consolidated balance sheets, with changes in fair value reported within changes in fair value of financial instruments on the condensed consolidated statements of operations and comprehensive loss.

As discussed in Note 2, the warrants were reclassified from liability to equity upon the IPO. The difference between the fair value of the warrants immediately prior to the reclassification and its prior fair value was recorded in the consolidated statement of operations and comprehensive loss as changes in fair value of financial instruments. The fair value immediately prior to the reclassification was $131.7 million, and is based on the total number of common stock issued upon exercise and conversion, multiplied by the public offering price of $21.00 per share.

For the nine months ended September 30, 2024, the Company recorded $5.1 million in changes in fair value of financial instruments, associated with the fair value changes of the 2018 and 2020 warrants.

2025 Convertible Notes

On April 1, 2025, the Company issued 2025 Convertible Notes to certain investors in aggregate principal amount of $30.0 million. The 2025 Convertible Notes were scheduled to mature on January 1, 2026, accrued interest at a rate of 8% per annum, and, upon the closing of the IPO, converted at a conversion price equal to 70% of the initial public offering price per share, or into 2,076,596 shares of the Company's common stock (inclusive of accrued interest), based on the initial public offering price of $21.00 per share. This legal-form conversion upon an initial public offering effectively functions as a share-settled redemption provision for accounting purposes and is accounted for as a bifurcated derivative liability in accordance with ASC 815. The 2025 Convertibles Notes were classified as a liability pursuant to the guidance in ASC 470 as they represented legal-form debt with a stated maturity and an obligation for the issuer to repay both principal and interest.

Upon the closing of the initial public offering, the 2025 Convertible Notes converted into common stock at a price equal to 70% of the initial public offering price per share. A loss on extinguishment of approximately $17.9 million was recognized, representing the excess of the fair value of the common stock issued over the combined carrying amount of the 2025 Convertible Notes and the related bifurcated derivative liability.

2025 Warrant Liability

On April 1, 2025, the Company also issued warrants to acquire shares of common stock to the holders of the 2025 Convertible Notes. These warrants were not initially exercisable for any shares of common stock, but such warrants became exercisable for a specified dollar value of shares on a monthly basis commencing on June 1, 2025 if the Company did not complete an initial public offering by such date. Additional warrants would have been issued each subsequent month that an initial public offering fails to occur based on a certain percentage. These warrants were classified as a liability pursuant to the guidance in ASC 480 as they represented a conditional obligation to issue a variable number of shares based on a fixed monetary amount known at inception. Therefore, these warrants were reported at fair value within warrant liabilities on the condensed consolidated balance sheets, with changes in fair value reported within changes in fair value of financial instruments on the condensed consolidated statements of operations and comprehensive loss. As discussed in Note 2, the 2025 warrants were net exercised into 784,231 shares of the Company's common stock connection with the IPO. The difference between the fair value of the warrants immediately prior to the IPO and its initial fair value was recorded in the consolidated statement of operations and comprehensive loss as changes in fair value of financial instruments. The fair value immediately prior to the IPO was $16.5 million, and was based on the total number of common stock issued upon exercise and conversion, multiplied by the public offering price of $21.00 per share. The initial allocated proceeds of the warrant was $10.3 million, which represents the fair value of the warrants on April 1, 2025.

Note 9. Commitments and Contingencies

Purchase Obligations

The Company enters into various supply agreements that contains purchase commitments. Most of the commitments are based on a binding forecast for an agreed-upon period, which is 12-month or less.

Corporate Liability and Insurance

The Company maintains professional liability, general liability, and other customary insurance on a claims-made basis in amounts deemed appropriate by the Company's management based upon historical claims and the nature and risks of the Company. The Company's business may subject the Company to litigation and liability for damages. The Company believes that current insurance protection is adequate for present business operations, but there can be no assurance that the Company will be able to maintain professional and general liability insurance coverage in the future or that such insurance coverage will be available on acceptable terms or adequate to cover any or all potential product or professional liability claims. A successful liability claim in excess of insurance coverage could have a material adverse effect on the Company.

Litigation

During the ordinary course of business, the Company has become and may in the future become subject to pending and threatened legal and regulatory actions and proceedings. While it is not feasible to predict or determine the ultimate outcome of these matters, the Company believes that none of its current legal proceedings are likely to have a material adverse effect on its financial position as of September 30, 2025 and December 31, 2024, nor its results of operations or cash flows for both the three months ended September 30, 2025 and 2024 and the nine months ended September 30, 2025 and 2024.

Note 10. Related Parties

The Company's officers and directors have ownership interests in certain vendors providing services to the Company. During the three months ended September 30, 2025 and 2024, the Company made payments to these entities for services and expenses for $0.6 million and $0.7 million, respectively. During the nine months ended September 30, 2025 and 2024, the Company made payments to these entities for services and expenses for $2.0 million and $1.5 million, respectively.

Additionally, during the three months ended September 30, 2025 and 2024, the Company recorded general and administrative expenses due to related parties of $0.7 million and $0.6 million, respectively. During the nine months ended September 30, 2025 and 2024, the Company recorded general and administrative expenses due to related parties of $1.9 million and $1.4 million, respectively.

Note 11. Net Income (Loss) Per Share Attributable to Common shareholders

The Company reports both basic net income (loss) per share, which is based on the weighted-average number of shares of common stock outstanding during the period without consideration for potential common stock equivalents, and diluted net income (loss) per share, which is based on the weighted-average number of common stock outstanding

and potentially dilutive shares outstanding during the period. The following table sets forth the computation of the basic and diluted net income (loss) per share attributable to common shareholders:

(amounts in thousands, except share and per share data)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Net income (loss)	$ 24,325	$ (67,729)	$ (150,045)	$ (244,943)
Deemed dividend from Series D redeemable convertible preferred stock	—	—	(384,436)	—
Adjustments of redeemable convertible preferred stock to redemption value	—	(24,661)	(85,433)	(71,368)
Net income (loss) attributable to common shareholders	$ 24,325	$ (92,390)	$ (619,914)	$ (316,311)
Denominator:				
Weighted-average shares - basic	282,099,073	35,643,589	128,447,673	35,442,927
Effect of dilutive securities:				
Dilutive awards and units	1,659,504	—	—	—
Dilutive options	13,453,261	—	—	—
Weighted-average shares - diluted	297,211,838	35,643,589	128,447,673	35,442,927
Net income (loss) per share attributable to common shareholders:				
Basic	$ 0.09	$ (2.59)	$ (4.83)	$ (8.92)
Diluted	$ 0.08	$ (2.59)	$ (4.83)	$ (8.92)

Potential dilutive securities include dilutive common stock from stock-based awards attributable to the assumed exercise of stock options and RSUs using the treasury stock method. Under the treasury stock method, potential common stock outstanding are not included in the computation of diluted net income per share if their effect is anti-dilutive.

The following common stock equivalents were excluded from the calculation of diluted net income (loss) per share attributable to common shareholders for the periods presented as they had an anti-dilutive effect:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Series A preferred stock	—	121,448,823	—	121,448,823
Series B preferred stock	—	7,407,408	—	7,407,408
Series C preferred stock	—	29,050,209	—	29,050,209
Series D preferred stock	—	25,629,071	—	25,629,071
Outstanding warrants	—	6,273,609	—	6,273,609
Unvested RSUs	74,786	695,625	4,368,855	695,625
Outstanding stock options	1,519,047	21,263,852	22,670,564	21,263,852
Unvested shares subject to repurchase	23,446	662,000	23,446	662,000
Total	1,617,279	212,430,597	27,062,865	212,430,597

Anti-dilutive potential shares from stock-based awards are excluded from the calculation of diluted earnings per share for all periods reported above because either their exercise price exceeded the average market price during the period or the stock-based awards were determined to be anti-dilutive based on applying the treasury stock method. Anti-dilutive potential shares from stock-based awards are excluded from the calculation of diluted earnings per share for the three months ended September 30, 2024 and the nine months ended September 30, 2025 and 2024 due to the net losses reported in those periods.

Note 12. Segment and Geographic Information

The Company operates as a single operating segment. An operating segment is defined as a component of an entity for which discrete financial information is available and regularly reviewed by the entity's chief operating decision maker ("CODM") in deciding how to allocate resources and in assessing performance. The Company's CODM, its Chairman and Chief Executive Officer, manages the Company's operations on a consolidated basis for the purposes of allocating resources, making operating decisions and evaluating financial performance.

Net loss as reported on the condensed consolidated statements of operations and comprehensive loss is used by the CODM to assess segment performance against management budgets and prior period operating results for the purpose of making results-driven decisions about organizational resource allocation.

Segment revenues are derived from molecular profiling, strategic data, and research services that are delivered to the Company's biopharmaceutical and clinical customers, who are predominantly located in the United States. The Company provides these services primarily by leveraging the Company's proprietary technologies and clinico-genomic database, which are core to the Company's operations and are deployed similarly across the service offerings.

The table below is a summary of the segment profit or loss, including significant segment expenses:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
	(amounts in thousands)			
Revenue:				
Molecular profiling services	$ 207,587	$ 93,803	$ 484,593	$ 254,692
Pharma research and development services	9,246	7,817	34,554	27,653
Revenue	216,833	101,620	519,147	282,345
Less:				
Cost of services - Molecular profiling services	66,980	54,810	193,195	167,134
Cost of services - Pharma research and development services	2,347	2,398	7,698	7,130
Selling and marketing expense	41,267	36,758	123,355	115,077
General and administrative expense	51,973	40,852	168,458	126,273
Research and development expense	21,624	27,644	69,739	86,807
Total costs and operating expenses	184,191	162,462	562,445	502,421
Income (Loss) from operations	32,642	(60,842)	(43,298)	(220,076)
Interest income	7,360	1,744	9,482	6,152
Interest expense	(13,507)	(13,799)	(45,497)	(36,763)
Changes in fair value of financial instruments	(2,081)	5,131	(52,285)	6,067
Other income (expense), net	(89)	37	(18,447)	(323)
Segment and consolidated net income (loss)	$ 24,325	$ (67,729)	$ (150,045)	$ (244,943)

The following table sets forth the Company's revenue by geographic areas based on the customer's location:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
	(amounts in thousands)			
United States	$ 213,550	$ 99,403	$ 510,161	$ 275,213
International	3,283	2,217	8,986	7,132
Total revenue	$ 216,833	$ 101,620	$ 519,147	$ 282,345

No single country outside of the United States accounted for more than 10.0% of total revenue during each of the three months ended September 30, 2025 and 2024, or the nine months ended September 30, 2025 and 2024. As of September 30, 2025 and December 31, 2024, approximately 99.0% of the Company's total assets are located in the United States.

Note 13. Employee Benefit Plan

The Company sponsors a 401(k) plan, and pursuant to its terms, eligible employees can elect to contribute to the 401(k) plan, subject to certain limitations, up to the lesser of the statutory maximum or 100.0% of eligible compensation on a pre-tax basis. For the three months ended September 30, 2025 and 2024, the Company contributed $1.7 million and $2.0 million, respectively, to match employee contributions as permitted by the plan. For the nine months ended September 30, 2025 and 2024, the Company contributed $6.5 million and $6.2 million, respectively, to match employee contributions as permitted by the plan. The Company pays the administrative costs for the plan.

Note 14. Subsequent Events

On October 20, 2025, the Company entered into a lease agreement with LMC-Papago Investment Company, LLC for approximately 38,640 rentable square feet of office space located on the 6th floor at 350 West Washington Street, Tempe, Arizona (the "Papago Gateway Center"). The lease has an initial term of ten years, with an option to extend for an additional five years. The lease commencement date is expected to occur upon delivery of the premises and substantial completion of tenant improvements, currently estimated to be in mid-2026, with rent payments commencing approximately six months thereafter. The Company expects that the lease will result in the recognition of a right-of-use asset and corresponding lease liability upon lease commencement in fiscal 2026.

There were no other significant subsequent events identified through the date that the condensed consolidated financial statements were issued, that could impact the financial statements.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and the related notes included in Item 1 of in this Quarterly Report. In addition to historical financial information, the following discussion and analysis contains forward-looking statements that involve risks, uncertainties, and assumptions. Our actual results and timing of selected events may differ materially from those anticipated in these forward-looking statements as a result of many factors, including those discussed under the section titled "Risk Factors" and elsewhere in this Quarterly Report. See the section titled "Special Note Regarding Forward-Looking Statements" elsewhere in this Quarterly Report. Our historical results are not necessarily indicative of the results that may be expected for any period in the future. Unless context requires otherwise, references to "we," "us," "our," "Caris," or "the Company" here refer to Caris Life Sciences, Inc. together with its wholly owned subsidiaries.

Overview

We are a leading, patient-centric, next-generation AI TechBio company and precision medicine pioneer. We develop and commercialize innovative solutions to transform healthcare through the use of comprehensive molecular information and AI/ML algorithms at scale. Our entire portfolio of precision medicine solutions is designed to benefit patients, with an initial focus on oncology, and serves the clinical, academic, and biopharma markets.

We founded Caris in 2008 with the belief and vision that combining a vast set of consistently generated molecular information with robust data-driven insights could realize the potential of precision medicine for patients. We have spent the last 17 years developing and building our portfolio of comprehensive, proprietary molecular profiling solutions and generating what we believe to be one of the largest and most comprehensive multi-modal clinico-genomic datasets in oncology based on the millions of tests we have run on over 959,000 cases. Our platform is purpose-built to leverage the convergence of next-generation sequencing ("NGS"), artificial intelligence ("AI") and machine learning ("ML") technologies, and high-performance computing. The power of our differentiated Caris platform has enabled us to develop the latest generation of advanced precision medicine diagnostic solutions designed to address the entire cancer care continuum, including early detection, minimal residual disease ("MRD") tracking, therapy selection, and treatment monitoring, as well as to create molecular signatures and discover and develop novel precision medicine therapeutics.

Our current commercial product portfolio consists of MI Profile, our tissue-based molecular profiling solution that has generated the majority of our revenue to date, and Caris Assure, our novel, universal blood-based molecular profiling solution that was broadly launched in the first quarter of 2024 for therapy selection. Our purpose-built, proprietary multi-omic profiling solutions capture and analyze molecular information from tissue and blood in a comprehensive manner. We believe this approach best positions us to provide actionable treatment pathways from targeted therapies to drive superior clinical outcomes for patients while also generating a rich dataset to power insights and innovation. Our molecular profiling solutions and the data generated by our multi-omic technology platform also provide value to our biopharma partners, such as Moderna, AbbVie, Xencor, and Merck KGaA, through partnerships that aim to increase the probability of technical and regulatory success of their therapeutic pipelines.

We believe that our early foresight to generate comprehensive data at scale over the past many years and build a robust, foundational infrastructure have uniquely positioned Caris to leverage the benefits of biological and technological advances to deliver transformative and advanced innovations in precision medicine and patient care into the future.

To our knowledge, we remain the only genomic profiling company to consistently utilize whole exome sequencing ("WES") and whole transcriptome sequencing ("WTS") as standard practice on every eligible patient sample. Our in-depth profiling of patient samples has led to the creation of what we believe to be one of the largest and most comprehensive multi-modal clinico-genomic datasets in oncology.

Our global annual clinical case volume has been growing rapidly, with year-over-year growth of 29% in 2022, 32% in 2023, 26% in 2024, and 23% through the third quarter of 2025. With our broad commercial launch of Caris Assure for therapy selection in the first quarter of 2024 and the FDA approval of MI Cancer Seek as a companion diagnostic in the fourth quarter of 2024 followed by the broad commercial launch of MI Cancer Seek in the first quarter of 2025 as the NGS component of MI Profile, we believe that increased profiling volumes will meaningfully contribute to our growth in 2025 and beyond.

Our Caris platform is designed to create a virtuous cycle that can enable continued innovation and improved impact for patients and physicians. We believe our comprehensive approach to profiling will continue to drive demand

for our genomic profiling capabilities, leading to further expansion of our clinico-genomic datasets, which provide additional valuable inputs to develop and enhance our solutions, with the ultimate goal of contributing to improved patient results. This continuous feedback loop enabled us to develop Caris Assure, which utilized genomic data generated by MI Profile to inform our blood-based bioinformatics algorithms, allowing us to detect previously unknown features and signals in the blood that provide advanced insights into disease development. We believe we will be able to further leverage this process to continue meaningful innovation in precision oncology as well as other chronic disease states, including cardiology, neurology, and metabolic conditions.

For the three months ended September 30, 2025 and 2024, we generated total revenue of $216.8 million and $101.6 million, respectively, and incurred net income (loss) of $24.3 million and $(67.7) million, respectively. For the nine months ended September 30, 2025 and 2024, we generated total revenue of $519.1 million and $282.3 million, respectively, and incurred net losses of $150.0 million and $244.9 million, respectively. Our Adjusted EBITDA was $51.2 million and $(45.6) million for the three months ended September 30, 2025 and 2024, respectively, and $31.7 million and $(166.6) million for the nine months ended September 30, 2025 and 2024. While we have achieved net profit for the three months ended September 30, 2025, we may incur net losses in the near future, and our expenses will increase as we continue to invest in developing new solutions, expand our organization, and increase our marketing efforts to continue to drive market adoption of our solutions. These investments, together with general and administrative expenses, have resulted in positive (negative) cash flows from operations of $38.4 million and $(206.3) million for the nine months ended September 30, 2025 and 2024, respectively. Our free cash flow was $27.2 million and $(212.4) million for the nine months ended September 30, 2025 and 2024, respectively. For additional information regarding Adjusted EBITDA and free cash flow, non-GAAP financial measures, see "—Non-GAAP Financial Measures." Additionally, as of September 30, 2025, we had cash, cash equivalents, restricted cash and marketable securities of $759.3 million, and the aggregate principal amount of debt outstanding under our existing term loan was $400.0 million. For additional information regarding our liquidity and capital resources, see "—Liquidity and Capital Resources."

On June 20, 2025, we completed our initial public offering ("IPO") of our common stock, in which the Company issued and sold 23,529,412 shares of its common stock at a price of $21.00 per share, which resulted in net proceeds of $459.5 million after deducting underwriting discounts and commissions and before deducting offering costs of $9.0 million. Additionally, on June 25, 2025, the underwriters exercised their full over-allotment option and purchased from the Company an additional 3,529,411 shares of common stock at the IPO price, which resulted in net proceeds to the Company of $68.9 million after deducting discounts and commissions.

Key Factors Affecting Our Performance

We believe that our operating performance and future success depend on a number of factors that present significant opportunities for us and may pose risks and challenges, including those discussed below and in the "Risk Factors" section of this Quarterly Report.

- ***Market acceptance and commercial success of our solutions.*** Our success and future growth will depend on maintaining and expanding market acceptance of our molecular profiling solutions along with commercial success of these solutions across existing and new customers. Our MI Profile and Caris Assure case volumes have continued to increase over time. Changes in our case volumes and the pricing of our solutions, however, are generally not impacted by the cancer type. For the three months ended September 30, 2025 and 2024, the number of clinical cases was 50,763 and 42,956, respectively. For the nine months ended September 30, 2025 and 2024, the number of clinical cases was 146,653 and 118,856, respectively. We commercially launched our MI Cancer Seek solution in January 2025 as the WES/WTS NGS component of MI Profile. We initiated the broad commercial launch of Caris Assure for therapy selection in the first quarter of 2024, and realizing the potential of Caris Assure across the cancer treatment continuum is a key component of our business strategy. The commercial success of Caris Assure will depend upon, among other things, additional clinical trials that demonstrate the effectiveness of Caris Assure, particularly for early detection, multi-cancer early detection ("MCED"), MRD tracking, and treatment monitoring, and the continued adoption of Caris Assure by patients, the medical community, and third-party payers. In addition, we expect that our ability to maintain and expand our sales, marketing, and distribution capabilities to support the increased adoption of our molecular profiling solutions will play a key factor in our success.
- ***Biopharma partners.*** Our revenue also depends on our ability to maintain and expand relationships with our biopharma partners and attract new biopharma partners. As we continue to develop these relationships, we expect to support a growing number of projects and continue to have opportunities to offer our platform to such customers for development and research services. For the three months ended September 30, 2025 and the

nine months ended September 30, 2025, our year-over-year growth in pharma research and development services revenue has been 18% and 25%, respectively.

- ***Development and introduction of new solutions.*** Our business success will also depend on our ability to develop and commercialize new solutions. We plan to continue to invest in the enhancement of our molecular profiling solutions, the development of new solutions to achieve meaningful innovation in precision oncology and other disease states, and the expansion of our clinico-genomic datasets to drive breakthrough science. We intend to expand the application of Caris Assure to early detection, MCED, MRD tracking, and treatment monitoring. Our ability to develop and commercialize new solutions and services could face many challenges that could impact our future performance and results of operations. Such challenges include, but are not limited to, obtaining regulatory approvals; completing certain clinical development activities, validation studies, and/or clinical trials; having guidelines or recommendations for healthcare providers, administrators, payers, and patient communities relating to such solutions; and receiving favorable exposure in peer-reviewed publications and from key opinion leaders ("KOLs").
- ***Payer coverage and reimbursements.*** Our revenue and future revenue growth will depend on our success in achieving broad coverage and adequate reimbursement for our solutions from third-party payers. Coverage and reimbursement by third-party payers, including managed care organizations, private health insurers, and government healthcare programs for the types of solutions we offer can be limited and uncertain and may depend on a number of factors, including a payer's determination that a product is appropriate, medically necessary, and cost-effective. Each payer will make its own decision as to whether to establish a policy or enter into a contract to cover our products and the amount it will reimburse for such products. While the average selling prices ("ASPs") for Caris Assure, MI Tumor Seek Hybrid and MI Cancer Seek reimbursed by a particular payer are determined by our arrangements with that payer and do not materially differ by cancer type, any fluctuation or differences in coverage and reimbursement among our third-party payers may impact our overall ASPs and gross margins. Moreover, if we are unable to obtain and/or maintain broad coverage and adequate reimbursement for our solutions from third-party payers, we may not be able to effectively increase our clinical case volume and our revenue would be impacted.
- ***Scaling infrastructure to meet increasing demand.*** Our financial results are also dependent upon our ability to support current and future levels of demand for our solutions, including MI Profile and Caris Assure. As the volumes of our current and new molecular profiling solutions continue to grow, we will need to simultaneously increase our capacity for sample intake and storage, enhance our customer service, improve our billing and general processes, expand our internal quality assurance programs, incorporate new equipment, implement new technology systems and processes, expand laboratory capacity, and otherwise extend our operational capabilities to support comprehensive genomic analyses at a larger scale while retaining expected turnaround times. This may result in us purchasing additional equipment, constructing additional facilities, hiring additional qualified labor, and implementing new systems, technology, controls, and procedures. As such, our capital expenditures and cost of services may increase as we continue our efforts to expand capacity. In addition, revenue may be impacted in the event that we are not able to meet the increase in demand.

Components of Results of Operations

Revenue

Revenue consists primarily of the following:

Molecular Profiling Services

Molecular profiling services revenue is generated from the provision of precision oncology solutions to ordering physicians utilizing MI Profile, MI Cancer Seek (NGS component of MI Profile), and Caris Assure. Revenue is recorded when performance obligations are satisfied, which is deemed to be when the results of the profiling services are provided to the ordering physicians, including certain hospitals, cancer centers, and institutions. Revenue is recorded at the amount that reflects the consideration to which we expect to be entitled from customers and third-party payers in exchange for providing such services.

Pharma Research and Development Services

Pharma research and development services revenue is generated from the provision of research and development services for biopharma partners utilizing our Caris platform. Given the nature of these services, each contract may contain multiple performance obligations, such as molecular profiling solutions, target discovery services,

and strategic data services. Each performance obligation is analyzed, and revenue is recognized as or when such performance obligations are satisfied. The timing and extent of revenue recognized may vary from contract to contract.

Costs and Operating Expenses

We allocate certain overhead expenses, such as rent, utilities, and depreciation to cost of services and operating expense categories based on headcount and facility usage. As a result, an overhead expense allocation is reflected in cost of services and operating expenses.

Cost of Services - Molecular profiling services

Cost of molecular profiling services generally consists of cost of materials, direct labor (including bonus and stock-based compensation), equipment maintenance and depreciation expenses associated with processing cases (including accessioning, sequencing, quality control analyses, and shipping charges to transport samples), and freight. Costs associated with completing the molecular profiling services are recorded as the service is performed, regardless of whether revenue is recognized with respect to the service.

Cost of Services - Pharma research and development services

Cost of services for pharma research and development services generally consists of costs incurred for the performance of the services requested by our biopharma partners related to research and development services. For the development of new products, costs incurred before technological feasibility has been achieved are reported as research and development expenses, while costs incurred thereafter are reported as cost of services. Cost of services for pharma research and development services will vary depending on the nature, timing, and scope of customer projects.

We expect cost of services to increase in absolute dollars as our revenue grows. In the short term, increases to cost of services may outpace revenue growth as we invest in expanding our laboratory capacity and implementing new processes. However, over time, the cost per clinical case is expected to decrease due to economies of scale.

Selling and Marketing Expense

Our selling and marketing expense includes costs associated with our sales organization, including our direct sales force and sales management, marketing, and business development personnel. These expenses consist principally of salaries, incentive compensation, bonuses, employee benefits, travel, and stock-based compensation, as well as marketing and educational activities. We expense all selling and marketing expenses as incurred.

We believe that our marketing activities continue to drive awareness and differentiate our existing solutions and future solutions. We expect our selling and marketing expenses to continue to increase in absolute dollars as we expand our sales force and continue to grow our presence within and outside of the United States.

General and Administrative Expense

Our general and administrative expense includes costs for our executive, accounting and finance, legal, information technology, billing, and human resources functions. These expenses consist principally of salaries, bonuses, employee benefits, travel, and stock-based compensation, as well as professional services fees (such as audit and tax consulting), general corporate costs, and allocated overhead expenses. While we expect our general and administrative expenses will increase in absolute dollars as we continue to invest in our growth and operate as a public company, we expect them to decline as a percentage of revenue over time as we scale our business and leverage our investments already made.

We expect to incur additional expenses, primarily due to the additional costs of operating as a public company, which include additional legal, accounting, corporate governance, and investor relations expenses, as well as higher directors' and officers' insurance premiums. In addition, as a public company, we also expect to incur increased stock-based compensation expense related to our long-term equity incentive plan.

Research and Development Expense

Our research and development expense consists of costs incurred in performing research and development activities. These expenses include direct costs for salaries and benefits, supplies used in research and development, contract services and other outside costs, costs to acquire in-process research and development projects and technologies that have no alternative future use, and allocated overhead expenses.

We expect that our overall research and development expenses will vary from period to period as a percentage of revenue, as projects are initiated and completed.

Other Income (Expense), Net

Interest Income

Interest income consists primarily of interest earned on our cash and cash equivalents and marketable securities.

Interest Expense

Interest expense consists primarily of contractual interest expense on our term loan, amortization of the debt discount related to our term loan and convertible notes, and interest expense on our finance leases.

Changes in Fair Value of Financial Instruments

Changes in fair value of financial instruments consists of changes in the fair value of the warrant liability and changes in the fair value of derivative liabilities. Our warrants are classified as a liability on our condensed consolidated balance sheets and re-measured to fair value at each balance sheet date with the corresponding changes in fair value recorded within changes in fair value of financial instruments. All warrants were exercised upon the closing of the IPO.

Other Income (Expense), Net

Other income (expense), net consists of items related to foreign currency gains and losses, debt extinguishment expense and additional immaterial items.

Results of Operations

The following table sets forth a summary of our results of operations for the periods presented:

(amounts in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Revenue:				
Molecular profiling services	$ 207,587	$ 93,803	$ 484,593	$ 254,692
Pharma research and development services	9,246	7,817	34,554	27,653
Total revenue	**216,833**	**101,620**	**519,147**	**282,345**
Costs and operating expenses [1]:				
Cost of Services - Molecular profiling services	66,980	54,810	193,195	167,134
Cost of Services - Pharma research and development services	2,347	2,398	7,698	7,130
Selling and marketing expense	41,267	36,758	123,355	115,077
General and administrative expense	51,973	40,852	168,458	126,273
Research and development expense	21,624	27,644	69,739	86,807
Total costs and operating expenses	**184,191**	**162,462**	**562,445**	**502,421**
Income (Loss) from operations	32,642	(60,842)	(43,298)	(220,076)
Other expense, net:				
Interest income	7,360	1,744	9,482	6,152
Interest expense	(13,507)	(13,799)	(45,497)	(36,763)
Changes in fair value of financial instruments	(2,081)	5,131	(52,285)	6,067
Other income (expense), net	(89)	37	(18,447)	(323)
Total other expense, net	**(8,317)**	**(6,887)**	**(106,747)**	**(24,867)**
Income (Loss) before income taxes and provision for income taxes	**24,325**	**(67,729)**	**(150,045)**	**(244,943)**
Provision for income taxes	—	—	—	—
Net income (loss)	**$ 24,325**	**$ (67,729)**	**$ (150,045)**	**$ (244,943)**

(1) Costs and operating expenses contains the following stock-based compensation expense:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
	(amounts in thousands)			
Cost of services - Molecular profiling services	$ 1,104	$ 411	$ 2,452	$ 1,237
Cost of services - Pharma research and development services	17	3	20	6
Selling and marketing expense	3,322	1,092	6,554	3,177
General and administrative expense	6,410	2,148	39,438	6,147
Research and development expense	2,802	1,069	8,175	3,099
Total	$ 13,655	$ 4,723	$ 56,639	$ 13,666

The following table sets forth our results of operations as a percentage of revenue for the periods presented:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Revenue:				
Molecular profiling services	96 %	92 %	93 %	90 %
Pharma research and development services	4 %	8 %	7 %	10 %
Total revenue	**100 %**	**100 %**	**100 %**	**100 %**
Costs and operating expenses:				
Cost of Services - Molecular profiling services	31 %	54 %	37 %	59 %
Cost of Services - Pharma research and development services	1 %	2 %	1 %	3 %
Selling and marketing expense	19 %	36 %	24 %	41 %
General and administrative expense	24 %	40 %	32 %	45 %
Research and development expense	10 %	27 %	13 %	31 %
Total costs and operating expenses	**85 %**	**160 %**	**108 %**	**178 %**
Income (Loss) from operations	15 %	(60)%	(8)%	(78)%
Other expense, net:				
Interest income	3 %	2 %	2 %	2 %
Interest expense	(6)%	(14)%	(9)%	(13)%
Changes in fair value of financial instruments	(1)%	5 %	(10)%	2 %
Other income (expense), net	— %	— %	(4)%	— %
Total other expense, net	**(4)%**	**(7)%**	**(21)%**	**(9)%**
Income (Loss) before income taxes and provision for income taxes	**11 %**	**(67)%**	**(29)%**	**(87)%**
Provision for income taxes	— %	— %	— %	— %
Net income (loss)	**11 %**	**(67)%**	**(29)%**	**(87)%**

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

Revenue

	Three Months Ended September 30,		Change	
	2025	2024	$	%
	(amounts in thousands)			
Molecular profiling services	$ 207,587	$ 93,803	$ 113,784	121.3 %
Pharma research and development services	9,246	7,817	1,429	18.3 %
Total revenue	$ 216,833	$ 101,620	$ 115,213	113.4 %

Total revenue was $216.8 million for the three months ended September 30, 2025, compared to $101.6 million for the three months ended September 30, 2024, an increase of $115.2 million, or 113.4%.

Molecular Profiling Services Revenue

Molecular profiling services revenue increased to $207.6 million for the three months ended September 30, 2025, from $93.8 million for the three months ended September 30, 2024, an increase of $113.8 million, or 121.3%.

This increase in revenue was primarily due to the increase in ASP of our MI Profile solution, driven by the launch of MI Cancer Seek and associated higher reimbursement, as well as the increase in clinical cases associated with MI Profile and Caris Assure for therapy selection from 38,409 and 4,547 cases, respectively, for the three months ended

September 30, 2024, to 43,226 and 7,537 cases, respectively, for the three months ended September 30, 2025, a total increase of 7,807 cases, or 18.2%. We believe the growth in MI Profile clinical case volume is driven by increased market acceptance and adoption of MI Profile by ordering physicians year over year, and increased market acceptance and adoption of Caris Assure following its broad commercial launch in the first quarter of 2024.

Revenue from clinical cases for patients covered by Medicare represented approximately 39.4% and 38.6% of our molecular profiling services revenue for the three months ended September 30, 2025 and 2024, respectively, due to mix.

The following table sets forth the relative impacts of clinical volume and ASP on our increase in molecular profiling services revenue.

	(In thousands)
Molecular profiling services revenue for the three months ended September 30, 2024	$ 93,803
MI Profile volume increase	10,796
MI Profile ASP increase due to solution and payer mix	87,836
Caris Assure for therapy selection volume and ASP increase	15,152
Molecular profiling services revenue for the three months ended September 30, 2025	$ 207,587

Pharma Research and Development Services Revenue

Pharma research and development services revenue increased to $9.2 million for the three months ended September 30, 2025, from $7.8 million for the three months ended September 30, 2024, an increase of $1.4 million, or 18.3%. The increase is mainly driven by increased deal activities in the strategic data pillar.

Cost of Services

	Three Months Ended September 30,		Change	
	2025	2024	$	%
	(amounts in thousands)			
Cost of services - Molecular profiling services	$ 66,980	$ 54,810	$ 12,170	22.2 %
Cost of services - Pharma research and development services	$ 2,347	$ 2,398	$ (51)	(2.1)%

Cost of Services - Molecular Profiling Services

Cost of services - Molecular profiling services was $67.0 million for the three months ended September 30, 2025, compared to $54.8 million for the three months ended September 30, 2024, an increase of $12.2 million, or 22.2%.

The Caris Assure laboratory contributed to the majority of the increase. The Caris Assure increase was primarily driven by an increase in materials and related testing costs of $6.8 million, $1.3 million increase in utilities, rent, and allocated overhead, and an increase in labor costs of $1.0 million, due to the increased volume.

Cost of Services - Pharma Research and Development Services

Cost of services - Pharma research and development services was $2.3 million for the three months ended September 30, 2025, compared to $2.4 million for the three months ended September 30, 2024, a decrease of $0.1 million, or 2.1%. The decrease was driven primarily by a decrease within costs associated with the research services of $0.1 million.

Gross Profit

Gross profit, calculated as total revenue less cost of services, was $147.5 million for the three months ended September 30, 2025, compared to $44.4 million for the three months ended September 30, 2024, an increase of $103.1 million, or 232.1%, primarily due to the increase in molecular profiling services revenue.

Selling and Marketing Expense

	Three Months Ended September 30,		Change	
	2025	2024	$	%
	(amounts in thousands)			
Selling and marketing expense	$ 41,267	$ 36,758	$ 4,509	12.3 %

Selling and marketing expenses were $41.3 million for the three months ended September 30, 2025, compared to $36.8 million for the three months ended September 30, 2024, an increase of $4.5 million, or 12.3%. This increase was primarily due to a $2.9 million increase in personnel costs to support existing solutions, and a $1.3 million increase in professional services and travel and marketing expenses.

General and Administrative Expense

	Three Months Ended September 30,		Change	
	2025	2024	$	%
	(amounts in thousands)			
General and administrative expense	$ 51,973	$ 40,852	$ 11,121	27.2 %

General and administrative expenses were $52.0 million for the three months ended September 30, 2025, compared to $40.9 million for the three months ended September 30, 2024, an increase of $11.1 million, or 27.2%. This increase was primarily due to an increase of $4.3 million in stock-based compensation expense, a $3.9 million increase in labor costs and benefits associated with an expansion of personnel, a $4.1 million increase in consulting, audit and legal professional fees, a $0.8 million increase in insurance expenses, and a $0.8 million increase in travel expenses, offset by a $2.6 million decrease in depreciation expense.

Research and Development Expense

	Three Months Ended September 30,		Change	
	2025	2024	$	%
	(amounts in thousands)			
Research and development expense	$ 21,624	$ 27,644	$ (6,020)	(21.8) %

Research and development expenses were $21.6 million for the three months ended September 30, 2025, compared to $27.6 million for the three months ended September 30, 2024, a decrease of $6.0 million, or 21.8%. The decrease was primarily driven by a reduction of $6.2 million in material and reference testing costs associated with the development of Caris Assure and FDA submission of MI Cancer Seek, and a $0.6 million reduction in allocated overhead, offset by an increase of $1.4 million in labor costs, benefits and stock-based compensation.

Other Income (Expense), Net

	Three Months Ended September 30,		Change	
	2025	2024	$	%
	(amounts in thousands)			
Interest income	$ 7,360	$ 1,744	$ 5,616	322.0 %
Interest expense	(13,507)	(13,799)	292	(2.1)%
Changes in fair value of financial instruments	(2,081)	5,131	(7,212)	(140.6)%
Other income (expense), net	(89)	37	(126)	(340.5)%
Total other income (expense), net	$ (8,317)	$ (6,887)	$ (1,430)	20.8 %

Interest Income

Interest income was $7.4 million for the three months ended September 30, 2025, compared to $1.7 million for the three months ended September 30, 2024, an increase of $5.6 million, or 322.0%. This increase was primarily due to a higher amount of cash earning interest in our bank accounts..

Interest Expense

Interest expense was $13.5 million for the three months ended September 30, 2025, compared to $13.8 million for the three months ended September 30, 2024, a decrease of $0.3 million, or 2.1%. This decrease was primarily due to lower interest rate associated with the 2023 Term Loan.

Changes in Fair Value of Financial Instruments

Changes in fair value of financial instruments were $(2.1) million for the three months ended September 30, 2025, compared to $5.1 million for the three months ended September 30, 2024, a decrease of $7.2 million, or 140.6%.

Other Income (Expense), Net

Other income (expense), net was $(0.1) million for the three months ended September 30, 2025, compared to $0.0 million for the three months ended September 30, 2024, a decrease of $0.1 million, or 340.5%. This decrease was primarily due to changes in gains and losses from foreign exchange rate differences.

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

Revenue

	Nine Months Ended September 30,		Change	
	2025	2024	$	%
	(amounts in thousands)			
Molecular profiling services	$ 484,593	$ 254,692	$ 229,901	90.3 %
Pharma research and development services	34,554	27,653	6,901	25.0 %
Total revenue	$ 519,147	$ 282,345	$ 236,802	83.9 %

Total revenue was $519.1 million for the nine months ended September 30, 2025, compared to $282.3 million for the nine months ended September 30, 2024, an increase of $236.8 million, or 83.9%.

Molecular Profiling Services Revenue

Molecular profiling services revenue increased to $484.6 million for the nine months ended September 30, 2025, from $254.7 million for the nine months ended September 30, 2024, an increase of $229.9 million, or 90.3%.

This increase in revenue was primarily due to the increase in ASP of our MI Profile solution, driven by the launch of MI Cancer Seek and associated higher reimbursement, as well as the increase in clinical cases associated with MI Profile and Caris Assure for therapy selection from 107,930 and 10,926 cases, respectively, for the nine months ended September 30, 2024, to 126,160 and 20,493 cases, respectively, for the nine months ended September 30, 2025, a total increase of 27,797 cases, or 23.4%. We believe the growth in MI Profile clinical case volume is driven by increased market acceptance and adoption of MI Profile by ordering physicians year over year, and increased market acceptance and adoption of Caris Assure following its broad commercial launch in the first quarter of 2024.

Revenue from clinical cases for patients covered by Medicare represented approximately 46.4% and 39.7% of our molecular profiling services revenue for the nine months ended September 30, 2025 and 2024, respectively.

The following table sets forth the relative impacts of clinical volume and ASP on our increase in molecular profiling services revenue.

	(amounts in thousands)
Molecular profiling services revenue for the nine months ended September 30, 2024	$ 254,692
MI Profile volume increase	39,946
MI Profile ASP increase due to solution and payer mix	153,811
Caris Assure for therapy selection volume and ASP increase	36,144
Molecular profiling services revenue for the nine months ended September 30, 2025	$ 484,593

Pharma Research and Development Services Revenue

Pharma research and development services revenue increased to $34.6 million for the nine months ended September 30, 2025, from $27.7 million for the nine months ended September 30, 2024, an increase of $6.9 million, or 25.0%. The increase is mainly driven by increased deal activities in the strategic data pillar.

Cost of Services

	Nine Months Ended September 30,		Change	
	2025	2024	$	%
	(amounts in thousands)			
Cost of services - Molecular profiling services	$ 193,195	$ 167,134	$ 26,061	15.6 %
Cost of services - Pharma research and development services	$ 7,698	$ 7,130	$ 568	8.0 %

Cost of Services - Molecular Profiling Services

Cost of services - Molecular profiling services was $193.2 million for the nine months ended September 30, 2025, compared to $167.1 million for the nine months ended September 30, 2024, an increase of $26.1 million, or 15.6%.

The Caris Assure laboratory contributed $20.9 million of the increase. The Caris Assure increase was primarily driven by an increase in materials and related testing costs of $14.8 million, $3.5 million increase in utilities, rent, and allocated overhead, and an increase in labor costs of $2.7 million, due to the increased volume from broad launch in the first quarter of 2024.

Cost of Services - Pharma Research and Development Services

Cost of services - Pharma research and development services was $7.7 million for the nine months ended September 30, 2025, compared to $7.1 million for the nine months ended September 30, 2024, an increase of $0.6 million, or 8.0%. The increase was driven primarily by an increase in utilities of $0.5 million.

Gross Profit

Gross profit, calculated as total revenue less cost of services, was $318.3 million for the nine months ended September 30, 2025, compared to $108.1 million for the nine months ended September 30, 2024, an increase of $210.2 million, or 194.5%, primarily due to the increase in molecular profiling services revenue.

Selling and Marketing Expense

	Nine Months Ended September 30,		Change	
	2025	2024	$	%
	(amounts in thousands)			
Selling and marketing expense	$ 123,355	$ 115,077	$ 8,278	7.2 %

Selling and marketing expenses were $123.4 million for the nine months ended September 30, 2025, compared to $115.1 million for the nine months ended September 30, 2024, an increase of $8.3 million, or 7.2%. This increase was primarily due to a $8.0 million increase in personnel costs to support existing solutions and a $0.7 million increase in professional services, offset by a $0.8 million decrease in travel and marketing expenses.

General and Administrative Expense

	Nine Months Ended September 30,		Change	
	2025	2024	$	%
	(amounts in thousands)			
General and administrative expense	$ 168,458	$ 126,273	$ 42,185	33.4 %

General and administrative expenses were $168.5 million for the nine months ended September 30, 2025, compared to $126.3 million for the nine months ended September 30, 2024, an increase of $42.2 million, or 33.4%. This increase was primarily due to an increase of $33.3 million in stock-based compensation, primarily driven by expense from awards with an IPO-related vesting condition, an $8.9 million increase in labor costs and benefits associated with an expansion of personnel, a $6.2 million increase in consulting, audit and legal professional fees, a $2.3 million increase related to utilities and cloud computing usages, a $0.9 million increase in insurance expenses, and a $2.6 million increase in travel expenses, offset by an $11.9 million decrease in depreciation expense.

Research and Development Expense

	Nine Months Ended September 30,		Change	
	2025	2024	$	%
	(amounts in thousands)			
Research and development expense	$ 69,739	$ 86,807	$ (17,068)	(19.7)%

Research and development expenses were $69.7 million for the nine months ended September 30, 2025, compared to $86.8 million for the nine months ended September 30, 2024, a decrease of $17.1 million, or 19.7%. The decrease was primarily driven by a reduction of $18.4 million in material and reference testing costs associated with the development of Caris Assure and FDA submission of MI Cancer Seek, a reduction of $0.6 million in labor costs and benefits, and a $1.4 million reduction in allocated overhead, offset by a $4.1 million increase in labor costs, benefits, and stock-based compensation primarily from awards with an IPO-related vesting condition.

Other Income (Expense), Net

	Nine Months Ended September 30,		Change	
	2025	2024	$	%
	(amounts in thousands)			
Interest income	$ 9,482	$ 6,152	$ 3,330	54.1 %
Interest expense	(45,497)	(36,763)	(8,734)	23.8 %
Changes in fair value of financial instruments	(52,285)	6,067	(58,352)	(961.8)%
Other expense, net	(18,447)	(323)	(18,124)	5,616.7 %
Total other income (expense), net	$ (106,747)	$ (24,867)	$ (81,880)	329.3 %

Interest Income

Interest income was $9.5 million for the nine months ended September 30, 2025, compared to $6.2 million for the nine months ended September 30, 2024, an increase of $3.3 million, or 54.1%. This increase was primarily due to higher amounts of cash earning interest in our bank accounts.

Interest Expense

Interest expense was $45.5 million for the nine months ended September 30, 2025, compared to $36.8 million for the nine months ended September 30, 2024, an increase of $8.7 million, or 23.8%. This increase was primarily due to increased interest expense associated with $200.0 million of additional borrowing under the 2023 Term Loan, which was drawn on March 5, 2024, and increased amortization of debt discount associated with the 2025 Convertible Notes.

Changes in Fair Value of Financial Instruments

Changes in fair value of financial instruments were $(52.3) million for the nine months ended September 30, 2025, compared to $6.1 million for the nine months ended September 30, 2024, a decrease of $58.4 million, or 961.8%.

Other Expense, Net

Other expense, net was $18.4 million for the nine months ended September 30, 2025, compared to $0.3 million for the nine months ended September 30, 2024, an increase of $18.1 million, or 5,616.7%. This increase was primarily due to the debt extinguishment expense of the 2025 Convertible Notes recorded of $17.9 million upon the IPO, during the nine months ended September 30, 2025.

Non-GAAP Financial Measures

We use certain non-GAAP financial measures to supplement our condensed consolidated financial statements, which are presented in accordance with GAAP. We believe the non-GAAP financial measures we use, Adjusted EBITDA and free cash flow, are useful in evaluating our performance and liquidity. Our non-GAAP financial measures have limitations as analytical tools, however, and you should not consider them in isolation or as substitutes for analysis of our results as reported under GAAP.

Adjusted EBITDA

We define Adjusted EBITDA as net loss, adjusted to exclude interest income, interest expense, changes in fair value of financial instruments, other expense, net, the provision for (benefit from) income taxes, depreciation and amortization, and stock-based compensation expense.

We use Adjusted EBITDA in conjunction with GAAP measures as part of our overall assessment of our performance, including the preparation of our annual operating budget and quarterly forecasts, to evaluate the effectiveness of our business strategies, and to communicate with our board of directors concerning our financial performance. We believe that Adjusted EBITDA provides useful information to investors and others in understanding and evaluating our operating results in the same manner as our management team and board of directors. In addition, it provides a useful measure for period-to-period comparisons of our business, as it removes the effect of certain non-cash expenses and certain variable charges. Some of the limitations related to the use of Adjusted EBITDA as an analytical tool include:

- it does not reflect interest income, interest expense or other non-operating gains and losses, which may represent an increase to or reduction in cash available to us;
- it does not reflect recurring, non-cash expenses of depreciation of property and equipment and amortization of right-of-use assets and intangible assets, and although these are non-cash expenses, the assets being depreciated and amortized may have to be replaced in the future;
- it does not reflect the impact of stock-based compensation expense, which has been, and will continue to be a part of our compensation strategy; and
- it may be calculated differently than similarly titled measures used by other companies, which reduces its usefulness as a comparative measure.

Because of these limitations, you should consider Adjusted EBITDA alongside other financial performance measures, including net loss and our other GAAP results. In evaluating Adjusted EBITDA, you should be aware that in the future we may incur expenses that are the same as, or similar to, some of the adjustments in this presentation. Our presentation of Adjusted EBITDA should not be construed to imply that our future results will be unaffected by the types of items excluded from the calculation of Adjusted EBITDA.

The following table provides a reconciliation of net income (loss), the most directly comparable financial measure presented in accordance with GAAP, to Adjusted EBITDA for the periods presented:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
	(amounts in thousands)			
Net income (loss)	$ 24,325	$ (67,729)	$ (150,045)	$ (244,943)
Interest income	(7,360)	(1,744)	(9,482)	(6,152)
Interest expense	13,507	13,799	45,497	36,763
Changes in fair value of financial instruments	2,081	(5,131)	52,285	(6,067)
Other income (expense), net	89	(37)	18,447	323
Provision for income taxes	—	—	—	—
Depreciation and amortization expense	4,870	10,532	18,324	39,847
Stock-based compensation expense	13,655	4,723	56,639	13,666
Adjusted EBITDA	$ 51,167	$ (45,587)	$ 31,665	$ (166,563)

Free Cash Flow

We define free cash flow as net cash used in operating activities less purchases of property and equipment. We believe free cash flow is a useful measure of liquidity that provides an additional basis for assessing our ability to generate cash. Some of the limitations related to the use of free cash flow as an analytical tool include:

- it does not reflect our future contractual commitments;
- it does not represent our total residual cash flow for a given period; and
- it may be calculated differently than similarly titled measures used by other companies, which reduces its usefulness as a comparative measure.

Because of these limitations, you should consider free cash flow alongside other financial performance measures, including net cash used in operating activities, capital expenditures, and our other GAAP results.

The following table provides a reconciliation of net cash used in operating activities, the most directly comparable financial measure presented in accordance with GAAP, to free cash flow for the periods presented:

	Nine Months Ended September 30,	
	2025	2024
	(amounts in thousands)	
Net cash provided by (used in) operating activities	$ 38,375	$ (206,278)
Less: purchases of property and equipment	(11,170)	(6,154)
Free cash flow	$ 27,205	$ (212,432)

Liquidity and Capital Resources

Sources of Liquidity

In the aggregate, we have incurred net losses and negative cash flows from operations since inception. We may incur net losses in the near future, and our expenses will increase as we continue to invest in developing new solutions, expand our organization, and increase our marketing efforts to continue to drive market adoption of our solutions. As of September 30, 2025, we had an accumulated deficit of $2.6 billion.

To date, we have funded our operations principally from the issuance of stock in private financings, issuance of common stock through our IPO, term loan borrowings and convertible debt, and through revenue from molecular profiling and pharma research and development services. As of September 30, 2025, we had cash and cash equivalents of $753.2 million and short-term marketable securities of $2.3 million. We believe our existing cash and cash equivalents,

which includes the net proceeds from our Pre-IPO Financing (as defined below) and the IPO, short-term marketable securities, and anticipated cash flows from operations will provide sufficient capital and liquidity to fund our operating expenses and capital expenditure requirements for at least the next 12 months. We may, however, continue to require additional capital to meet our operational needs. See "—Indebtedness" and "—Cash Requirements" below for additional information regarding our cash requirements and various factors that may impact our liquidity and capital resources.

Cash Flows

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

	Nine Months Ended September 30,	
	2025	2024
	(amounts in thousands)	
Net cash provided by (used in) operating activities	$ 38,375	$ (206,278)
Net cash provided by (used in) investing activities	$ (11,170)	$ 55,222
Net cash provided by financing activities	$ 661,590	$ 200,066

Operating Activities

Net cash used in operating activities during the nine months ended September 30, 2025 was $38.4 million, which was due to a net change in our operating assets and liabilities of $26.0 million and net non-cash charges of $162.5 million, offset by a net loss of $150.0 million. The net change in our operating assets and liabilities was primarily the result of a $61.2 million decrease in accounts receivable, offset by a $11.1 million increase in supplies, a $1.2 million decrease in accounts payable, a $4.8 million increase in prepaid expenses and other current assets, and a $17.8 million decrease in accrued expenses and other liabilities. Net non-cash charges primarily consisted of $18.3 million of depreciation and amortization expense, $56.6 million of stock-based compensation expense (including $19.5 million of stock-based compensation expense associated with RSUs vested upon the IPO), $4.3 million of non-cash operating lease expense, $12.2 million in amortization of debt discount costs, a $52.3 million loss within changes in the fair value of financial instruments associated with our IPO, and a $17.9 million loss on debt extinguishment associated with our IPO.

Net cash used in operating activities during the nine months ended September 30, 2024 was $206.3 million, which was primarily due to a net loss of $244.9 million and a net change in our operating assets and liabilities of $22.1 million, offset by net non-cash charges of $60.8 million. The net change in our operating assets and liabilities was primarily the result of a $15.0 million increase in accounts receivable, a $14.0 million decrease in accrued expenses and other liabilities, and a $2.2 million increase in prepaid expenses and other current assets, offset by a $5.1 million increase in accounts payable and a $4.2 million decrease in supplies. Net non-cash charges primarily consisted of $39.8 million of depreciation and amortization expense, $13.7 million of stock-based compensation expense, $4.2 million of non-cash operating lease expense, and $5.1 million in amortization of debt discount costs, offset by a $6.1 million gain within changes in the fair value of financial instruments.

Investing Activities

Net cash used in investing activities during the nine months ended September 30, 2025 was $11.2 million, which was due to purchases of property and equipment of $11.2 million.

Net cash provided by investing activities during the nine months ended September 30, 2024 was $55.2 million, which was due to maturities of marketable securities of $61.4 million, offset by purchases of property and equipment of $6.2 million.

Financing Activities

Net cash provided by financing activities during the nine months ended September 30, 2025 was $661.6 million, which was primarily due to proceeds from the IPO, net of underwriting discounts and commissions, of $528.5 million, offset by the payment of taxes withheld from net settlement of exercised options of exercised options of $18.2 million, payment of deferred offering costs of $7.7 million, and payments from debt modification of $4.0 million, issuance of Series E Preferred Stock, net of issuance costs, of $87.6 million, issuance of Series F Preferred Stock, net of issuance costs,

of $33.6 million, issuance of convertible notes, net of issuance costs, of $27.9 million, issuance of warrants of $10.3 million, and exercises of stock options of $3.8 million.

Net cash provided by financing activities during the nine months ended September 30, 2024 was $200.1 million, which was primarily due to proceeds from issuance of additional borrowings under the 2023 Term Loan Agreement on March 5, 2024, net of issuance costs, of $200.0 million, proceeds from exercises of stock options of $1.3 million, offset by the payment of deferred offering costs of $1.0 million.

Indebtedness

In January 2023, we entered into a term loan agreement, as amended with OrbiMed Royalty & Credit Opportunities III, LP, OrbiMed Royalty & Credit Opportunities IV, LP, and Braidwell Transaction Holdings LLC (the "Lenders"), pursuant to which we issued senior, secured promissory notes and the Lenders agreed to lend us up to an aggregate principal amount of $400.0 million, $200.0 million of which was drawn down upon issuance of the notes. Net cash proceeds to us were $189.0 million, after deducting customary debt discounts and debt issuance costs. The net proceeds were used to repay in full our then-outstanding term loans, including an aggregate principal amount of $175.0 million, a prepayment premium of $5.0 million, and accrued and unpaid interest of $1.0 million. In March 2024, we drew down the remaining $200.0 million under the 2023 Term Loan Agreement. As of September 30, 2025, we had $400.0 million of borrowings outstanding under the 2023 Term Loan Agreement.

The aggregate principal amount outstanding under the 2023 Term Loan Agreement is due and payable on January 18, 2028. If an event of default occurs and is continuing, the lenders may declare all amounts outstanding under the 2023 Term Loan Agreement to be immediately due and payable. A final payment exit fee equal to 1.0% of the amount funded under the 2023 Term Loan Agreement is due upon prepayment or maturity. Amounts borrowed pursuant to the 2023 Term Loan Agreement may be prepaid at any time. Upon prepayment, we may be subject to a prepayment penalty based on the timing of repayment.

The aggregate principal amount under the 2023 Term Loan Agreement bears interest at a rate per annum equal to a fixed margin of 6.5% plus the greater of (a) forward-looking three-month secured overnight financing rate ("SOFR") and (b) 2.5%. In the event of default, the fixed margin shall increase by 3.0% per annum. As of September 30, 2025, the interest rate was 10.8%. Regular quarterly payments are interest-only for the 60-month term of the 2023 Term Loan Agreement, with the principal due at maturity. The effective interest rate for the term loan is 12.3%.

Our obligations under the 2023 Term Loan Agreement are secured by a first lien security interest in substantially all of our assets and our subsidiaries' assets. The 2023 Term Loan Agreement contains certain customary representations and warranties, affirmative and negative covenants, financial covenants, and events of default applicable to us and our subsidiaries. Additional covenants include those restricting dispositions, fundamental changes to our business, mergers or acquisitions, indebtedness, encumbrances, distributions, investments, transactions with affiliates, and subordinated debt. As of September 30, 2025, we were in compliance with all covenants under the 2023 Term Loan Agreement.

On April 1, 2025, the Company closed a private financing in which it issued a combination of senior convertible notes (the "2025 Convertible Notes"), Series E Preferred Stock and Series F Preferred Stock, for an aggregate of $167.7 million. The 2025 Convertible Notes were issued in an aggregate principal amount of $30.0 million. The 2025 Convertible Notes accrued interest at a rate of 8% per annum, payable quarterly in cash, and were to mature on January 1, 2026 unless earlier converted. In connection with this financing, the Company also issued warrants to acquire shares of common stock to the holders of the 2025 Convertible Notes. These warrants were not initially exercisable for any shares of common stock, but such warrants became exercisable for a specified dollar value of shares on a monthly basis commencing on June 1, 2025 if we had not completed an initial public offering by such date. Any exercisable portion of the warrants were automatically exercised prior to the closing of the IPO and such warrants terminated upon the closing of the IPO.

Cash Requirements

Our primary use of cash is to fund operating expenses and capital expenditures (including leases of equipment and buildings), which consist of research and development expenditures, general and administrative expenditures, clinical and regulatory expenditures, purchases of testing equipment, and build out of our laboratories. Cash used to fund such activities is impacted by the timing of when we pay or prepay these expenses.

We will continue to require additional capital to fund our operations and to continue to fund investments in the development and marketing of our solutions for the foreseeable future. We may need or determine to raise additional

capital through private or public equity or debt financings, through collaborative or other arrangements with corporate sources, or through other sources of financing. Requirements for additional capital will depend on many factors, including:

- the scope, timing, rate of progress and costs of our research efforts, preclinical development activities, laboratory testing, and clinical trials for our solutions;
- the number and scope of clinical programs we decide to pursue;
- the cost, timing, and outcome of preparing for and undergoing regulatory review of our solutions;
- the scope and costs of development and commercial manufacturing activities;
- the cost and timing associated with commercializing our solutions if they receive marketing approval;
- the extent to which we acquire or in-license other complementary solutions or technologies;
- the costs of preparing, filing, and prosecuting patent applications, maintaining and enforcing our intellectual property rights, and defending intellectual property-related claims;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- our efforts to enhance operational systems and our ability to attract, hire, and retain qualified personnel;
- our success in achieving broad coverage and adequate reimbursement for our solutions from third-party payers;
- our implementation of operational, financial, and management systems; and
- the costs associated with being a public company.

A change in the outcome of any of these or other variables with respect to the development and commercialization of any of our solutions could significantly change the costs and timing associated with such development and commercialization. Furthermore, our operating plans may change in the future, and we will continue to require additional capital to meet operational needs and capital requirements associated with such operating plans.

Critical Accounting Policies and Estimates

Our condensed consolidated financial statements have been prepared in conformity with GAAP. Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASUs") of the Financial Accounting Standards Board ("FASB"). The preparation of the condensed consolidated financial statements in conformity with GAAP requires the use of estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements, and the reported amounts of revenues and expenses during the reporting periods.

While our significant accounting policies are described in Note 2 to our condensed consolidated financial statements, we believe that the following critical accounting policies are most important to understanding and evaluating our reported financial results.

Revenue

We recognize revenue in accordance with ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 606").

ASC 606 provides a five-step framework through which revenue is recognized when control of promised goods or services is transferred to a customer at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. To determine revenue recognition for arrangements that are within the scope of ASC 606, we perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract(s); (iii) determine the transaction price, including whether there are any constraints on variable consideration; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy a performance obligation. At contract inception, once a contract is determined to be within the scope of ASC 606, we assess whether individual goods or services promised within each contract are distinct and, therefore, represent separate performance obligations.

Molecular Profiling Services

We recognize revenue from our molecular profiling services at the time when the results of the profiling services are delivered to ordering physicians, including certain hospitals, cancer centers, and institutions. We identify each sale of our profiling case as a single performance obligation. We estimate the transaction price based on our historical collection experience using a portfolio approach for third-party payers and patients with similar reimbursement characteristics. This includes analysis of an average reimbursement per case per portfolio and a percentage of cases reimbursed by considering the historical reimbursement data (including any refunds and recoupments) from such third-party payers and

patients, current contractual and statutory requirements, patient insurance eligibility and payer reimbursement contracts, and any known or current or anticipated reimbursement trends not reflected in the historical data. We monitor the estimated amount to be collected in the portfolio at each reporting period. Subsequent changes to the estimate of the transaction price are generally recorded as adjustments to molecular profiling services in the period of change.

Pharma Research and Development Services

Contracts with biopharma partners may include multiple distinct performance obligations, such as provision of molecular profiling services, pharma research and development services, and strategic data services. For each of our contracts with biopharma partners, we evaluate the terms and conditions to identify distinct performance obligations. For each performance obligation determined, based on when and how it is delivered, we recognize revenue either when or as such obligation is delivered. Under contracts that include a performance obligation to provide molecular profiling services, to facilitate the development and regulatory approval of drugs, or to provide target discovery services, we receive payments upon the achievement of milestones, as well as provision of on-going support. We recognize pharma research and development services revenue over the period in which pharma research and development services are provided. Depending on the nature of the service, we recognize revenue using either the output or input method to measure progress, whichever provides a more faithful depiction of the transfer of goods or services. Use of an output method or input method to depict the transfer of services generally does not result in a material difference with respect to the timing of revenue recognition because most services commence and end within the same reporting period. We determine the transaction price of each performance obligation by considering the historical selling price of similar transactions, where applicable, as well as other factors, including, but not limited to, the price that customers in the market would be willing to pay, competitive pricing of our competitors, industry publications, and current pricing practices.

Stock-Based Compensation

We have granted stock-based awards consisting primarily of stock options and RSUs to employees, consultants, and members of our board of directors. We account for stock-based compensation in accordance with ASC Topic 718, *Compensation—Stock Compensation*. Stock-based compensation expense is measured based on the fair value of the awards as of the grant date and is recognized as expense over the requisite service period, which is generally the vesting period.

The fair value of stock option awards as of the date of the grant was estimated by applying the Black-Scholes option pricing model. The Black-Scholes option pricing model requires the use of highly subjective and complex assumptions, which determine the fair value of stock-based awards. These assumptions include the following:

- *Fair value per share of the underlying stock.* Prior to our common stock being publicly traded, the fair value of the common stock underlying our stock options was determined by our compensation committee, with input from management and valuation reports prepared by third-party valuation specialists.
- *Expected price volatility.* Prior to our common stock being publicly traded, the expected price volatility for our stock options was determined by using an average of historical volatilities of selected industry peers deemed to be comparable to our business and corresponding to the expected term of the awards.
- *Risk-free interest rate.* The risk-free interest rate was based on the U.S. treasury yield curve in effect at the time of grant for U.S. treasury notes with maturities corresponding to the expected term of the awards.
- *Expected term.* The expected term of stock options represented the period of time over which the options granted were expected to remain outstanding and was based on our estimate, taking into consideration vesting terms, contractual terms, and historical actual lives. Options granted have a maximum term of 10 years. Due to the lack of historical option exercise data, we utilized the simplified method for determining the expected term.
- *Expected dividend rate.* We have never declared or paid any cash dividends, and we do not intend to pay any cash dividends in the foreseeable future. Therefore, we use an expected dividend yield of zero percent.
- *Expected forfeitures.* Forfeitures are estimated at the time of grant and reduce compensation expense ratably over the vesting period. This estimate is based on historical forfeitures and is adjusted periodically based on the extent to which actual forfeitures differ, or are expected to differ, from the previous estimate.

We will continue to use judgment in evaluating the assumptions related to our stock-based compensation on a prospective basis. As we continue to accumulate additional data related to our common stock, we may refine our estimation process, which could materially impact our future stock-based compensation expense.

Emerging Growth Company Status

The JOBS Act permits an "emerging growth company" such as us to delay the adoption of new or revised accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this extended transition period for complying with new or revised accounting standards and, as a result, our results of operations and financial statements may not be comparable to those of companies that have adopted the new or revised accounting standards. We will remain an emerging growth company until the earliest to occur of: (1) the last day of the fiscal year in which we have at least $1.235 billion in total annual gross revenue; (2) the last day of the fiscal year in which we are deemed to be a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common stock held by non-affiliates exceeded $700 million as of the last business day of the second fiscal quarter of such year; (3) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period; and (4) the last day of the fiscal year ending after the fifth anniversary of the date of the completion of the IPO (*i.e.* the fiscal year ending December 31, 2030).

Recent Accounting Pronouncements

See Note 2 of our condensed consolidated financial statements for more information regarding recently issued accounting pronouncements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

The market risk inherent in our financial instruments and in our financial position represents the potential loss arising from adverse changes in interest rates. As of September 30, 2025, we had cash, cash equivalents, and restricted cash of $757.0 million, and short-term marketable securities of $2.3 million, consisting of interest-bearing money market accounts, for which the fair market value would be affected by changes in the general level of United States interest rates. However, due to the short-term maturities and the low-risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash and investments.

Our borrowings under the 2023 Term Loan Agreement also subject us to market risk associated with movements in interest rates associated with forward-looking three-month SOFR. We had $400.0 million in variable rate debt outstanding as of September 30, 2025. A hypothetical 100 basis point adverse movement in the interest rate would increase our annual interest expense by $4.0 million. We hedge interest rate risk on $200.0 million of this variable rate debt with a purchased interest rate cap derivative that has a strike rate of 6.0%, with a February 2026 maturity. We did not receive any settlement payments from the counterparty to the interest rate cap for the year ended December 31, 2024 or the nine months ended September 30, 2025.

Foreign Currency Risk

Substantially all of our revenue is generated in the United States, and we do not believe we are currently subject to significant foreign currency risk. To date, foreign currency transaction gains and losses have not had a material impact on our operations, and we have not engaged in any foreign currency hedging transactions. As we expand our presence in the international market, our results of operations and cash flows are expected to increasingly be subject to fluctuations due to changes in foreign currency exchange rates and may be adversely affected in the future due to changes in foreign exchange rates. We will continue to reassess our approach to manage risk relating to fluctuations in currency rates as our international operations grow.

Inflation Risk

We do not believe that inflation has had a material effect on our business, financial condition or results of operations, other than its impact on the general economy, which includes labor costs. Nonetheless, if our costs, in particular personnel-related costs, continue to become subject to significant inflationary pressures, we may not be able to fully offset such higher costs through price increases. Our inability or failure to do so could harm our business, financial condition and results of operations.

Item 4. Controls and Procedures

Limitations on Effectiveness of Controls and Procedures

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

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended), as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on such evaluation, our principal executive officer and principal financial officer have concluded that these disclosure controls and procedures were not effective at the reasonable assurance level as of September 30, 2025 due to the previously reported material weakness in our internal control over financial reporting pertaining to a lack of sufficient qualified accounting resources, including those with technical expertise necessary to account for and disclose accounting transactions which require complex calculations or thorough evaluation of the accounting literature.

Notwithstanding the material weakness in our internal controls over financial reporting as of September 30, 2025, management has concluded that the condensed consolidated financial statements included in this Form 10-Q present fairly, in all material respects, our financial position, results of operations and cash flows for the periods presented in conformity with accounting principles generally accepted in the United States.

Changes in Internal Control over Financial Reporting

During the quarter ended September 30, 2025, we continued our remediation efforts in connection with the identification of the material weakness discussed above. These remediation steps are ongoing and include the following:

- implementation of controls to enhance our review of significant accounting transactions and other new technical accounting and financial reporting issues and the preparation and review of accounting memoranda addressing these issues;
- implementation of controls to enable an effective and timely review of account analyses and account reconciliations; and
- continued hiring of additional accounting and finance resources with public company experience and expanding the capabilities of the existing accounting and financial personnel through continuous training and education in the accounting and reporting requirements under GAAP and SEC rules and regulations

While we took certain actions to remediate the material weakness, such remediation has not been fully evidenced. Accordingly, we continue to test our controls to assess whether our controls are operating effectively. We will not be able to conclude whether the steps we are taking will fully remediate these material weakness in our internal control over financial reporting until we have completed our remediation efforts and subsequent evaluation of their effectiveness. We may also conclude that additional measures may be required to remediate the material weaknesses in our internal control over financial reporting, which may necessitate additional implementation and evaluation time.

Other than the foregoing actions to remediate our material weakness, there was no change in our internal control over financial reporting identified during the period covered by this Quarterly Report on Form 10-Q 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

In March 2025, the Company received a Civil Investigative Demand ("CID") from the U.S. Department of Justice in connection with an investigation under the False Claims Act ("FCA") regarding the Company's compliance with Medicare's date of service rule (also referred to as the 14-day rule), particularly focused on patients of certain health care providers, and our policies, procedures, and training related to compliance with the 14-day rule. The related investigation continues to evolve and is in too early a stage to assess potential outcomes. The Company is cooperating with the investigation. We have implemented compliance policies, procedures, and training designed to foster compliance with the 14-day rule, but there can be no certainties regarding the outcome of this CID. In June 2022, we entered into a settlement agreement with the United States in connection with a previous investigation into our compliance with the 14-day rule. Pursuant to this settlement agreement, under which we admitted no fault or liability, we paid approximately $2.9 million in restitution and penalties and we obtained a nationwide release from all 14-day rule claims prior to January 1, 2018.

In addition to the matter described above, we are, from time to time, party to various claims and legal proceedings arising out of our ordinary course of business, including claims or proceedings relating to, among other things, regulatory matters, intellectual property, competition, tax, and employment matters, medical malpractice, product or professional liability or other tort claims. We cannot predict with certainty the results of any claims or proceedings. We may receive unfavorable preliminary or interim rulings in the course of litigation, and there can be no assurances that favorable final outcomes will be obtained.

Moreover, the existence of any claim or legal proceeding, regardless of the outcome, may adversely impact us because of diversion of management time and attention as well as the financial costs related to resolving such disputes. For additional information, see Part II, Item 1A, "Risk Factors—Risks Related to Regulation and Legal Compliance—We have been, are currently, and in the future may be the subject of government investigations, claims, audits, whistleblower and payer audits, overpayment and recoupment efforts and other litigation in the course of our business that could adversely affect our business and financial statements."

Item 1A. Risk Factors

A description of risks and uncertainties facing our business is set forth below. You should carefully consider the risks described below, as well as the other information in this Quarterly Report on Form 10-Q ("Quarterly Report"), including our financial statements and the related notes and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" in this Quarterly Report. Additional risks and uncertainties that we are not currently aware of, or that we currently believe are not material, may also adversely affect our business. This Quarterly Report also contains forward-looking statements that involve risks and uncertainties. See the section titled "Special Note Regarding Forward-Looking Statements." The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations, and growth prospects. In such an event, the price of our securities could decline, and you may lose all or part of your investment.

Risk Factors Summary

The following is a summary of the most significant risks, challenges and uncertainties facing our business. This summary should be read in conjunction with the risk factors described below in this section and should not be considered an exhaustive list or summary of all of the significant or material risks, challenges and uncertainties that we face.

- The precision medicine industry is highly competitive and subject to rapid change.
- We have incurred significant losses since inception, may incur additional losses in the near future, and may not be able to generate sufficient revenue to maintain profitability.
- Our current or future solutions may not achieve or maintain sufficient commercial market acceptance.
- Our solutions may not perform as expected, and the results of our validation studies or our clinical trials may not support the launch or use of our solutions and may not comply with the requirements, or be replicated in later trials required, for any necessary or desirable marketing authorizations. This could adversely affect our business, financial condition, results of operations, and growth prospects.
- Our current revenue is primarily generated from the continued adoption and use of our tissue-based profiling solution.
- Our future success and growth will depend in part on market acceptance and commercial success of our MI Cancer Seek and Caris Assure solutions. We may be unsuccessful in continuing the commercialization and

growing the adoption of MI Cancer Seek or Caris Assure, which would adversely affect our business, financial condition, results of operations, and growth prospects.

- If we are unable to support demand for MI Profile, Caris Assure, and any other solutions we develop, including ensuring that we have adequate capacity to meet increased demand, or if we are unable to successfully manage our anticipated growth, our business could suffer.
- Our results of operations may fluctuate significantly, which makes our future results of operations difficult to predict and could cause our results of operations to fall below expectations or any guidance we may provide.
- If our solutions, or solutions we develop in the future, do not receive adequate coverage and reimbursement from third-party payers, including government and commercial payers, our ability to expand access to our solutions beyond our existing sales channels, and thus our overall commercial success, will be limited.
- If we or our partners fail to comply with healthcare or other applicable laws and regulations, we could face substantial penalties and sanctions, and our business, reputation, financial condition and results of operations could be adversely affected.
- Our billing, collections, and claims processing activities are complex and time-consuming, and any delay in transmitting and collecting claims or failure to comply with applicable billing requirements could have an adverse effect on our future revenue.
- We rely on a limited number of third-party suppliers or, in many cases, sole suppliers, for some of our next-generation sequencers, lab materials, reagents, and supplies, and we may not be able to find replacements or immediately transition to alternative suppliers if necessary.
- We have current solutions marketed as laboratory-developed tests (LDT) and plan to launch future solutions as LDTs. The regulation of LDT products in the United States remains subject to significant uncertainty, and if we fail to comply with any new or existing legal requirements with respect to our LDT solutions, our business, financial condition, and results of operations could be adversely affected.
- We have been, are currently, and in the future may be the subject of government investigations, claims, audits, whistleblower and payer audits, overpayment and recoupment efforts and other litigation in the course of our business that could adversely affect our business and financial results
- If we are unable to obtain and maintain intellectual property protection for our technology, or if the scope of the intellectual property protection we obtain is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to our solutions, and our ability to successfully commercialize our solutions may be impaired.
- We have incurred substantial indebtedness, and we may not generate sufficient cash flow from operations to meet our debt service requirements, continue our operations, and pursue our growth strategy, and we may be unable to raise capital when needed or on acceptable terms.
- Our executive officers, directors, and principal shareholders, including, in particular, David D. Halbert, our Founder, Chairman, and Chief Executive Officer, to have the ability to control or significantly influence matters submitted to shareholders for approval, which could limit the ability of our other shareholders to affect the outcome of key corporate decisions and transactions, including a change of control.

Risks Related to Our Business and Industry

The precision medicine industry is highly competitive and subject to rapid change.

Our industry is highly competitive and characterized by rapid changes, including technological and scientific breakthroughs, frequent new product introductions and enhancements, and evolving industry standards. Our future success will depend on our ability to compete successfully and keep pace with the evolving needs of physicians, patients, and our biopharma partners on a timely and cost-effective basis and to pursue new market opportunities that develop as a result of technological and scientific advances. In recent years, there have been numerous advances in technologies relating to the diagnosis and treatment of cancer and advances in methods used to analyze large amounts of genomic information. We must continuously enhance our proprietary profiling and signature offerings and develop new solutions in a cost-effective way to achieve meaningful innovation in precision oncology and other chronic disease states. If we do not update our suite of solutions to reflect new scientific knowledge or technological advancements, including as they relate to precision medicine, therapeutic developments, or relevant validation studies or clinical trials, adoption and use of our current solutions and any new solutions we may develop could decline, which would adversely affect our business, financial condition, and results of operations.

Moreover, as an AI TechBio company that has experienced significant recent growth in the rapidly evolving field of precision medicine, our current business, our future success, and the risks and challenges we may encounter can be difficult to evaluate or accurately predict. If we fail to address the risks and difficulties that we face, including those described elsewhere in this “Risk Factors” section, our business, financial condition, and results of operations could be

adversely affected. We have encountered in the past, and expect to encounter in the future, risks and difficulties frequently experienced by companies operating in rapidly evolving fields. If our assumptions regarding these risks and difficulties, which we use to plan and operate our business, are incorrect or change, or if we do not address these risks and difficulties, our results of operations could differ materially from our or your expectations, and our business, financial condition, and results of operations could be adversely affected.

We have incurred significant losses since inception, may incur losses in the future, and may not be able to generate sufficient revenue to achieve and maintain profitability.

We have incurred significant losses since our inception. For the years ended December 31, 2024 and 2023, we incurred net losses of $281.9 million and $341.4 million, respectively. For the nine months ended September 30, 2025 and 2024, we incurred net losses of $150.0 million and $244.9 million, respectively. As of September 30, 2025, we had an accumulated deficit of $2.6 billion. To date, we have financed our operations principally from the sale of convertible preferred stock, the incurrence of indebtedness, the proceeds of our June 2025 initial public offering ("IPO"), and revenue from molecular profiling and pharma R&D services. Over the last 17 years, we have devoted significant resources towards developing our current portfolio that consists of tissue- and blood-based profiling solutions, building our multi-modal clinico-genomic datasets, expanding our operational capacity, and strengthening our AI/ML-driven data analysis capabilities. We also devote significant resources to clinical and regulatory initiatives to obtain marketing authorization, sales and marketing activities, and R&D activities. We anticipate incurring significant costs to continue developing and commercializing our solutions.

In addition, because of the various risks and uncertainties associated with developing and commercializing our solutions, we are unable to predict the extent of future costs that may impact our prospects for profitability. Our future expenses will depend, in part, on the level of our expenditures and our ability to continue generating revenue at scale. We expect to continue to incur significant expenses for the foreseeable future, and may incur operating losses in the short term if and as we, among other things:

- attract, hire, and retain qualified personnel;
- continue our R&D activities and scale our R&D infrastructure;
- expand our laboratory capacity and operating capabilities, including completing the build-out of our laboratory facility in Irving, Texas;
- further build our sales, marketing, and distribution infrastructure;
- continue to invest in the expansion and enrichment of our clinico-genomic datasets and related analysis capabilities;
- seek marketing authorization or other regulatory approvals that may be necessary or desired for our solutions;
- obtain, maintain, protect, and enforce our intellectual property portfolio, including intellectual property obtained through license agreements;
- meet the requirements and demands of being a public company; and
- defend against any claims or other lawsuits related to our solutions or otherwise.

Our expenses could increase beyond expectations if we are required by the FDA or other regulatory agencies to delay the launch of any new solutions, narrow or change our intended use or product claims, modify or expand our clinical trials or to perform additional clinical trials, either pre- or post-approval, in addition to those that we currently anticipate.

We will also need to generate significant additional revenue to sustain and then grow profitability, and we cannot be sure that we will remain profitable for any substantial period of time. While we have commercially launched MI Cancer Seek, a new WES/WTS NGS assay, in the United States and seek to drive its increased adoption, and also plan to capitalize on the potential of Caris Assure applications for early detection, MRD tracking, and treatment monitoring and in chronic disease states beyond oncology, we cannot assure you that we will successfully be able to do so as planned, if at all, and our failure to do so may prevent us from generating increased revenue. Our failure to maintain profitability could negatively impact the value of our common stock.

Our current or future solutions may not achieve or maintain sufficient commercial market acceptance.

The commercial success of any of our solutions, including our MI Profile and Caris Assure platforms, or solutions that are marketed in the future, will depend upon the degree of commercial market acceptance, including by government payers, insurance companies, integrated health systems, healthcare providers, patients, biopharma companies and other third-party payers. The degree of market acceptance of our solutions will depend on a number of factors, including:

- the performance and clinical utility of such solutions as demonstrated in clinical trials and published in peer-reviewed journals;
- the rate of adoption and/or endorsement of our solutions by clinicians, KOLs, advocacy groups, and biopharma companies;
- the ability of our newer solutions, such as Caris Assure, and solutions that may be marketed in the future, to demonstrate the same performance in real-world intended use populations as in clinical trials or analytical or clinical validation studies;
- the willingness of medical providers to utilize our solutions as they are commercially released;
- the willingness of commercial third-party payers and government payers to cover and reimburse for our solutions;
- the development or introduction of competing products, including the expansion of the capabilities of existing products;
- the market acceptance of existing competitive products, including tests that are currently reimbursed;
- publicity concerning our solutions or competing products; and
- the strength of our marketing and sales support.

We cannot assure you that we will be successful in addressing each of these factors or other factors that might affect the market acceptance of our solutions. Failure to achieve broad market acceptance of our solutions, would harm our business, financial condition, and results of operations. For additional information, see "—Our current revenue is primarily generated from the continued adoption and use of our tissue-based profiling solution" and "—Our future success and growth will depend in part on market acceptance and commercial success of our MI Cancer Seek and Caris Assure solutions. We may be unsuccessful in continuing the commercialization and growing the adoption of MI Cancer Seek or Caris Assure, which would adversely affect our business, financial condition, results of operations, and growth prospects."

Our solutions may not perform as expected, and the results of our validation studies or our clinical trials may not support the launch or use of our solutions and may not comply with the requirements, or be replicated in later trials required, for any necessary or desirable marketing authorizations. This could adversely affect our business, financial condition, results of operations, and growth prospects.

Our success depends on the market and the medical community's confidence that we can provide reliable, high-quality solutions, as well as our ability to complete validation studies and clinical trials and comply with applicable regulatory requirements that would allow us to commercialize our solutions. Our solutions may not perform as expected, and the results obtained from our ongoing or future studies and trials may be inconsistent with certain results obtained from our previous studies or trials. In addition, the application of Caris Assure in early detection, MRD tracking, and treatment monitoring, for which we are still collecting data to support, may not be as effective as we anticipate. If Caris Assure or our other solutions are ineffective or do not consistently perform as expected, either before or after launch, our business, financial condition, results of operations, and growth prospects would suffer.

Our solutions require a number of complex and sophisticated biochemical and bioinformatics processes, many of which are highly sensitive to external factors. An operational or technological failure in one of these complex processes or fluctuations in external variables may result in sensitivity and specificity rates that are lower than we anticipate or that vary between test runs or in a higher than anticipated number of tests that fail to produce consistent results. In addition, we regularly evaluate and refine our AI/ML algorithms and other processes under development. These refinements may inadvertently result in unanticipated issues that may reduce our sensitivity and specificity rates or otherwise adversely affect the performance of our solutions and their results, such that supplemental submissions to the FDA may be required.

We have obtained a PMA approval from the FDA for MI Cancer Seek and may decide to seek FDA approval for Caris Assure and additional solutions, though whether we will do so and the timing thereof is uncertain. The FDA and other regulators may request additional information or require that we generate additional clinical data to support such future approval applications, which could result in delays, increased costs, or other limitations on our ability to receive such approval. Additionally, the FDA included certain conditions of approval and limitations in the PMA approval letter for MI Cancer Seek, namely that we submit data evaluating the effects of interfering substances such as necrotic tissue, melanin, and fatty acids and also conduct a study and submit data regarding formalin-fixed paraffin-embedded block and slide stability duration claims, which submissions were completed in early November 2025. Our failure to satisfactorily comply with these limitations and conditions could result in the withdrawal of the PMA approval for MI Cancer Seek.

Further, we plan to enhance, iterate, and improve our solutions, scalability, and/or reduce our cost of goods. However, we may not be successful in transitioning our solutions to new or enhanced versions or iterations, or reducing our cost of goods. The improvement of our solutions involves a lengthy and complex process, may require regulatory approval, and we may be unable to commercialize, validate, or improve performance of any of our solutions on a timely basis, or at all. Our failure to successfully develop new and/or improved solutions (including new versions of existing solutions) on a timely basis could adversely affect our business, financial conditions, and results of operation.

Finally, generating the clinical data necessary to validate and support the launch of our solutions and new versions of solutions and subsequently obtain marketing authorization or third-party reimbursement, is time-consuming and carries with it the risk of not yielding the desired results. The performance achieved in our analytical validation studies, clinical trials, or published studies may not be replicated in later studies that may be required to obtain or maintain marketing authorization. For example, limited results from earlier-stage analytical validation studies, such as our analytical validation studies on the use of Caris Assure for early detection, MRD tracking, and treatment monitoring, may not predict results from studies in larger numbers of participants drawn from more diverse populations over a longer period of time. Unfavorable results from ongoing analytical validation studies or clinical trials, or delays in publication of such results, could lead to delays, modifications, or abandonment of ongoing or future studies and trials, or abandonment of a solution development program, or may delay, limit, or prevent marketing authorizations or commercialization of our solutions. In addition, results from such studies and trials may not be consistent with the results from real-world application of our solutions, if commercialized, for a particular care setting.

Our current revenue is primarily generated from the continued adoption and use of our tissue-based profiling solution.

Our ability to execute our growth strategy and become profitable is highly dependent on the continued adoption and use of MI Profile, our tissue-based profiling solution, which accounted for 78.20% and 91.00% of our revenue in the years ended December 31, 2024 and 2023, respectively, and 93.34% and 90.21% of our revenue for the nine months ended September 30, 2025 and 2024, respectively. Continued adoption and use of MI Profile will depend on several factors, including the prices we charge for our solution, the scope of coverage and amount of reimbursement available from government and third-party payers for our solution, the availability of clinical data that supports the value of MI Profile and the inclusion of MI Profile solutions in industry treatment guidelines. The commercial success of our tissue-based profiling solution depends significantly on its broad adoption and use by oncologists and other physicians. Many physicians and biopharma companies have existing relationships with companies that develop molecular diagnostic tests, including our competitors, and may continue to use their tests instead of MI Profile. Despite our business development efforts, it could be difficult, expensive, and/or time-consuming for physicians and/or biopharma companies to switch diagnostic tests for their products, and MI Profile may not be widely accepted, if at all, which could in turn hinder the rate of adoption and continued use of our solutions. We cannot assure you that MI Profile will continue to maintain or gain market acceptance, and any failure to do so would harm our business, financial condition, and results of operations. Moreover, as we have leveraged the data we have generated to date with MI Profile to develop Caris Assure and other solutions, if the adoption and use of MI Profile wanes or if reliability or other issues with the data we generate with MI Profile are discovered, the further development and future success and growth of Caris Assure and other solutions would be adversely impacted.

Our future success and growth will depend in part on market acceptance and commercial success of our MI Cancer Seek and Caris Assure solutions. We may be unsuccessful in continuing the commercialization and growing the adoption of MI Cancer Seek or Caris Assure, which would adversely affect our business, financial condition, results of operations, and growth prospects.

Driving increased adoption among physicians of, and obtaining reimbursement for, MI Cancer Seek are key expected drivers of our growth, particular in the near and medium term. The success of MI Cancer Seek will depend upon, among other things, the extent to which our FDA approval drives increased adoption and use of the solution by physicians as a companion diagnostic tool.

Caris Assure, for which we initiated the broad commercial launch for therapy selection in the first quarter of 2024, ultimately aims to address the entire continuum of cancer treatment. Realizing the potential of Caris Assure across disease states is a key component of our long-term business strategy. The commercial success of Caris Assure for therapy selection and in other applications across the cancer treatment continuum will depend upon, among other things, analytical validation studies and clinical trials that demonstrate the effectiveness of Caris Assure, particularly for early detection, MRD tracking, and treatment monitoring, the continued adoption of Caris Assure by physicians, the medical community, patients, and third-party payers, and our ability to successfully run and market Caris Assure in substantial

quantities or to manage and expand the required infrastructure to do so, including large-scale laboratory and information technology systems. Maintaining and expanding market acceptance of our solutions, marketing, and laboratory capabilities are expensive and time-consuming. If MI Cancer Seek and Caris Assure are not successfully commercialized, we will not be able to recover the significant investment we have made in developing these solutions, and our business, prospects, financial condition, and results of operations would be harmed.

If we are unable to support demand for our MI Profile, Caris Assure platforms, and any other solutions we develop, including ensuring that we have adequate capacity to meet increased demand, or if we are unable to successfully manage our anticipated growth, our business could suffer.

As and to the extent the volumes of our current and new solutions continue to grow, we will need to simultaneously increase our capacity for sample intake, storage, and processing enhance our customer service, improve our billing and general processes, expand our internal quality assurance programs, incorporate new equipment, implement new technology systems and processes, expand laboratory capacity, and otherwise extend our operational capabilities to support comprehensive genomic analyses at a larger scale while retaining expected turnaround times. We will also need additional equipment and certified and licensed laboratory personnel to process higher volumes of solutions. We may face difficulties increasing the scale of our operations, including implementing changes in infrastructure or programs or acquiring additional equipment or personnel. As we refine our solutions and develop additional solutions, we may need to bring new equipment on-line, implement new systems, technology, controls and procedures, and hire personnel with different qualifications, licenses, or certifications.

We are also in the process of constructing additional facilities in order to increase capacity, including our laboratory facility in Irving, Texas. We may not be able to complete construction of such facilities and obtain necessary certifications, permits, licenses, and accreditations in a timely or cost-effective manner, or at all. Therefore, we may be unable to support our development and commercial activities in a timely manner, if at all. There is no assurance that any of these increases in scale, expansion of personnel, equipment, software and computing capacities or process enhancements will be successfully implemented, or that we will have adequate resources and facilities to accommodate such required expansion.

The value of our MI Profile and Caris Assure platforms, and related solutions will depend, in part, on our ability to perform tests and return test results to providers on a timely basis and at an appropriate quality standard, and on our reputation for such timeliness and quality. If our business grows too quickly, our ability to meet demand for our solutions in a timely and efficient manner could be challenged, and our quality standards or turnaround time may be compromised. Failure to implement necessary procedures, to transition to new equipment or processes, or to hire the appropriate, qualified personnel could result in higher costs of processing, longer turnaround times, declining product quality, deteriorating customer service, an inability to meet market demand, or slower responses to competitive challenges, all of which could make it difficult for us to meet market expectations for our solutions and could damage our reputation and the prospects for our business. There can be no assurance that we will be able to perform tests on a timely basis at a level consistent with demand, that we will be able to maintain the quality of our test results as we scale our commercial operations, or that we will be successful in responding to the growing complexity of our laboratory operations, including the related data analysis requirements.

As we grow, we expect to add new associates in our Phoenix and Tempe, Arizona and Irving, Texas facilities. We will need additional laboratory scientists, technicians, and other scientific and technical personnel with different qualifications, licenses, or certifications. As our development plans and strategies develop, and as we operate as a public company, we must add a significant number of additional managerial, operational, financial, and other personnel. Future growth will impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, retaining, and motivating employees;
- managing our internal development and commercialization efforts effectively, including creating and maintaining compliant programs and processes, such as a laboratory and manufacturing quality system, and managing the regulatory requirements for our solutions, while adhering with our contractual obligations to contractors and other third parties;
- expanding our operational, human resources, financial and management controls, reporting systems, and procedures; and
- managing the increasing complexity associated with a larger organization and expanded operations.

Our growth may place a significant strain on our management, operating and financial systems, R&D, and our sales, marketing, and administrative resources. As a result of our growth, our operating costs may escalate even faster

than planned, and some of our internal systems may need to be enhanced or replaced. If we cannot effectively manage our expanding operations and our costs, we may not be able to successfully commercialize future solutions and grow successfully, and our business could be adversely affected.

Our results of operations may fluctuate significantly, which makes our future results of operations difficult to predict and could cause our results of operations to fall below expectations or any guidance we may provide.

Our quarterly and annual results of operations may fluctuate significantly, which makes it difficult for us to predict our future results of operations. These fluctuations may occur due to a variety of factors, many of which are outside of our control, including, but not limited to:

- the level of demand for our solutions, which may vary significantly;
- the timing and cost of, and level of investment in, research, development, regulatory approval, or certification and commercialization activities relating to our solutions, which may change from time to time;
- the volume and customer mix of our solutions;
- the introduction of new solutions or solution enhancements by us or others in our industry;
- coverage and reimbursement policies with respect to our solutions and products that compete with our solutions;
- seasonal variations in patients' ordering of diagnostic tests or scheduling of medical procedures;
- expenditures that we may incur to acquire, develop, or commercialize additional solutions and technologies;
- changes in governmental regulations or in the status of our regulatory approvals or certifications or applications;
- future accounting pronouncements or changes in our accounting policies;
- developments or disruptions in the business and operations of physicians and our biopharma partners;
- the impact of natural disasters, political instability, including wars, terrorism, and political unrest, epidemics or pandemics, boycotts, and curtailment of trade and other business restrictions; and
- the effects of inflation or other general market and economic conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors.

Additionally, due to the inherent variability and unpredictability of the reimbursement landscape, including related to the amount that payers reimburse us for any of our solutions, when we recognize revenue we estimate the transaction price based on our historical collection experience and on the historical selling price of similar transactions, where applicable, and subsequent changes to the estimate of the transaction price are generally recorded as adjustments to revenue in the period where such changes occur. Both the estimate and any subsequent revision are uncertain and require the use of management's judgment in the estimation of the variable consideration and application of the constraint for such variable consideration. Due to this variability and unpredictability, previously recorded revenue adjustments are not necessarily indicative of future revenue adjustments from actual cash collections, which may fluctuate significantly. Moreover, we receive a substantial portion of our revenue from a limited number of third-party commercial payers. If one or more of these payers were to significantly reduce or cease to pay the amount such payer reimburses us for our solutions, or if such payer does not reach or maintain favorable coverage and reimbursement decisions for our solutions, it could have an adverse effect on our business, financial condition, and results of operations. We have experienced situations where commercial payers proactively reduced the amounts they were willing to reimburse for our solutions, and in other situations, payers have determined that the amounts they previously paid were too high and have sought to recover those perceived excess payments by deducting such amounts from payments otherwise being made. For additional information regarding risks associated with the reimbursement landscape, see "—If our solutions, or solutions we develop in the future, do not receive adequate coverage and reimbursement from third-party payers, including government and commercial payers, our ability to expand access to our solutions beyond our existing sales channels, and thus our overall commercial success, will be limited."

The cumulative effects of factors discussed above could result in large fluctuations and unpredictability in our quarterly and annual results of operations. As a result, comparing our results of operations on a period-to-period basis may not provide investors with a complete picture of the health of our business. Investors should not rely on our past results as an indication of our future performance.

This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our results of operations fall below the expectations of analysts or investors or below any guidance we may provide, or if the guidance we provide is below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide, and which could harm our business, financial condition, and results of operations.

If we do not have the support of KOLs or if clinical data using our solutions is not published in peer-reviewed journals or is otherwise not well received, it may be difficult to drive adoption and use of our solutions and establish them as a component of the standard of care for patients with cancer.

If Caris POA members or other KOLs within the broader precision oncology industry determine that our platforms, our existing solutions, or other solutions that we develop are not clinically effective, that alternative technologies are more effective, or if they elect to use internally developed products or services, we may see lower demand for our solutions and face difficulty establishing our solutions as an integral component of the applicable standard of care, which would limit our revenue growth and our ability to achieve or sustain profitability.

The publication of clinical data using our solutions in peer-reviewed journals is also crucial to our success. We are unable to control when, if ever, results are published, which may delay or limit broad adoption and use of our solutions. Our ability to publish clinical data relating to our solutions in peer-reviewed publications may be limited by many factors, including increased difficulty in obtaining acceptance for publication from journals, conflicts of interest, lack of qualified experts willing to participate in the peer review process, delays in the completion of, poor design of, or lack of compelling data from, validation studies or clinical trials, as well as delays in the review, acceptance, and publication process. If our solutions do not receive sufficient favorable exposure in peer-reviewed publications or are not well received by clinicians, the rate of clinician adoption and use of our solutions and positive reimbursement coverage determinations for our solutions, even if approved with guideline inclusion, could be adversely affected.

If our solutions, or solutions we develop in the future, do not receive adequate coverage and reimbursement from third-party payers, including government and commercial payers, our ability to expand access to our solutions beyond our existing sales channels, and thus our overall commercial success, will be limited.

Our revenue and commercial success depend on achieving coverage and reimbursement for assays that comprise our MI Profile and Caris Assure platforms, and any solutions we may offer in the future, from third-party payers, including both government and commercial payers. Obtaining approvals from third-party payers to cover our solutions and establishing adequate coding recognition and reimbursement levels is an unpredictable, challenging, time-consuming, and costly process, and we may not always be successful. Coverage determinations from third-party payers may depend on a number of factors, including a payer's determination that a solution is appropriate, medically necessary, and cost-effective. Each payer will make its own decision as to whether to establish a policy or enter into a contract to cover our solutions and the amount it will reimburse for such solutions. In addition, determinations by a payer whether to cover and the amount it will reimburse for our solutions are often made on an indication-by-indication basis. If we are unable to provide payers with sufficient evidence of the clinical utility and validity of our solutions, they may not provide coverage, may provide limited coverage, or may terminate coverage for our solutions, which will adversely affect our revenues and our financial condition. In addition, the fact that one of our solutions has been approved for reimbursement in the past does not guarantee that such solution will remain approved for reimbursement, that the approved reimbursement amount will not be reduced in the future, or that similar or additional solutions will be approved in the future. Moreover, there can be no assurance that any new solutions we launch will be reimbursed at rates that are comparable to the rates that we historically obtained for our existing portfolio or rates that other industry participants receive. Third-party payers may not cover or provide adequate payment for our current or future molecular and other solutions to enable us to maintain past levels of revenue or profitability with respect to such solutions. Further, third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on investment in the development of our solutions.

Healthcare providers may not order our solutions unless third-party payers cover and provide reimbursement rates for a substantial portion of the price of our solutions. If we are unable to obtain adequate coverage and an acceptable level of reimbursement for our solutions from third-party payers, patients could incur a greater co-insurance, co-payment, and/or deductible obligation. Uninsured patients or patients whose insurance does not cover our solutions may also be forced to pay for our solutions out-of-pocket. Such scenarios could dissuade physicians from ordering our solutions or, if ordered, could result in a delay in or decreased likelihood of our collection of payment. We thus believe our revenue and revenue growth will depend on our success in achieving and maintaining broad coverage and adequate reimbursement for our solutions from third-party payers.

In addition, the coding process used by third-party payers to identify various medical procedures during the billing process is complex, may not adapt well to the types of solutions we offer, and may not enable coverage and adequate reimbursement rates. Moreover, changes to the codes used to report our solutions to payers may result in significant changes in reimbursement.

Third-party payers are increasingly attempting to contain healthcare costs by limiting coverage of certain diagnostic tests and the amounts that they will pay for such tests. Payers may also create conditions for coverage or may contract with third-party vendors to manage laboratory benefits, in both cases creating administrative hurdles for ordering physicians and patients that may make our services more difficult to sell. U.S. and foreign governments continue to propose and pass legislation designed to reduce the cost of healthcare. In some foreign markets, the government controls the pricing of many healthcare products. In the United States, we expect that there will continue to be federal and state proposals to implement governmental controls or impose healthcare requirements, which may increase the pressure to reduce spending on genetic testing and comprehensive molecular profiling. In addition, the Medicare program and increasing emphasis on managed care in the United States will continue to put pressure on product pricing. Cost control initiatives could decrease the price that we would receive for any solutions in the future, which would limit our revenue and profitability.

Obtaining approvals from third-party payers to cover our existing and new solutions and establishing adequate coding recognition and reimbursement levels is an unpredictable, challenging, time-consuming, and costly process, and we may not always be successful. If third-party payers do not provide adequate coverage and reimbursement for our solutions, our ability to succeed commercially will be limited.

Medicare

Medicare is the single largest U.S. payer and a particularly important payer for many cancer-related laboratory services given the demographics of the Medicare population. Medicare coverage is limited to items and services that are within the scope of a Medicare benefit category that are reasonable and necessary for the diagnosis or treatment of an illness or injury. Medicare coverage criteria that define when items and services are reasonable and necessary are defined in National Coverage Determinations ("NCDs") made by CMS through an evidence-based process, with opportunities for public participation, and Local Coverage Determinations ("LCDs") made by Medicare Administrative Contractors ("MACs") that apply within the specific jurisdictions. Medicare's NCD for NGS (NCD 90.2), first established in 2018 and subsequently updated in 2020, provides national Medicare coverage for certain molecular diagnostic tests (1) performed in a laboratory certified by the Clinical Laboratory Improvement Amendments of 1988 ("CLIA"), (2) ordered by a treating physician, (3) the patient meets certain clinical and treatment criteria, including having recurrent, relapsed, refractory, metastatic, or advanced stages III or IV cancer, (4) the test is approved or cleared by the FDA as a companion IVD for an FDA-approved or -cleared therapeutic for use in that patient's cancer, and (5) results are provided to the treating physician for management of the patient using a report template to specify treatment options. The NGS NCD also provides discretion to the MACs to provide local coverage of other NGS tests for cancer patients only when the test is performed by a CLIA-certified laboratory, ordered by a treating physician and the patient meets the same clinical and treatment criteria required of nationally covered NGS tests under the NGS NCD. Palmetto GBA is the MAC responsible for administering MolDX, which issues coverage determinations applicable to molecular diagnostic tests within the scope of the program, including for molecular assays that are LDTs. Our MAC for the Phoenix laboratory locations is Noridian, and Noridian relies on MolDX to make local coverage and pricing determinations relating to molecular testing. To achieve coverage under MolDX, laboratories must apply for and obtain a DEX Z-Code that is unique to the laboratory's specific test and must also submit a technical assessment to demonstrate analytical and clinical validity, and clinical utility at a level that meets the Medicare reasonable and necessary requirement. Analytical validity relates to technical performance, such as that an assay accurately and reliably measures a specific feature. Clinical validity means whether a test can accurately identify, measure, or predict a clinical condition or characteristic in patients.

We received a PMA approval for MI Cancer Seek from the FDA in November 2024 and commercially launched the solution in January 2025. We have obtained Medicare coverage under the NGS NCD for MI Cancer Seek for CPT code 0211U at $8,455 under the CLFS.

Our MI Tumor Seek Hybrid solution is covered for solid tumor testing as allowable under the NGS NCD and related LCD and are reported to Medicare with unlisted molecular pathology CPT code 81479 and the unique DEX Z-Code identifier issued by MolDX. MI Tumor Seek Hybrid is covered by Medicare as of August 3, 2022, with current MolDX pricing of $3,500.

Our Caris Assure solution is currently reported to Medicare using a PLA code, CPT code 0485U, and a unique DEX Z-Code identifier issued by MolDX. Caris Assure is covered for therapy selection by Medicare as of December 8, 2023 for Comprehensive Genomic Profiling from ctDNA of patients with recurrent, relapsed, refractory, metastatic, or advanced solid tumors who are seeking treatment, and for whom tissue-based, comprehensive genomic profiling ("CGP") is infeasible (for example, quantity not sufficient for tissue-based CGP or invasive biopsy is medically contraindicated), with current MolDX pricing of $3,649. In November 2024, CMS determined to price Caris Assure for therapy selection using the

"Gapfill" method, which resulted in Caris Assure for therapy selection being listed on the CLFS at pricing of $3,649, commencing in 2026.

Immunohistochemical Tests

As part of our MI Profile solution, we perform certain third-party IHC tests. Medicare coverage and payment for these tests is under the Molecular Pathology Procedures Billing and Coding Article, with payment amounts assigned to specific HCPCS and CPT codes.

Protecting Access to Medicare Act

Medicare payment for clinical diagnostic laboratory tests ("CDLTs") is generally made under the CLFS based on payment rates that are assigned to specific HCPCS or CPT codes. Under the Protecting Access to Medicare Act of 2014 ("PAMA"), laboratories that meet certain requirements related to volume and type of Medicare revenues are required to report to CMS, beginning in 2017 and every three years thereafter, their private payer payment rates and volume for each test they perform that is reported with a specific HCPCS code (defined by PAMA to exclude miscellaneous or unlisted codes). We are subject to these reporting requirements under PAMA for any solution we perform that is not reported with a miscellaneous HCPCS or CPT code, including the third-party IHC tests we perform, and for any profiling solutions that commercial payers currently require us to report using a HCPCS code that has been identified by CMS as subject to PAMA reporting requirements. In addition, MI Cancer Seek, which is reported with PLA code 0211U, Caris Assure, which is reported using PLA Code 0485U, and any other solution for which we obtain a specific HCPCS or CPT code, will be subject to these reporting requirements in future PAMA reporting cycles, and that the Medicare CLFS payment rates for such solutions will be calculated in the future based on our private payer rates. Congress passed legislation that delayed data reporting requirements for CDLTs and further delayed the phase-in of payment reductions under the CLFS from private payer rate implementation. Any reductions to reimbursement rates resulting from the new methodology are limited to 0% in 2025 and 15% per test per year in each of 2026 through 2028. The subsequent data reporting periods for CDLTs will occur in three-year cycles, with the next cycle beginning in 2026. CLFS rates for CDLTs will be updated every three years. For many tests and/or laboratories, the result of the PAMA pricing methodology has been lower pricing and reimbursement. As a result, our Medicare CLFS pricing for any solutions that may be subject to PAMA reporting requirements in the future could be negatively impacted by PAMA. In addition, private payer payment levels have more significance in setting Medicare reimbursement and, therefore, future Medicare payments may fluctuate more often and become subject to the willingness of private payers to recognize the value of diagnostic tests generally and any given test individually. Given the many uncertainties built into PAMA's price-setting process, we cannot predict how payments we receive under the CLFS, and thus our revenue, may change from year to year.

In addition to the reporting requirements and pricing methodology described above, PAMA codified Medicare coverage rules for laboratory tests by requiring any local coverage determination to be made following the local coverage determination process. PAMA also authorizes CMS to consolidate coverage policies for clinical laboratory tests among one to four laboratory specific MACs. These same contractors may also be designated to process claims if CMS determines that such a model is appropriate. It is unclear whether CMS will proceed with contractor consolidation under this authorization.

Molecular Signature Tests, and Screening and Early Detection Intended Uses for Our Solutions

Our proprietary molecular signature tests, GPSai and FOLFIRSTai, as well as early detection indications for our blood and tissue-based profiling solutions, are not currently covered by Medicare. Obtaining Medicare coverage for these molecular signatures would require significant investments and may ultimately be unsuccessful or may take several years to achieve.

In addition, we are developing screening capabilities for Caris Assure for MRD tracking and treatment monitoring in colorectal cancer ("CRC"), breast cancer, lung cancer, and other indications. On January 19, 2021, CMS released an NCD that covers future tests for CRC screening if and when such screening tests have FDA approval and meet pre-specified CMS criteria. In addition, MolDX LCDs provide coverage for MRD for CRC, breast cancer, lung cancer, and other indications when applicable coverage criteria are satisfied. While this NCD and applicable LCDs may provide a pathway to coverage of Caris Assure in CRC and other indications under Medicare if applicable coverage criteria are satisfied, and we successfully obtain MolDX approval, there is no assurance that we will be successful in completing the required studies, trials, or publications or obtaining FDA approval, or obtaining Medicare coverage, and if we are not successful, our business, financial condition, and results of operations would be harmed.

Commercial Payers and Other Payers

Our commercial success also depends on achieving acceptable coverage and reimbursement for our solutions from commercial payers. When we contract with a payer as a participating provider, reimbursements by the payer are generally made pursuant to a negotiated fee schedule and are limited to only covered indications, and in many cases require prior authorization. Becoming a participating provider can result in higher reimbursement amounts for covered uses of our solutions and, potentially, no reimbursement for non-covered uses identified under the payer's medical policies or the contract. Although we are a participating provider with many commercial payers, certain payers may not cover based on existing medical policy and may treat our solutions or solutions that we develop in the future as experimental and investigational or import restrictive coverage criteria. If we are not successful in obtaining coverage from such payers, or if other payers issue non-coverage policies or change their coverage policies, our business, financial condition, and results of operations could be adversely affected.

Because current codes applicable to our solutions are not always test-specific, each insurance claim will have different submission criteria, including appending our DEX Z-Code, and typically must be examined to determine what test was provided, whether the test was appropriate and medically necessary, and whether payment should be rendered, which may require progress notes, medical records, or a letter of medical necessity from the ordering physician. This process can result in a delay in processing the claim, a lower reimbursement amount or denial of the claim. As a result, obtaining approvals from third-party payers to cover our solutions and establishing adequate reimbursement levels is an unpredictable, challenging, time-consuming, and costly process, and we may never be successful in obtaining such approvals.

Some payers have implemented, or are in the process of implementing, laboratory benefit management programs, often using third-party benefit managers to manage these programs. The stated goals of these programs are to help improve the quality of outpatient laboratory services, support evidence-based guidelines for patient care and lower costs. The impact on laboratories, such as ours, of active laboratory benefit management by third parties is unclear, and we expect that it would have a negative impact on our revenue in the short term. Payers may resist reimbursement for our solutions in favor of less expensive tests, require pre-authorization for our solutions, or impose additional pricing pressure on, and substantial administrative burden on, reimbursement for our solutions. We expect to continue to focus substantial resources on increasing adoption of, and coverage and reimbursement for, our current solutions and any future solutions we may develop. We believe it may take several years to achieve broad coverage and adequate contracted reimbursement with a majority of payers for our new solutions. However, we cannot predict whether, under what circumstances, or at what price levels payers will cover and reimburse our existing and future solutions. If we fail to establish and maintain broad adoption of, and coverage and reimbursement for, our solutions, our ability to generate revenue could be harmed and our business, financial condition, and results of operations could be adversely affected.

Even where we establish relationships with commercial payers to provide our future solutions at negotiated rates, such agreements do not obligate any healthcare providers to order our solutions or guarantee that we would receive reimbursement for our solutions from these or any other payers at adequate levels. Thus, these payer relationships, or any similar relationships, may not result in acceptable levels of coverage and reimbursement for our solutions, or meaningful increases in the number of billable tests we perform. In addition to the available Medicare coverage for therapy selection, we plan to market Caris Assure platform for early detection, MRD tracking, and treatment monitoring, as well as other solutions that we are developing or may develop in the future, to large self-insured employers, commercial insurance plans, certain physician directed channels, concierge medicine and executive health programs, and innovative health systems. Additionally, a third-party payer's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future.

Our billing, collections, and claims processing activities are complex and time-consuming, and any delay in transmitting and collecting claims or failure to comply with applicable billing requirements could have an adverse effect on our future revenue.

Depending on the billing arrangement and applicable law, we bill and expect to bill various payers, such as governmental payers, insurance companies, hospitals, and patients, which may each have different billing requirements. We may face increased risk in our collection efforts, including long collection cycles and the risk that we never collect at all, either of which could adversely affect our business, financial condition, and results of operations.

Our failure to timely submit claims for our solutions to payers or failure to comply with applicable billing requirements could have an adverse effect on our revenue and our business, and could result in our inability to receive payment for our services or in attempts by private payers and state and federal healthcare programs, such as Medicare and Medicaid, to recover payments already made. Submission of claims in violation of billing requirements and applicable laws and regulations can result in recoupment of payments already received, substantial civil monetary penalties, and exclusion from state and federal health care programs, and can subject us to liability under the federal False Claims Act (the "FCA") and similar laws. For example, in March 2025, we received a Civil Investigative Demand ("CID") from the DOJ in connection with an investigation under the False Claims Act regarding our compliance with Medicare's date of service rule (also referred to as the 14-day rule). For additional information, see " —We have been, are currently, and in the future may be the subject of government investigations, claims, audits, whistleblower and payer audits, overpayment and recoupment efforts and other litigation in the course of our business that could adversely affect our business and financial results" and Part II, Item 1. "Legal Proceedings." The failure to report and return an overpayment to the Medicare or Medicaid program within 60 days of identifying its existence can also give rise to liability under the FCA. Further, a government agency could attempt to hold us liable for causing the improper submission of claims by another entity for services that we performed if we were found to have knowingly participated in the arrangement at issue.

In addition, our claims for reimbursement may be denied and we may have to appeal such denials in order to get paid. Such appeals may not result in payment and can be time-consuming and costly. Moreover, payers often perform audits of historically paid claims and regularly attempt to recoup funds years after the funds were initially distributed if the payers believe the funds were paid in error or determine that our solutions were medically unnecessary. If a payer's audit of our claims results in a negative finding, and we are unable to reverse the finding through appeal or subsequent litigation, any subsequent recoupment could have an adverse effect on our revenue. Additionally, in some cases commercial payers for whom we are not a participating provider may elect at any time to review claims previously paid and determine the amount they paid was excessive. In these situations, the payer typically notifies us of its decision and then offsets the amount it determines to be overpaid against amounts it owes us on current claims. We may not have a mechanism to dispute these retroactive adjustments, and we cannot predict when, or how often, a payer might engage in these reviews. We have been, are currently, and may in the future be, subject to overpayment demands, recoupment efforts, and related disputes from or with payers, managed care plans, and government healthcare programs relating to the billing and coding of our solutions.

Furthermore, we maintain financial assistance programs under which we assess patient financial need and offer to provide solutions at a discount, or at no cost, to certain eligible patients. These practices may result in scrutiny of our financial assistance programs by governmental and commercial payers and could result in recoupment actions or termination of coverage of our solutions, as well as scrutiny under health care fraud and abuse laws. For additional information, see "—We have been, are currently, and in the future may be the subject of government investigations, claims, audits, whistleblower and payer audits, overpayment and recoupment efforts and other litigation in the course of our business that could adversely affect our business and financial results" and "Item 1. Legal Proceedings."

We currently handle our own billing and coding for our solutions but use a a vendor for revenue cycle management services, such as billing and coding software and other related operations. Our business, financial condition, and results of operations may be affected by the ability of us and our vendor to timely, accurately, and appropriately code and bill claims and collect payments in compliance with the stringent billing, coding and documentation requirements imposed by government healthcare programs and other payers. Terminating or transitioning arrangements with revenue cycle management vendors could result in additional costs and a risk of operational problems, delays in collections from payers, potential errors and possible control issues during the termination and transition processes, any of which could adversely affect our business, financial condition, and results of operations.

We rely on a limited number of third-party suppliers or, in many cases, sole suppliers, for some of our next-generation sequencers, lab materials, reagents, and supplies, and we may not be able to find replacements or immediately transition to alternative suppliers if necessary.

We rely on Illumina, Inc. ("Illumina") as the sole supplier of NGS instruments and the associated sequencing reagent kits for our solutions. Illumina is also the sole provider of maintenance and repair services for these sequencing instruments. Without access to these sequencers, we may be unable to run our solutions and commercialize our solutions. Additionally, we rely on several sole suppliers, including, among others, Roche Diagnostics Corporation ("Roche"), Gene Link, Inc., Life Technologies (operated by Thermo Fisher Scientific), and Agilent Technologies, Inc. ("Agilent"), for certain lab materials, reagents, and supplies. If we do not have timely access or access to sufficient quantities of these lab materials, reagents, and supplies, we may be unable to run our solutions and commercialize our solutions. We also rely on several sole suppliers, or manufacturers, for blood collection tubes, including the cfDNA

PAXgene tubes for use with liquid biopsy profiling, for total nucleic acid extraction kits, and for the NGS panels and library preparation kits we use. Given the specialized function of certain instruments and reagents, suitable replacements may not be available if a product is discontinued or the product specification undergoes substantial changes due to their own external competition or otherwise. This may significantly delay our ability to continue to develop and commercialize any other future commercial products. All changes to instruments, associated software and reagents will undergo a risk evaluation to determine the level of validation required per the product regulatory status and may require supplementary submissions to, and approval of, regulatory agencies such as the FDA. Whether transitioning to a new supplier, instrument or reagent, the process is likely to be time-consuming, expensive and could affect test performance metrics.

We have obtained a PMA approval from the FDA for MI Cancer Seek and may decide to seek FDA approval for Caris Assure for therapy selection and additional solutions. We do not manufacture the instruments or reagents used with our solutions, nor do we control such processes, and we rely on external suppliers to maintain development and commercialization activities. The molecular testing performed by us is highly complex and requires specialized instruments and reagents, some of which are considered critical and could not be substituted without significant impact to our operations. Any failures or delays in negotiating appropriate agreements with our suppliers on reasonable terms, or their inability to obtain any required marketing authorizations, may increase our costs or delay or prevent us from obtaining or maintaining FDA marketing authorization of the related solutions.

Our current suppliers may also discontinue or substantially change the specification of products that we use or intend to use in our solutions. We believe there are few other manufacturers that are currently capable of supplying and servicing the equipment and materials necessary for our laboratory operations, including certain instruments, components, consumables, and reagents. Transitioning to a new supplier for this equipment or these materials would be time-consuming and expensive, could result in interruptions in or otherwise affect the performance specifications of our laboratory operations and sample processing or could require that we revalidate our solutions and could require a new submission to the FDA and other regulatory bodies to authorize such changes for any of our solutions that have received FDA approval. We also cannot guarantee that we will appropriately prioritize or select alternative suppliers, where necessary. In addition, we do not have written supply agreements with certain of our suppliers, including Agilent and PAXgene, and instead purchase certain products on a purchase order basis, which exposes us to potential price increases and termination of supply without notice or recourse. We cannot guarantee a consistent source of supply and cannot assure you that any efforts to enter into written agreements with our suppliers will be successful. The use of equipment or materials provided by a replacement supplier could require us to alter our laboratory operations and sample collection and processing and related procedures. Moreover, replacement instruments and associated reagents, tubes, and panels that meet our quality control and performance requirements may not be available at all, or may not be available on reasonable terms or in a timely manner. If we encounter delays or difficulties in securing, reconfiguring, or revalidating the equipment, reagents, and other materials that we require for our solutions, laboratory operations and same collection and processing, in particular for those products that are sole sourced, we would likely face significant disruptions or delays in commercializing our solutions and our business, financial condition, results of operations, and growth prospects would be adversely affected.

If we seek and fail to obtain additional financing, we may be unable to execute on our business strategies and our growth prospects could be harmed.

Our operations have required substantial amounts of cash since our inception. The development of our solutions is expensive, and we expect to continue to spend substantial amounts as we continue to enhance our solutions, broaden the applications of our existing solutions, and develop new solutions. In addition, obtaining any necessary or desirable marketing authorizations for our solutions will require substantial additional funding.

We may consider raising additional capital in the future to expand our business, meet existing obligations, pursue acquisitions or strategic investments, take advantage of financing opportunities, or for other reasons, including to:

- increase our sales and marketing efforts to drive market adoption of our current solutions and address competitive developments;
- fund development and marketing efforts of new solutions or any other future solutions;
- expand our technologies into other types of cancer management and detection solutions for other chronic disease states;
- acquire, license, or invest in our existing and future technologies;
- acquire or invest in complementary businesses or assets; and
- finance capital expenditures and general and administrative expenses.

As of September 30, 2025, we had $753.2 million of cash and cash equivalents and $2.3 million of short-term marketable securities. We could use our available capital resources sooner than we expect, including due to changing circumstances or those beyond our control that may cause us to increase our spending significantly faster than we anticipate, requiring us to raise additional funds sooner than we anticipate. Our future capital requirements depend on many additional factors, including:

- the cost of development and commercialization activities, including marketing and sales, for our solutions;
- our ability to achieve revenue growth;
- the cost related to scaling operating capabilities to support demand for our solutions, including the cost of completing the build-out of our laboratory in Irving, Texas;
- the timing of, and the costs involved in, obtaining any required or desired marketing authorizations for our solutions;
- the timing, scope, progress, results and costs of developing additional solutions, and of conducting validation studies, clinical trials, and other studies that may be required in order to market our solutions;
- the costs involved in obtaining, maintaining, protecting, and enforcing patent and other intellectual property rights and claims, including litigation costs and the outcome of such litigation;
- the timing and amount of sales of our solutions, if any, and collection of related receivables;
- the extent to which our solutions are eligible for coverage and reimbursement from third-party payers and government payers;
- the emergence of new technologies, scientific breakthroughs, or any competing tests, products, or services, and other adverse market developments; and
- other potential adverse developments.

Additional capital may not be available when we need it, on terms acceptable to us or at all. We have no committed source of additional capital. Furthermore, any additional capital raised through the sale of equity or equity-linked securities will dilute shareholders' ownership interests in us, may require shareholder approval, may have an adverse effect on the price of our common stock, and holders of these securities may have rights, preferences, or privileges senior to those of our then-existing shareholders. Debt financing, if available, may include restrictive covenants that could limit how we conduct our business. Our ability to incur additional indebtedness also is currently restricted by the terms of our 2023 Term Loan Agreement (as defined below). If adequate capital is not available to us on a timely basis, we may be required to significantly delay, scale back, or discontinue the commercialization of our solutions or R&D programs, or be unable to continue or expand our operations or otherwise capitalize on our business opportunities, as desired, which could adversely impact our business, financial condition, and results of operations and cause the price of our common stock to decline.

If our facilities or those of our third-party collaborators are insufficient or become inoperable, our ability to provide our solutions will be significantly impaired and our business will be harmed.

We currently perform all R&D and commercial profiling in our multiple laboratories in Phoenix and Tempe, Arizona and are building out our newest facility in Irving, Texas. Any disruption to the operations of these facilities could compromise the integrity of our samples and impede our ability to accurately perform our profiling and ultimately adversely impact our reputation, business, financial condition, and results of operations. In addition, we may maintain samples for several years. It is possible that some, if not all, of these samples may degrade over time, which could negatively impact our ability to use such samples for research and development or to validate future solutions, and which could adversely impact our business, financial condition, and results of operations.

One or more of our facilities may be harmed, rendered inoperable by physical damage or otherwise become partially or completely unusable due to fire, floods, earthquakes, power loss, telecommunications failures, break-ins, accidents, water shortages, floods, tornadoes, hurricanes, fires, extreme weather conditions, health epidemics, pandemics, and similar events, which may render it difficult or impossible for us to provide our solutions for some period of time. Our laboratories and the equipment we use to perform our R&D or commercialization work could be unavailable or costly and time-consuming to repair or replace. It would be difficult, time-consuming, and expensive to rebuild one of our facilities, particularly in light of the licensure, permits, and accreditation requirements for clinical laboratories like ours. Although we carry insurance for damage to our properties and the disruption of our business, this insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, or at all.

We have started the process of constructing a new laboratory facility in Irving, Texas to increase product development and operational capacity. Such construction requires significant resources, and we may encounter

difficulties and delays in construction, procuring laboratory equipment, obtaining necessary validation, permits, licenses, and certifications (including CLIA certification and College of American Pathologists ("CAP") accreditation, or completing the technology implementation) for this new facility. If we are unable to complete construction and go-live in a timely and satisfactory manner, obtain the necessary permits, licenses, certificates, and accreditations within our currently anticipated timelines, or meet demand for our solutions at our Arizona facilities, on a timely basis or at all, our reputation and commercial activities would be negatively impacted. We may be unable to regain customers or repair our reputation in the future, which would negatively impact our business, financial condition, and results of operations.

We also rely on our third-party collaborators, consultants, contractors, vendors, suppliers, and service providers. The facilities of these partners could be subject to fire, floods, earthquakes, power loss, telecommunications failures, break-ins, accidents, water shortages, floods, tornadoes, hurricanes, fires, extreme weather conditions, health epidemics, pandemics and other natural or man-made disasters or business interruptions. In addition, they may be affected by government shutdowns, changes to applicable laws, regulations, and policies, or withdrawn funding. The occurrence of any of these business disruptions could seriously harm their ability to complete their contracted services to us, which may adversely impact our business, financial condition, and results of operations.

If our solutions result in direct or indirect patient harm or injury, we could be subject to significant reputational and liability risks, and our business, financial condition, and results of operations could suffer.

Our success depends on the market's confidence that our solutions, including MI Profile, MI Cancer Seek, Caris Assure, MI Tumor Seek Hybrid, GPSai and other solutions that we may develop in the future, can provide reliable and high-quality results. We believe that patients, physicians, and regulators are likely to be particularly sensitive to errors in the use of our solutions or failure of our solutions to perform as described, and there can be no guarantee that our solutions will meet their expectations. Performance failures could establish a negative perception of our solutions among physicians, patients, and regulators, jeopardize our ability to successfully commercialize our solutions, impair our ability to obtain marketing authorizations or secure favorable coverage and reimbursement, or otherwise result in reputational harm. The costs incurred in correcting any defects or errors may be substantial and could adversely affect our operating margins. Identifying the root cause of quality issues, particularly those affecting reagents and third-party components, may be difficult, which increases the time needed to address quality issues as they arise, and increases the risk that similar problems could recur. In addition, we may be subject to legal claims arising from any errors in the use, manufacture, design, labeling or performance of our solutions, including any false-positive or false-negative results.

Our anticipated application of Caris Assure for early detection, MRD tracking, and treatment monitoring poses additional risks. Caris Assure for early detection can be used to detect cancers in patients. A detection of cancer by Caris Assure would need to be followed up with a cancer diagnosis by a physician. Because Caris Assure may not detect all forms of cancer, a negative test would not rule out the presence of cancer. Additionally, an individual undergoing further diagnostic procedures on the basis of a false-positive result or an erroneous cancer lineage could expose us to significant liability and reputational risks, notwithstanding the emotional and mental health effects to which the patient may be exposed. Similarly, an individual who receives a cancer diagnosis shortly following an inaccurate result, such as a negative test or false negative result, may create adverse publicity about our solutions, which could damage our reputation and have a negative impact on our business, financial condition, and results of operations. Failure to accurately detect cancer and other performance failures could establish a negative perception of our solutions among physicians, patients, customers, and regulators, jeopardize our ability to successfully commercialize our solutions, impair our ability to obtain marketing authorizations or secure favorable coverage and reimbursement, or otherwise result in reputational harm or enforcement action or inquiry by a regulatory body. These risks may be more pronounced and could expose us to claims of injury or other adverse events under medical liability, product liability, or other liability laws if a provider uses our tests inaccurately or inappropriately for diagnosis purposes, as our solutions would be directly involved with the choice to use certain treatments. In addition, we may be subject to legal claims arising from any errors in the use, manufacture, design, labeling, marketing, or performance of our products, including from inaccurate results. If our solutions result in direct or indirect participant or patient harm or injury, we could be subject to significant reputational and liability risks, may be required to initiate corrective actions, recalls or suspend sales of our products, which may adversely impact our reputation, business, financial condition, and results of operations.

If we were to be sued for product liability or professional liability, we could face substantial liabilities that exceed our resources, including any insurance coverage.

The marketing, adoption, and use of our solutions could lead to the filing of product liability claims if someone alleges that our solutions identified inaccurate or incomplete information regarding the genomic alterations of the tumor or malignancy analyzed, reported inaccurate or incomplete information concerning the available therapies for a certain

type of cancer, or otherwise failed to perform as designed. We may also be subject to professional liability for errors in, a misunderstanding of, or inappropriate reliance upon, the information we provide in the ordinary course of our business activities. A product liability or professional liability claim could result in substantial damages and be costly and time-consuming for us to defend.

We maintain product and professional liability insurance, but this insurance may not fully protect us from the financial impact of defending against product liability or professional liability claims. Any product liability or professional liability claim brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage in the future. Additionally, any product liability or professional liability lawsuit could damage our reputation or cause current clinical customers to terminate existing agreements with us and potential clinical customers to seek other partners, any of which could adversely impact our business, financial condition, and results of operations.

Our business and results of operations will suffer if we fail to compete effectively.

The precision oncology industry, which is the focus of our current commercial portfolio, is intensely competitive. Our competitors include numerous companies offering or seeking to offer tissue-based molecular profiling, blood-based early detection, blood-based molecular profiling for therapy selection, MRD tracking, and/or treatment monitoring, core biopharma services, and genomic data and AI services to biopharma companies. Our competitors have or may have substantially greater financial, technical, and other resources, such as larger R&D staff and more well-established marketing and sales forces. Our competitors may succeed in developing, acquiring, or licensing, on an exclusive basis or otherwise, tests or services that are more effective or less costly than our solutions. In addition, established medical technology, biotechnology, or biopharma companies, some of whom may be our customers, may invest heavily to accelerate discovery and development of tests that could make our solutions less competitive than we anticipate.

Our ability to compete successfully will depend largely on our ability to:

- successfully commercialize and expand the features of our solutions and develop new solutions to achieve meaningful innovation in precision oncology and other chronic disease states;
- demonstrate and validate compelling advantages in the performance and convenience of our solutions, including on a cost competitive basis;
- achieve market acceptance of our solutions by patients and healthcare providers;
- the rate of adoption and/or endorsement of our solutions by clinicians, KOLs, advocacy groups, and biopharma companies;
- achieve adequate coverage and reimbursement recognition from governmental payers, health insurance organizations, and other third-party payers for our solutions;
- address any technological, scientific, and market developments to differentiate our solutions from products and services offered by current and potential competitors;
- attract qualified scientific, data science, clinical development, solution development, and commercial personnel;
- obtain, maintain, defend, and enforce patent and other proprietary protection as necessary for our solutions and platform;
- obtain and maintain any necessary or desirable marketing authorizations from regulators in the United States and other jurisdictions for any versions of our current solutions and any future solutions that we may develop;
- successfully collaborate with institutions in the discovery, development, and commercialization of our solutions;
- establish and maintain supply and manufacturing relationships with third parties that can timely and consistently provide adequate, in both amount and quality, products and services to support clinical development and the market demand for our solutions; and
- successfully expand our operations infrastructure and implement a successful sales and marketing strategy to support increased commercialization.

We may not be able to compete effectively or keep pace with the rapid rate of change in our industry if we are unable to accomplish one or more of these or similar objectives. This could render our solutions obsolete or less attractive, result in significant price reductions, or substantially limit the volume of products that we offer.

Failure of, or defects in, our AI/ML models and on-premise, co-located, and cloud-based computing infrastructure, including interruption of services through Amazon Web Services, or increased regulation in the AI/ML space, could impair our ability to process our data, develop solutions, or provide test results, and harm our business and results of operations.

The design, development, maintenance, and operation of our technology over time is expensive and complex, and may involve unforeseen difficulties including material performance problems, undetected defects, or errors.

Overcoming technical obstacles and correcting defects or errors could prove to be impossible or impracticable, and the costs incurred may be substantial and adversely affect our business, financial condition, and results of operations. Additionally, regulation in the AI/ML space is constantly evolving. See "—Regulatory, social and ethical issues relating to our use of new and evolving technologies, such as AI and ML, may result in reputational harm, additional costs, and liability." If our technology does not function reliably, fails to meet expectations in terms of performance, or cannot be fully utilized due to increasing regulation, including regulation by the FDA of AI or medical device software, we may be unable to provide, or our customers may stop using, our solutions.

We currently host our data on, and conduct certain data analysis through, Amazon Web Services ("AWS") cloud-based hosting facilities as well as on our own co-located or on-premise computing infrastructure. Any technical problems or outages that may arise in connection with AWS's or our data center hosting facilities, such as the recent AWS outage, could result in operational disruption, loss of our data or delayed or ineffective data processing. A variety of factors, including infrastructure changes, human or software errors, viruses, malware, security attacks, fraud, denial of service or technical support issues could cause interruptions in our service. Such service interruptions may reduce or inhibit our ability to provide our solutions, delay our clinical trials, and damage our relationships with our customers. We could also be exposed to potential lawsuits, customer reputational impact, liability claims or regulatory actions, for example, if AWS or we experienced a privacy or data security breach. If we were required to transfer our data to an alternative hosting provider, the transfer and acclimation to the new provider could result in significant business delays and subject us to technological risks and require additional resources.

Regulatory, social and ethical issues relating to our use of new and evolving technologies, such as AI and ML, may result in reputational harm, additional costs, and liability.

We utilize AI/ML algorithms for data analysis of patient information and other data. As with many cutting-edge innovations, AI and ML present new risks and challenges, including social and ethical issues and a quickly evolving legal and regulatory environment, which may cause us to incur increased compliance or R&D costs, or to divert resources from other development efforts. Regulation of AI/ML usage continues to evolve, and limitations placed on the use of data, including personal information, health data, or genetic/genomic data in such systems may make it difficult or more costly for us to continue using our ML algorithms. Existing laws and regulations may be interpreted to apply to us in new ways due to our use of AI and ML, the nature and extent of which are difficult to predict. The risks and challenges presented by AI and ML could undermine public confidence in AI and ML, which could slow its adoption, impact patients' and physicians' confidence in our solutions, and otherwise affect our business. Failure to adequately address ethical and social issues related to our use of AI/ML could adversely affect the adoption of our solutions and subject us to reputational harm, regulatory action, or legal liability, which may harm our financial condition and results of operations.

Potential government regulation related to AI ethics or usage may also increase the burden and cost of R&D in this area. Certain U.S. states have passed or are considering the passage of laws intended to regulate and/or require disclosures in connection with the usage of AI, including in interactions with customers or other market participants. For example, Colorado passed the Colorado Artificial Intelligence Act, which will require disclosures and compliance efforts associated with different uses of AI, and Utah passed the Utah Artificial Intelligence Policy Act, which requires certain disclosures to customers and confirms companies' responsibility for legal violations caused by their AI applications. Other states have passed laws regulating the use of AI in patient-facing communications, generation of medical reports,claims processing, and other areas that may in the future apply to or impact our business. It is possible that these or other states or the federal government could pass additional legislation or implement regulations further impacting businesses' use of AI/ML, which could impact our operations and impose additional costs or liability on us. Additionally, employees or customers who are dissatisfied with our public statements, policies, practices, or solutions related to the development and use of AI and ML may express opinions that could introduce reputational or business harm, or legal liability.

We use AI/ML to assist us in making certain diagnostic and benefit prediction decisions, which AI/ML is regulated by certain privacy laws. Due to inaccuracies or flaws in the training, development, inputs, outputs, and logic of an AI/ML model, the model could be biased. Any bias in a model could result in limits on the applicability or accuracy of the model across patient populations or could lead us to make decisions that could disadvantage certain individuals (or classes of individuals) and adversely impact their rights, employment, and ability to obtain certain pricing, products, services, or benefits.

We are highly dependent on our key personnel, and if we lose key members of our senior management, scientific or technical teams or are not successful in attracting, motivating, and retaining highly qualified personnel, we may not be successful.

Our ability to compete in the competitive precision medicine industry depends upon our ability to attract, motivate, and retain highly qualified personnel. We are particularly dependent on key members of our senior management team, including David D. Halbert, our Founder, Chairman, and Chief Executive Officer. The loss or incapacity of existing members of our senior management team could adversely affect our operations if we experience difficulties in hiring qualified successors and could hamper or delay the development and commercialization of our solutions and harm our business, financial condition, and results of operations. We do not maintain "key person" insurance policies on the lives of these individuals or the lives of any of our other employees.

Our R&D programs and laboratory operations depend on our ability to attract and retain highly skilled scientists, technicians, and data scientists. We may not be able to attract or retain qualified scientists and technicians in the future due to the competition for qualified personnel among life science businesses. We also face competition from universities and public and private research institutions in recruiting and retaining highly qualified scientific personnel. In addition, we may have difficulties locating, recruiting, or retaining qualified sales representatives and business development managers. Recruiting and retention difficulties can limit our ability to support our R&D and sales programs.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we provide equity incentive grants with vesting conditions. The value of these equity grants may be significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers made to our employees from other companies. Although we have employment agreements with certain key employees, consistent with all of our employment arrangements, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. If we are unable to attract and incentivize highly qualified personnel on acceptable terms, or at all, our business, financial condition, and results of operations may suffer.

If our information technology systems or those of third parties with whom we work, or our data are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions, litigation, fines and penalties, disruptions of our business operations, reputational harm, loss of revenue or profits, and other adverse consequences.

In the ordinary course of our business, we and the third-parties with whom we work collect, store, receive, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, "Process") personal information, including health-related information, individually identifiable health information and protected health information ("PHI") as defined by the Health Insurance Portability and Accountability Act, as amended by the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations (collectively, "HIPAA"), personally identifiable information, credit card and other financial information, and intellectual property and proprietary business information (collectively "Sensitive Information").

As a result, we and the third parties with whom we work face numerous and evolving cybersecurity risks that threaten the confidentiality, integrity, and availability of our information technology and telecommunications systems and Sensitive Information. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including telecommunications or network failures, malicious human acts, and natural disasters.

We and the third parties with whom we work are subject to threats from various threat actors, such as state-sponsored organizations, criminal threat actors, organized crime outfits, opportunistic hackers and "hacktivists," as well as a variety of evolving threats, such as social engineering/phishing (including through deep fakes, which may be increasingly more difficult to identify as fake), malware (including ransomware and as a result of advanced persistent threat intrusions), network reconnaissance and intellectual property theft, use of illegitimate virtual private networks or anonymization tools, malfeasance by insiders (such as personnel misconduct or error), human or technological error, malicious code (such as viruses and worms), denial-of-service attacks, database compromises, business email compromises, credential stuffing, credential harvesting, credential theft, software "bugs," misconfigurations, or other vulnerabilities in software that is integrated into our (or the third parties with whom we work) IT systems, misuse of company resources and software, lack of adherence to company policy, products or services, adware, attacks enhanced or facilitated by AI, physical or electronic break-ins, earthquakes, fires, floods, and similar disruptive threats.

Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times

of war and other major conflicts, we and the third parties with whom we work are vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our services.

Remote work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers, and devices outside our premises or network, including working at home, while in transit and in public locations. Additionally, future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

We depend on information technology and telecommunications systems, including those provided by third parties and their vendors (some of which are legacy systems developed internally and may carry additional information security vulnerabilities), for significant elements of our operations, such as our laboratory information management systems, including test validation, specimen tracking, and quality control; personal information collection, storage, maintenance, and transmission; our profiling report production systems; and our billing and reimbursement, R&D, scientific and medical data analysis, and general administrative activities that collect, store and transmit large amounts of Sensitive Information, including intellectual property, proprietary business information, PHI, and other personal information of our customers, patients, business partners, employees, and contractors on such systems. In turn, the third parties and vendors with whom we work depend upon technology and telecommunications systems provided by outside vendors.

Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If the third parties with whom we work experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if the third parties with whom we work fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or that of the third parties with whom we work have not been compromised.

Cyber-attacks, malicious internet-based activity, online and offline fraud, insider threats and other similar activities 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. Furthermore, 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 and the third parties with whom we work may be unable to anticipate these techniques or implement adequate preventative measures. We and the third parties with whom we work may also experience security incidents that may remain undetected for an extended period. There can also be no assurance that our cybersecurity risk management program and processes, including our policies, controls, or procedures, will be fully implemented, complied with or effective in protecting our information technology and telecommunications systems and Sensitive Information.

In addition, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, ability to provide our products or services, loss of Sensitive Information and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Some of these attacks have also been coupled with attackers directly threatening executives with physical harm.

Applicable privacy and data security obligations may require us to notify relevant stakeholders, including affected individuals, customers, regulators, and investors, of security incidents, or to implement other requirements such as providing credit monitoring. Such disclosures and compliance with such requirements are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. For example, a growing number of legislative and regulatory bodies around the world have adopted breach notification and other requirements in the event that information subject to such laws is accessed by unauthorized persons and additional regulations regarding the use, access, accuracy, and security of such data are possible. In particular, we are a "Covered Entity" as defined under HIPAA, and, in the event of a breach as defined by HIPAA, we have specific reporting requirements under HIPAA regulations.

Under HIPAA, in the event of a significant breach, the reporting requirements could include notification to the general public, in addition to affected individuals and certain governmental agencies. In addition, in the United States, we are subject to state and other laws that require notification. Complying with such numerous and complex regulations in the event of unauthorized access would be expensive and difficult, and failure to comply with these regulations could subject us to regulatory scrutiny and additional liability, could harm our reputation and our ability to compete, and could adversely affect our business, financial condition, and results of operations.

We take steps designed to detect, mitigate, and remediate vulnerabilities in our information systems (such as our hardware and/or software, including that of third parties with whom we work). We may not, however, detect or remediate all such vulnerabilities including on a timely basis. By way of example, in the spring of 2024, a security researcher informed us of a previously unknown vulnerability in one of our systems, which we have remediated. Further, we may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident. If attackers are able to exploit vulnerabilities before patches are installed or mitigating measures are implemented, compromises could impact our information technology systems and Sensitive Information.

Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our Sensitive Information or our information technology systems, or those of the third parties with whom we work. A security incident or other interruption could disrupt our ability (and that of third parties with whom we work) to provide our services. If an attacker were to gain sufficient access to our systems, our data contained in those systems could be discovered by the attacker.

We, and the third parties with whom we work have been the target of cybersecurity attacks in the past and expect that such cybersecurity incidents will continue to occur in the future. For example, the February 2024 cybersecurity attack on Change Healthcare, who we used to process certain insurance claims, resulted in a delay in our ability to submit claims for payment and could require us to issue notifications to impacted individuals and various regulators if Change Healthcare determines that any PHI of our patients was impacted. While we may be entitled to damages as a result of this incident, any award may be insufficient to cover all such damages, or we may be unable to recover such award.

We may expend significant resources or modify our business activities to try to protect against security incidents. Additionally, certain privacy and data security obligations may require us to implement and maintain specific security measures or industry-standard or reasonable security measures to protect our information technology systems and Sensitive Information.

Despite the precautionary measures we and the third parties with whom we work have taken to detect and prevent or solve problems that could affect our information technology and telecommunications systems and Sensitive Information, there is a risk that our security measures will not be fully effective in the future. Failures or significant downtime of these systems or those used by the third parties with whom we work could prevent us from conducting tests, preparing and providing reports to future customers, billing payers, conducting R&D activities, maintaining our financial controls and other reporting functions, and managing the administrative aspects of our business. Any failure by us or the third parties with whom we work to prevent or mitigate security incidents, or other adverse impact to the availability, integrity, or confidentiality of our information technology systems or Sensitive Information, or improper access to, or use, acquisition, disclosure, alteration or destruction of, any such Sensitive Information, including loss of PHI or other data subject to privacy laws or proprietary business information, could result in operational or business delays, significant liability, regulatory action, a material loss of revenue resulting from the adverse impact on our reputation and brand, a diminished ability to retain or attract new customers, disruption to our business, and adversely affect our business, financial condition, and results of operations.

Our existing cyber liability insurance policies may not cover, or may cover only a portion of, any potential claims related to security breaches to which we are exposed or may not be adequate to indemnify us for all or any portion of liabilities that may be imposed. We also cannot be certain that our existing insurance coverage will continue to be available on acceptable terms or in amounts sufficient to cover the potentially significant losses that may result from a security incident or breach or that the insurer will not deny coverage of any future claim.

In addition to experiencing a security incident, third parties may gather, collect, or infer Sensitive Information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. Additionally, Sensitive

Information of the Company or our customers could be leaked, disclosed, or revealed as a result of or in connection with our employees', personnel's, or vendors' use of AI/ML technologies.

We may not be successful in developing and commercializing new solutions or new applications for our current solutions.

We continue to expand our R&D efforts to use our solutions and our multi-modal clinico-genomic datasets to develop enhanced versions of our solutions and create new solutions. These initiatives include expanding the application of Caris Assure to early detection, MRD tracking, and treatment monitoring, developing Caris ChromoSeq for hematological (blood) cancers, developing additional AI signatures using NGS or image data, and additional solutions, including for chronic disease states beyond cancer. The commercialization of any new solutions or new applications for our current solutions will require the completion of certain clinical development activities, validation studies and/or clinical trials, having guidelines or recommendations for healthcare providers, administrators, payers, and patient communities relating to such solutions, and receiving favorable exposure in peer-reviewed publications and from KOLs. We cannot assure you that we can successfully complete the clinical development or applicable subsequent requirements of any such solutions in order to commercialize such solutions.

We may fail to build a sustainable data licensing business, and our data licensing efforts may result in reputational harm that has an adverse effect on our business, financial condition, and results of operations.

We and our biopharma and academic partners leverage high-powered computing and AI/ML algorithms to analyze our data to find the key molecular characteristics of a particular disease or dysfunction that drives disease. As part of these efforts, we license data to our partners, and certain of our partners license data to us. We are in the early stages of these data licensing efforts and may not be able to grow these efforts into a sustainable business.

The outbound licensing of data for research purposes is a novel business model without an established track record, which makes it difficult to evaluate our future prospects and the risks and challenges we may encounter in seeking to execute on this opportunity. Although we have negotiated data licensing agreements with several partners, these partners may have rights to terminate these agreements before the initial term has been completed, and these arrangements may not be renewed, or they may be renewed on less favorable terms. In addition, many of our data licensing agreements involve the use of third-party clinical data that is combined with our molecular data and then licensed to biopharma companies or other end users, and these third-party clinical data partners may not be willing to work with us in the future. We also depend on these third-party partners to provide access to data from their own data partners. We cannot guarantee that our third-party partners will enter into new data sharing arrangements with us, continue to provide their data, or that of their partners, to us, or include their data as part of combined data sets, and in the event that any of these arrangements terminate, we may not be able to find a replacement, or a replacement may not be available on reasonable terms or in a timely manner. Any of the foregoing could result in us losing access to real-world evidence, longitudinal patient data, and clinical outcomes that are key to maintaining, expanding, and enriching our datasets, which could have an adverse effect on our business, financial condition, and results of operations.

The commercial market for licensing this type of data may not develop or may be limited by regulation or other factors, which could diminish the value of licensing this data over time and make it challenging to secure arrangements with these partners on similar terms, or at all, with any additional licensees. While our data licensing arrangements include protections against abuse and misuse of patient data, we may be unable to adequately control how our partners, or the commercial customers that they license our data to as part of a combined data set, use the data, and any abuse or misuse could adversely impact our reputation, which could have an adverse effect on our business, financial condition, and results of operations.

If we cannot maintain our current relationships, or enter into new relationships, with biopharma companies, our development of solutions could be delayed or our business, financial condition, and results of operations could be adversely affected.

We deploy our proprietary profiling and signature offerings to analyze tissue and blood samples provided by biopharma partners.

Our success in the future depends in part on our ability to maintain and expand relationships with our biopharma partners. This can be difficult due to several factors, including internal and external constraints placed on these organizations that can limit the number and type of relationships with companies like us they can consider and consummate; that certain of our agreements governing our relationships are terminable at will by our biopharma partners; and that our biopharma partners may be dissatisfied with our services. Continued usage of our services by

particular biopharma partners may also depend on whether the partner obtains positive data in its clinical trials, is able to successfully obtain regulatory approval and subsequently commercializes a therapy for which we have partnered with them to develop a companion diagnostic, or other administrative factors that are outside our control. Additionally, some of our biopharma partners have contracted with us to provide profiling for large numbers of samples, which could strain our testing capacity and restrict our ability to perform tests for other customers. If we fail to maintain these relationships or enter into new ones, our business could suffer.

From time to time, we expect to engage in discussions with biopharma companies regarding commercial opportunities. There is no assurance that any of these discussions will result in a commercial agreement, or if an agreement is reached, that the resulting engagement will be successful or that any clinical trials conducted as part of the engagement will produce successful outcomes. Speculation in the industry about our existing or potential engagements with biopharma companies can be a catalyst for adverse speculation about us, our services, and our technology, which can result in harm to our reputation and our business.

We rely on third-party services to collect, process, transport, and store our samples in a secure and cost-efficient manner. If these services were disrupted, our business would be harmed.

We rely on third-party providers to collect tissue and blood samples for our solutions. If third-party providers fail to adequately and properly obtain and collect viable blood and tissue samples from patients and to properly and timely package and ship the samples to us, our patients and their physicians may experience problems and delays in receiving test results, which could lead to dissatisfaction with our solutions, therefore harming our reputation and adversely affecting our business, financial condition, and results of operations. If our current third-party providers become unable to continue to collect samples for us or if our clients are unable to readily access a provider to collect a blood or tissue sample that we can analyze, we may be unable to compete effectively with other laboratories that have greater access to phlebotomy providers and our business, may be harmed.

In addition, we may maintain samples and extracted material for several years. It is possible that the long-term stability of these samples may not be maintained with the passage of time, which could negatively impact our ability to use such samples to validate our solutions. Further, interruptions in collection, processing, freezing, storing, or transportation of samples performed by third parties, whether due to labor disruptions, weather conditions, natural disaster, terrorist acts, threats, or for other reasons could adversely affect the samples and our ability to process the samples in a timely manner, which could negatively affect our ongoing research studies and harm our business.

The validation and clinical trial process is lengthy and expensive with uncertain outcomes. We have encountered delays, and may encounter future substantial delays, in our validation studies or clinical trials, and may therefore be unable to complete our validation studies or clinical trials on the timelines we expect, if at all, which could adversely impact our ability to market our solutions or receive adequate reimbursement.

Clinical testing is expensive, time-consuming, and subject to uncertainty. Initiating and completing validation studies and clinical trials necessary to validate and market our solutions, and to support any submissions to CMS, MolDX, or other payers for reimbursement, or the FDA for marketing authorization for our solutions, will be time-consuming and expensive and the outcomes are inherently uncertain. Validation studies and clinical trials must be conducted in accordance with the laws and regulations of the FDA and other applicable regulatory authorities' legal requirements and regulations, and are subject to oversight by these governmental agencies and institutional review boards ("IRBs").

The results of preclinical studies and clinical trials of our solutions conducted to date and ongoing or future studies and trials of our current, planned, or future solutions may not be predictive of the results of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Our interpretation of data and results from our validation studies and clinical trials does not ensure that we will achieve similar results in future validation studies or clinical trials. In addition, preclinical and clinical data are often susceptible to various interpretations and analyses, and many companies that have believed their products performed satisfactorily in validation studies, preclinical studies and earlier clinical trials have nonetheless failed to replicate results in later validation studies or clinical trials. Products in later stages of validation studies or clinical trials may fail to show the desired analytical validity and clinical validity despite having progressed through validation studies, nonclinical studies, and earlier clinical trials.

In addition, we cannot guarantee that any validation studies or clinical trials will be conducted as planned or completed on schedule, if at all. The timely completion of validation studies in accordance with their protocols depends, among other things, on our ability to locate and test a sufficient number of samples to demonstrate satisfaction of the validation study criteria. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of participants who remain in the trial until its conclusion. Many of our

validation studies and clinical trials require enrolling a large number of participants without cancer who may not see value in enrollment. Additionally, we may encounter delays as a result of the administrative complexities in managing and recruiting for validation studies and trials of this scope and size. If we are unable to recruit and enroll sufficient participants for our validation studies or clinical trials, or maintain sufficient participation of enrolled participants, our product development, commercialization activities and our ability to seek marketing authorization for our solutions could be delayed, modified, or prevented.

The initiation and completion of validation studies and clinical trials may be prevented, delayed, or halted for numerous reasons, including related to the following:

- the inability to generate sufficient in vitro or in vivo data to support the initiation or continuation of validation studies or clinical trials;
- the requirement to submit an IDE application to the FDA, which must become effective prior to commencing certain human clinical trials of significant risk medical devices, and which the FDA may disapprove;
- delays caused by participants withdrawing from clinical trials or failing to return for follow-up or by institutions failing to timely submit data, including follow-up data, if at all;
- delays or failure in reaching a consensus or agreement, if required, with regulatory agencies on trial design or feedback from regulatory agencies necessitating changes to ongoing or planned clinical trial design;
- delays or failure in reaching agreement on acceptable terms with prospective contract research organizations ("CROs"), service providers, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- delays or failure in obtaining any required IRB approvals or ethics committee ("EC") approvals for our clinical trial sites;
- delays in amending, or the inability to amend, our IRB-approved protocols at clinical trial sites when necessary or desired;
- difficulty or delays in collaborating with sites, institutions, and investigators;
- failure by us, investigators, sites, or participants to comply with the applicable trial protocol or applicable regulatory requirements and standards for data collection, reporting, records maintenance, or data integrity;
- failure by us, investigators, sites or any CROs or other third parties to adhere to clinical trial requirements, including the applicable protocol;
- failure to perform in accordance with good clinical practice ("GCP") and good laboratory practice requirements, and/or other applicable regulations and requirements of the FDA or other applicable governmental authorities;
- failure to comply with applicable privacy and data security laws related to clinical trials;
- failure of our solutions to achieve acceptable performance and safety endpoints;
- unacceptable safety findings, including findings related to the risk of the false positive tests (which could lead to unnecessary biopsy or anxiety) or false negative tests (which could lead to a delay in diagnosis or disease progression);
- termination or suspension of a trial or site by us or the data safety monitoring board, suspension or termination of a trial or site by an IRB, EC, or institution, or clinical hold or termination of a trial or site by a regulatory authority, including the FDA;
- disqualification, termination, or suspension of a clinical investigator;
- adverse inspections of our clinical trial sites or results by any applicable regulatory authority, including the FDA;
- changes in statutory or regulatory requirements or guidance, or clinical guidelines, that require amending existing or designing new clinical protocols, obtaining new IRB or EC approvals, modifying our clinical trials, modifying our consent process or obtaining additional consent from trial participants, or altering the pathway to marketing authorization of our solutions;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional clinical trials;
- the cost of clinical trials of our solutions being greater than we anticipate;
- destruction or compromise of, or other inability to access or receive, clinical trial samples processed, stored, or managed at a third-party site or otherwise in the control of a third party;
- clinical trials of our solutions producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon development programs; and
- lack of adequate funding.

Any such delays could adversely affect the costs, timing, or successful completion of any future clinical trials. Moreover, we may depend on our collaborators and on medical institutions and CROs to conduct any future clinical trials in compliance with applicable GCP requirements, and while we may have agreements governing their committed activities, we may have limited influence over their actual performance. To the extent any future collaborators, the CROs,

or clinical sites fail to enroll participants for our clinical trials, fail to conduct the trial to GCP requirements or are delayed for a significant time in the execution of trials, including achieving full enrollment, we may be affected by increased costs, program delays, and/or enforcement actions. In addition, any future clinical trials that are conducted in countries outside the United States may subject us to further delays and expenses.

Any inability to initiate or complete clinical trials successfully could result in additional costs to us, slow down or prevent our product development and receipt of positive reimbursement and coverage decisions, or impair our ability to generate revenue. Delays in initiating or completing our planned clinical trials could also allow our competitors to bring competing products to market before we do or sooner than expected, which could impair our ability to successfully commercialize our solutions, if launched, and may harm our business, financial condition, and results of operations. In addition, many of the factors that may cause, or lead to, a delay in initiation or completion of clinical trials may also ultimately lead to the delay or the narrowing or denial of any marketing authorization we may seek with respect to our solutions. Delays in the initiation or completion of any clinical trial of our solutions, such as Caris Assure for early detection, MRD tracking, or treatment monitoring, or seeking coverage and reimbursement, will increase our costs, slow down, or jeopardize our product development and marketing authorization process, and delay or potentially jeopardize broad adoption of our solutions and their ability to generate revenue.

Risks Related to Regulation and Legal Compliance

If we or our partners fail to comply with healthcare and other applicable laws and regulations, we could face substantial penalties and sanctions, and our business, reputation, financial condition, and results of operations could be adversely affected.

Our operations in the United States are subject to various U.S. federal and state laws and regulations that govern, among other things, the manner in which we provide and bill for tests and collect reimbursement from governmental programs, third-party payers and patients, our relationships with referral sources, and our marketing and advertising activities. In addition, the commercialization of our solutions outside the United States would also subject us to foreign equivalents of the healthcare laws described below, among other foreign laws. The laws that may impact our operations include:

- the federal Anti-Kickback Statute (the "AKS"), which prohibits, among other things, knowingly and willfully soliciting, receiving, offering, or paying any remuneration (including any kickback, bribe, rebate, a provision of free or discounted goods, services or items), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order, recommendation, or arrangement of any good, facility, item, or service for which payment may be made, 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 statute or specific intent to violate it in order to have committed a violation, and many courts have interpreted the AKS as being violated if merely one purpose of any arrangement is to induce referrals or purchases. The AKS includes statutory exceptions and regulatory safe harbors that protect certain arrangements. Failure to meet the requirements of an exception or safe harbor, however, does not render an arrangement illegal. Rather, the government may evaluate arrangements that do not fit into an exception or safe harbor on a case-by-case basis, taking into account all facts and circumstances, including the parties' intent and the arrangement's potential for abuse, and such arrangements may be subject to greater scrutiny by enforcement agencies;
- the Eliminating Kickbacks in Recovery Act of 2018 ("EKRA"), which establishes an all-payer anti-kickback prohibition for, among other things, knowingly and willfully paying or offering any remuneration directly or indirectly to induce a referral of an individual to or in exchange for an individual using the services of a clinical laboratory. EKRA applies to all payers including commercial payers and government payers. EKRA adopted safe harbors that are not directly analogous to the safe harbors under the AKS, and certain conduct that is permissible under the AKS may violate EKRA;
- the federal physician self-referral prohibition, commonly known as the Stark Law, which, in the absence of an applicable exception, prohibits a physician from making a referral for certain designated health services covered by the Medicare or Medicaid program if the physician or an immediate family member of the physician has a financial relationship (including an ownership interest or a compensation arrangement) with the entity providing the designated health services. The Stark Law also prohibits the entity furnishing the designated health services from billing, presenting, or causing to be presented a claim for the designated health services furnished pursuant to the prohibited referral. The term "designated health services" includes, among other things, clinical laboratory services. Unlike the AKS, the Stark Law is violated if the financial arrangement does not meet an

applicable exception, regardless of any intent by the parties to induce or reward referrals or the reasons for the financial relationship and the referral;

- the FCA, which imposes civil and criminal liability on individuals or entities that knowingly submit false or fraudulent claims for payment to the government or knowingly make, or cause to be made, a false statement in order to have a false claim paid. Actions under the FCA may be brought by the government or by a private person under a qui tam, or "whistleblower," suit. There are many potential bases for liability under the FCA. For example, the government has used the FCA to prosecute Medicare and other government healthcare program fraud such as coding errors, coding and billing for tests not compliant with coverage and reimbursement requirements, including MolDX reimbursement and coverage standards and requirements, waiver of patient copayments and deductibles, and performing tests that are not medically necessary or that are substandard in quality. In addition, a claim including items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the FCA, and courts have held that claims for services furnished pursuant to a referral prohibited by the Stark Law also are considered false for purposes of the FCA;
- the criminal healthcare fraud provisions of HIPAA and related rules that prohibit knowingly and willfully executing a scheme or artifice to defraud any healthcare benefit program or falsifying, concealing, or covering up a material fact or making any materially false, fictitious, or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items, or services. These criminal healthcare fraud provisions are not limited to benefits, items, or services that may be paid for by federal or state healthcare programs, and similar to the AKS, a person or entity does not need to have actual knowledge of these statutes or specific intent to violate them in order to have committed a violation;
- the federal Civil Monetary Penalties Law, which provides civil penalties for a wide variety of conduct relating to federal and state healthcare programs, including, subject to certain exceptions, prohibiting, among other things, the offer or transfer of remuneration, including free services, discounts, or waivers of copayments and deductible amounts (or any part thereof), 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;
- the federal Physician Payment Sunshine Act, created under the Affordable Care Act (the "ACA"), and its implementing regulations, which require manufacturers of drugs, devices, biologicals, and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the U.S. Department of Health and Human Services ("HHS") under the Open Payments Program, information related to payments or other transfers of value made to physicians (as defined by statute), teaching hospitals and other healthcare practitioners such as physician assistants and nurse practitioners, as well as ownership and investment interests held by such physicians and their immediate family members and similar state laws with various reporting requirements;
- state self-referral, kickback, false claim, fraud, and abuse laws, some of which may apply to items or services reimbursed by any payer, including patients and commercial insurers, and include "whistleblower" provisions;
- federal and state "Anti-Markup" rules, which, among other things, typically prohibit a physician or supplier billing for clinical or diagnostic tests (with certain exceptions) from marking up the price of a purchased test performed by another physician or supplier that does not "share a practice" with the billing physician or supplier;
- federal and state laws applicable to test ordering, documentation of tests ordered, consent requirements, billing practices and claims payment and laws that prohibit other specified practices, such as providing tests at no or discounted cost to induce adoption, which may apply to laboratories; waiving co-insurance, deductibles or other amounts owed by patients; and billing a state healthcare program at a price that is higher than what is charged to other payers;
- the "No Surprises Act," which prohibits balance billing for certain non-emergency care, including for out-of-network clinical laboratory tests, and analogous state laws;
- state corporate practice prohibitions and professional fee-splitting laws that prohibit employing, exercising control over, or splitting fees with licensed medical professionals;
- federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- analogous state and foreign laws and regulations, such as state and foreign anti-kickback, self-referral, false claims, consumer protection, and unfair competition laws that may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements as well as submitting claims involving healthcare items or services reimbursed by any third-party payer, including commercial insurers; state laws that require healthcare companies to comply with the medical device industry's voluntary compliance guidelines, the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to healthcare providers, and other potential referral sources or state-specific standards on

financial interactions with healthcare providers; state laws that require healthcare companies to file reports with states regarding pricing and marketing information, such as the tracking and reporting of gifts, compensation, and other remuneration and items of value provided to healthcare professionals and entities; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

These laws and regulations, among other things, constrain our business and limit the types of financial arrangements we have with providers, customers, patients, vendors and third-party payers, and our billing, coding, and collection practices, including our patient financial assistance programs and our practices relating to collection of co-payments and deductibles. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available and lack of clear guidance, our business activities could be subject to challenge under one or more of such laws. To enforce compliance, the Office of the Inspector General ("OIG") and the DOJ recently have increased their scrutiny of interactions between healthcare companies, on the one hand, and healthcare providers and patients on the other, which has led to a number of investigations, prosecutions, convictions, and settlements in the healthcare industry. These investigations often are focused on billing and coding practices as well as financial arrangements with referral sources and patients. For example, the DOJ and HHS have created a DOJ-HHS False Claims Act working group to identify FCA violations involving priority enforcement areas. We expect that the federal government will continue to devote substantial resources to investigating healthcare providers' compliance with the FCA and other applicable fraud and abuse laws.

We also have been, are currently, and may be in the future, subject to actions or investigations relating to our arrangements and interactions with healthcare professionals and patients. For additional information, see "—We have been, are currently, and in the future may be the subject of government investigations, claims, audits, whistleblower and payer audits, overpayment and recoupment efforts and other litigation in the course of our business that could adversely affect our business and financial results."

Efforts to ensure that our business arrangements will comply with applicable laws, including healthcare laws and regulations, may involve substantial costs. In addition, the healthcare and other laws applicable to our business may change or be amended, and, it is possible that governmental and enforcement authorities will conclude that our business practices do not comply with current or then-existing statutes, regulations, or case law interpreting applicable fraud and abuse or other healthcare or applicable laws and regulations. We may not properly interpret certain requirements or fail to timely report activities, when required. If any such actions are instituted against us, and we are not successful in defending ourselves, those actions could have a material impact on our business, including the imposition of significant civil, criminal, and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, imposition of forward-looking compliance obligations, and curtailment of our operations, any of which could adversely affect our business, financial condition, and our results of operations.

We and the third parties with whom we work are subject to stringent and evolving U.S. and foreign privacy and data security laws, regulations, and rules, contractual obligations, industry standards, policies and other obligations related to privacy and data security. Our actual or perceived failure to comply with privacy and data security obligations (or such failure by the third parties with whom we work) could result in significant liability, administrative or governmental penalties, reputational harm and/or, other adverse business consequences.

In the ordinary course of business, we process Sensitive Information, including personal information, genetic information, and data about trial participants in connection with clinical trials. These data processing activities subject us to numerous federal, state, and foreign privacy and data security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations, including AI/ML usage, relating to privacy and data security.

In the United States, numerous state and federal laws and regulations govern the privacy and security of personal information, including health-related information, such as data breach notification laws, personal information privacy laws, consumer protection laws (for example, Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). HIPAA establishes a set of national privacy and security standards for the protection of individually identifiable health information, by health plans, healthcare clearinghouses and certain healthcare providers ("Covered Entities"), as well as for entities that perform certain services for or on behalf of such Covered Entities that involve creating, receiving, maintaining, or transmitting PHI ("Business Associates"), and their covered subcontractors.

We are a Covered Entity when performing our healthcare services for customers, and also act as a Business Associate when performing certain services for or on behalf of Covered Entities.

When we act as a Covered Entity, for example, through services provided by our subsidiary Caris MPI, Inc., we are subject to certain obligations such as notice of privacy practices and secure handling of protected health information. In addition, when we act as a Business Associate of Covered Entities, for example, through services provided by our other entities, we are subject to certain provisions of HIPAA and the terms of any business associate agreements we enter into with such other Covered Entities. In addition, we may obtain health information from third parties that are subject to privacy and security requirements under HIPAA.

Under HIPAA, Covered Entities must report breaches of unsecured PHI to affected individuals without unreasonable delay, not to exceed 60 days following discovery of the breach by a Covered Entity or its agents. Notification also must be made to the HHS Office for Civil Rights and, in certain circumstances involving large breaches, to the media. Business associates must report breaches of unsecured PHI to Covered Entities during the timeframe outlined in the operative Business Associate Agreement, but in no event longer than 60 days of discovery of the breach by the Business Associate or its agents. A non-permitted use or disclosure of PHI is presumed to be a breach under HIPAA unless the Covered Entity or Business Associate establishes that there is a low probability the information has been compromised consistent with requirements enumerated in HIPAA.

Entities that are found to be in violation of HIPAA as the result of a breach of unsecured PHI, a complaint about privacy practices or an audit by HHS may be subject to significant civil, criminal, and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance. HIPAA also authorizes state Attorneys General to file suit on behalf of their residents. Courts may award damages, costs and attorneys' fees related to violations of HIPAA in such cases. While HIPAA does not create a private right of action allowing individuals to sue us in civil court for violations of HIPAA, its standards have been used as the basis for duty of care in state civil suits such as those for negligence or recklessness in the misuse or breach of PHI.

Certain states have also implemented genetic testing and privacy laws imposing specific patient consent requirements and protecting test results by strictly limiting the disclosure of those results. In addition, in the past few years, many U.S. states have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data; however, many of these laws have exceptions for entities subject to HIPAA or include exemptions for data subject to HIPAA, including clinical data protected under HIPAA and clinical trial data. For example, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020 ("CPRA") (collectively, "CCPA"), applies to personal information of consumers, business representatives, and employees who are California residents, and gives California residents expanded rights regarding their personal information, including the right to opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for fines of up to $7,500 per intentional violation, as well as a private right of action for certain data breaches. Although the CCPA exempts some data processed in the context of clinical trials and information subject to HIPAA, the CCPA increases compliance costs and potential liability with respect to other personal information we maintain about California residents.

We may also be subject to new laws governing the privacy of consumer health data, including genetic information. For example, Washington's My Health My Data Act broadly defines consumer health data, imposes obligations and restrictions on processing consumer health data (including imposing stringent requirements for consents), provides consumers certain rights with respect to their health data, and creates a private right of action to allow individuals to sue for violations of the law. More than a dozen states have also adopted laws regarding the processing, privacy, and security of genetic information or expanded their comprehensive privacy laws to include additional restriction on companies with respect to processing of sensitive personal information, including genetic information; however, many of these laws have exceptions for entities subject to HIPAA or include exemptions for data subject to HIPAA, including clinical data protected under HIPAA and clinical trial data.

Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. While several of these laws exempt some data processed in the context of clinical trials or deidentified information under HIPAA, such laws could have potentially conflicting requirements and may increase our compliance costs and potential liability. We could be adversely affected if such laws and other state or federal legislation or regulations applicable to us require changes in our business practices (including our ability to license

deidentified information to biopharma companies) or privacy policies, or if governing jurisdictions interpret or implement their legislation or regulations in ways that adversely affect our business, financial condition, and results of operations.

Furthermore, violation of consumers' privacy rights or failure to take appropriate steps to keep consumers' personal information secure may constitute unfair and/or deceptive acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, including entities subject to HIPAA. The Federal Trade Commission ("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. Individually identifiable health information is considered sensitive data that merits particularly strong safeguards. We publish privacy policies, marketing materials, and other statements, such as compliance with certain certifications or self-regulatory principles, regarding privacy and data security. If these policies, materials, or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators, or other adverse consequences.

In addition, we seek to utilize biological samples and data from participants in our clinical trials and validation studies in accordance with applicable law, IRB requirements, and participant permissions (through consent forms and HIPAA authorizations). If we are unable or significantly restricted in using participant samples and data for secondary research purposes, our ability to develop additional solutions and/or improve or refine existing solutions will be limited, which may impact our business and prospects.

Moreover, we are subject to laws, regulations, and standards governing certain marketing, advertising, and other communications conducted by telephone, fax, or text. In particular, sending short message service text messages to participants and prospective participants in our clinical trials is governed by the Telephone Consumer Protection Act ("TCPA") which imposes various consumer consent requirements and other restrictions on communications with consumers. Although we may be able to rely on certain exemptions for healthcare-related purposes, any actual or perceived violations of the TCPA can result in significant financial penalties, including penalties or criminal fines imposed by the Federal Communications Commission or fines of up to $1,500 per violation imposed through private litigation or by state authorities.

In addition, because we accept debit and credit cards payments, we are subject to the Payment Card Industry Security Standard ("PCI-DSS"), issued by the Payment Card Industry Security Standards Council; however, we rely on third-party payment processors to process such payments who are also separately subject to PCI-DSS. Noncompliance with PCI-DSS can result in penalties ranging from $5,000 to $100,000 per month by credit card companies, litigation, damage to our reputation, and revenue losses. If we or our third-party payment processors are unable to comply with the PCI-DSS, we may be subject to fines, restrictions, expulsion from card acceptance programs, or other consequences which could affect our business. Moreover, it is not guaranteed that PCI-DSS compliance will prevent illegal or improper use of our third-party payment processors' payment systems or the theft, loss or misuse of payment card data or transaction information.

Our business also increasingly relies on AI to improve our services. However, the development and use of AI presents various privacy and data security risks that may impact our business and is subject to various laws. For example, several countries, states, and localities have proposed or enacted measures related to the use of AI in products and services, including the EU's AI Act, which may limit our ability to utilize AI or make utilization of such technology more expensive. The effects of these regulations are difficult to predict, and we expect other jurisdictions will adopt similar laws. Additionally, certain privacy laws extend rights to consumers (such as the right to delete certain personal information) and regulate automated decision making, which may be incompatible with our use of artificial intelligence. These obligations may make it harder for us to conduct our business using artificial intelligence, lead to regulatory fines or penalties, require us to change our business practices, retrain our artificial intelligence, or prevent or limit our use of artificial intelligence. For example, the FTC has required other companies to turn over (or disgorge) valuable insights or trainings generated through the use of AI where they allege the company has violated privacy and consumer protection laws. If we cannot use AI or that use is restricted, our business may be less efficient, or we may be at a competitive disadvantage.

Outside the United States, an increasing number of laws, regulations, and industry standards may govern privacy and data security. For example, the European Union General Data Protection Regulation (the "EU GDPR") and to the United Kingdom General Data Protection Regulation and Data Protection Act 2018 (collectively, the "UK GDPR") (the EU GDPR and UK GDPR together referred to as the "GDPR") impose strict requirements for processing personal data. The GDPR imposes stringent and comprehensive data protection requirements, and provides for greater penalties for

noncompliance. The GDPR expands the rights that individuals have to request access, correction, and deletion of their personal data, although certain exceptions exist for scientific research, and makes notification of data breaches to supervisory authorities and data subjects mandatory in certain circumstances. In addition, the GDPR imposes additional compliance obligations and local law derogations in relation to the processing of special category or sensitive personal data under the GDPR (e.g., health data); we may be subject to diverging requirements under EU member state laws and the United Kingdom ("UK") laws, such as whether consent can be used as a legal basis for processing. Where we rely on consent as a legal basis for processing, the validity of informed consent from patients may be challenged, which could force us to stop offering our services, which could hinder our business and operations. In addition, as laws develop, we may need to make operational changes to adapt to diverging rules, which could increase our costs and adversely affect our business. The GDPR also regulates cross-border transfers of personal data outside of the EEA (in the case of the EU GDPR) and UK (in the case of the UK GDPR) and recent case law and regulatory guidance have increased legal complexity and uncertainty regarding international personal data transfers, which we expect to continue. In particular, we expect international transfers to the United States and to other jurisdictions more generally to continue to be subject to enhanced scrutiny by regulators. As the regulatory guidance and enforcement landscape in relation to data transfers continue to develop, we could suffer additional costs, complaints and/or regulatory investigations or fines; we may have to stop using certain tools and vendors and make other operational changes.

Penalties and fines for failure to comply with the GDPR include fines of up to 20 million euros under the EU GDPR, 17.5 million pounds sterling under the UK GDPR or, in each case, 4% of annual global revenue, whichever is greater, and since we are subject to the supervision of relevant data protection authorities under both the EU GDPR and UK GDPR, we could be fined under each of those regimes independently in respect of the same breach. In addition to fines, a breach of the EU GDPR and/or UK 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).

In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross-border data flows. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, we expect the existing legal complexity and uncertainty regarding international data transfers from the European Economic Area ("EEA") and the UK to continue. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA's standard contractual clauses, the UK's International Data Transfer Agreement/Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges. As the regulatory guidance and enforcement landscape in relation to data transfers continues to develop, there is no assurance that we can continue to satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK, or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers of personal data out of Europe for allegedly violating the GDPR's cross-border data transfer limitations.

We furnish biopharma partners and academic researchers information that has been de-identified in accordance with applicable laws, regulations, and the requirements governing the clinical trial. Any data transferred pursuant to international health information privacy regulations is transferred under relevant data protection agreements at the direction of the Data Controller. We may also furnish our biopharma partners and academic researchers with identifiable genomic information for research purposes, so long as such disclosure has been consented to by the patient and/or approved by an IRB or other ethical or privacy review board. The laws of certain states and countries may require specific consent from the individual either to retain or utilize certain genetic information for research or other purposes even if such information has been de-identified, or may require that we obtain a waiver of such consent from an ethical or privacy review board. Even where we furnish to biopharma partners and academic researchers genomic information that has been de-identified in accordance with applicable laws and regulations, biopharma partners or academic researchers may use technology or other methods to link that de-identified genomic information to the patient from whom it was

obtained in contravention of one or more applicable laws and regulations. A finding that we have failed to comply with any such laws and any remedial activities required to ensure compliance with such laws could cause us to incur substantial costs, to be subject to unfavorable publicity or public opinion, to change our business practices, or to limit the retention or use of genetic information in a manner that, individually or collectively, could be adverse to our business.

Obligations related to privacy and data security (and consumers' data privacy expectations) are quickly changing, becoming increasingly stringent, and creating uncertainty. For example, HHS issued a notice of proposed rulemaking on January 6, 2025, clarifying existing requirements and imposing new security requirements for entities subject to HIPAA. The agency received thousands of proposed comments, and may adjust or clarify the rule as part of the rule making process. It is uncertain whether the proposed rule will move forward in its current state and what the timing of a final rule will be. If adopted in a form similar to the proposed rule, we anticipate our compliance costs could increase substantially. We would need to invest in additional cybersecurity technologies, hire specialized personnel, and potentially redesign certain aspects of our systems and processes. These investments were not contemplated in our current business plan and could impact our profitability. If we are unable to comply with new requirements by any prescribed deadlines, we could face penalties, enforcement actions, reputational damage, and potential loss of business from customers. While we have begun assessing our current security posture against the proposed requirements, the uncertainty regarding the final rule makes comprehensive preparation difficult.

Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. We also expect that there will continue to be new laws, regulations, and industry standards concerning privacy and data security proposed and enacted in various jurisdictions in which we do business. In addition to privacy and data security laws, we are also bound by other contractual obligations related to privacy and data security. Preparing for and complying with these obligations requires us to devote significant resources and may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf.

Compliance with privacy and data security obligations could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business. We strive, and contractually obligate our vendors, to comply with applicable laws, regulations, policies, and other legal obligations relating to privacy and data security. However, the various regulatory frameworks for privacy and data protection are, and are likely to remain, uncertain, and it is possible that these or other actual or alleged obligations may be interpreted and applied in a manner that is inconsistent from one jurisdiction to another and may conflict with other rules and subject our business practices to uncertainty. In addition, it is not guaranteed that regulators or consumers will agree with our interpretation of our obligations or our steps to comply with them. Any actual or perceived failure by us to comply with privacy and data security laws, rules, regulations, industry standards and other obligations could result in proceedings or actions against us by individuals, consumer rights groups, government agencies, or others, or orders to cease/ change our data processing activities. We could incur significant costs in investigating and defending such claims and, if found liable, pay significant damages or fines or be required to make changes to our business practices. Further, these proceedings and requires to any subsequent adverse outcomes may subject us to significant negative publicity and an erosion of trust. If any of these events were to occur, our business, financial condition, and results of operations could be adversely affected.

We have current solutions marketed as LDTs and plan to launch future solutions as LDTs. The regulation of LDT products in the United States remains subject to significant uncertainty, and if we fail to comply with any new or existing legal requirements with respect to our LDT solutions, our business, financial condition, and results of operations could be adversely affected.

We have obtained PMA approval from the FDA for MI Cancer Seek as a companion diagnostic device. We have also contemplated seeking FDA approval for Caris Assure and additional solutions. Except for MI Cancer Seek, we currently offer our NGS solutions, MI Tumor Seek Hybrid and Caris Assure, and our AI solutions, such as GPSai and FOLFIRSTai, as LDTs. The FDA has historically considered LDTs to be IVD tests that are intended for clinical use and are designed, manufactured, and used within a single laboratory, and the FDA has historically viewed LDTs as medical devices subject to FDA's medical device authority. Notwithstanding this position, the FDA historically exercised enforcement discretion and did not enforce certain medical device requirements, including requirements for premarket review, with respect to LDTs, with certain exceptions.

Even under that enforcement discretion policy, the FDA has issued warning letters to, and published Medical Device Safety Communications about, manufacturers for commercializing laboratory tests that were purported to be LDTs but the FDA alleged failed to meet the definition of an LDT or that otherwise were not subject to the FDA's prior

enforcement discretion policy. If our current solutions fail to meet the definition of an LDT, our business, financial condition, and results of operations could be adversely affected.

However, the FDA had for a number of years stated its intention to modify its enforcement discretion policy with respect to LDTs and enforce applicable medical device requirements to LDTs more broadly, and on May 6, 2024, the FDA issued a final rule in effort to clarify the FDA's historical view that LDTs are medical devices subject to the requirements applicable to IVDs (the "LDT Final Rule"), and to phase out the FDA's enforcement discretion policy over a period of four years from issuance of the LDT Final Rule.

However, on March 31, 2025, the United States District Court for the Eastern District of Texas vacated the LDT Final Rule, reasoning that LDTs are not medical devices, and remanded the matter to the FDA for further consideration. The FDA did not appeal the ruling within the required timeline and in August 2025 sent a final rule to the White House for review that would officially rescind the LDT Final Rule. Accordingly, it is uncertain whether or when the FDA may be able to otherwise exercise its medical device authority with respect to LDTs. This uncertainty could adversely affect the FDA's ability to apply and enforce its medical device requirements with respect to diagnostic tests more broadly, including any LDTs for which we have obtained or plan to obtain PMAs. Such uncertainty and the FDA's actions in response could have a material adverse effect on our business and operations.

In light of this uncertainty, we do not know if or when our offerings could become or will remain subject to FDA medical device requirements, including the need to seek and obtain marketing authorization. If we were unable to comply with any medical device requirements applicable to LDTs if and when such requirements become applicable, we could be required to cease marketing any solutions that we market as LDTs. In addition, further efforts by the FDA or Congress to impose more regulation on LDTs could create a negative public perception about the validity, safety, effectiveness, or performance of LDTs, including our solutions, which could adversely affect patient, provider, and customer perception about, and confidence in, our solutions.

Moreover, the FDA may assert that we are improperly marketing our solutions as LDTs, or otherwise assert we do not comply with applicable requirements, and in such cases may take enforcement action against us and/or require premarket review and marketing authorization, which may require us to cease marketing any commercially marketed solutions that are marketed as LDTs until such marketing authorization is obtained or the applications are submitted. There can be no assurance that we will be able to obtain such marketing authorization or that any labeling claims would be consistent with the claims we have made or intend to make for such solutions when launched as LDTs, or that such claims will be adequate to support continued adoption of and reimbursement for our solutions. In the event we are required to seek FDA marketing authorization for any current or planned LDT solutions, the FDA may request that we provide additional analyses and information beyond that which we intend to produce based on the designs of our current and planned validation studies or clinical trials, or that we modify or narrow our intended use or product claims. It is possible that the FDA, among other things, could disagree with our interpretation of data we have relied on to support our LDT launches for our intended uses. If we are required to provide additional analyses or additional data or perform additional clinical trials beyond those we currently contemplate to support the intended uses of our solutions, our planned commercial launches may be delayed and we may be required to cease commercialization of any solutions we currently market as LDTs. Even if our solutions are allowed to remain on the market prior to any required marketing authorization, demand or reimbursement for our solutions may decline if there is uncertainty about our solutions, if we are required by the FDA to label our solutions as RUO or IUO, or if the FDA limits the labeling claims we are permitted to make for our solutions. As a result, we could experience significantly increased development costs and a delay in generating additional revenue from our current or future solutions, which could reduce our revenues or increase our costs and adversely affect our business, financial condition, and results of operations. Additionally, an FDA enforcement action against us, a delay in the launch of our solutions, or significantly narrowing their intended uses, could negatively impact our business, financial condition, and results of operations.

In addition, Congress has, for over the past decade, considered a number of proposals, which if enacted, would subject LDTs to additional regulatory requirements. Any such legislation could substantially alter our marketing of LDTs and negatively impact our business, financial condition, and results of operations.

Our early detection and MRD tracking assays are intended to introduce new approaches to cancer detection, which present a number of novel and complex issues for FDA review. Because the FDA has never provided marketing authorization for an early detection test and has only granted marketing authorization in limited instances for MRD tests, it is difficult to predict what information we will need to submit to obtain approval of a PMA from the FDA for a

proposed intended use of early detection or MRD tracking, or if we will be able to obtain such approval on a timely basis or at all.

To our knowledge, the FDA has never granted marketing authorization for an early detection test and has only granted marketing authorization in limited instances for MRD tests. Therefore, obtaining FDA approval for Caris Assure for early detection and/or MRD tracking presents a number of novel issues. For example, in November 2023, the Molecular and Clinical Genetics Panel (the "Panel") of the FDA's Medical Devices Advisory Committee held a public meeting in which the Panel discussed and made recommendations on the design of MCED IVD devices as well as potential study designs and study outcomes of interest that could inform the assessment of the probable benefits and risks of MCED screening tests. The FDA may continue to modify its thinking on how to evaluate the performance of these types of tests, as well as its views around MRD tests. As such, we believe the FDA requirements that will govern any early detection or MRD tracking test we develop, as well as the breadth and nature of data we must provide the FDA, to support the proposed intended use, will remain subject to change.

Given the novel nature and complexity of our early detection and MRD tracking assays, we cannot be certain whether we will receive FDA marketing authorization for our screening tests and whether the trials we eventually conduct will be sufficient to provide the data that the FDA requires to support a proposed intended use. The FDA may require us to perform new analyses of future clinical data or perform additional clinical trials beyond any trials that we may conduct in the future. We may be required to undertake significant efforts to address the FDA requests, which could delay or prevent approval, lead to a more limited intended use statement than the broader intended use statement we plan to pursue, and/or lead to significant post-approval limitations or restrictions, if approval is obtained at all.

Our business could be adversely affected by legal challenges to our business model or by actions restricting our ability to provide the full range of our solutions.

Many states prohibit, by statute, regulation, guidance from professional licensing boards or state attorneys general or under common law, the unlicensed practice of medicine. Corporate practice restrictions are generally designed to prohibit a non-professional entity, such as us, from practicing medicine, employing physicians, or controlling or unduly influencing the professional practice and clinical decision making of physicians. The laws relating to corporate practice vary from state to state and are subject to change and to evolving interpretations by courts, state licensing boards and state attorneys general, among others. Further, changes to the membership or staff of state agencies, licensing boards or attorney general offices could lead to increased enforcement of these laws and regulations. In addition, many states also have laws that prohibit a non-professional entity or individual from sharing in or splitting profits or professional fees for patient care, often referred to as "fee-splitting." Some states also prohibit entities from engaging in certain financial arrangements, such as fee-splitting, with physicians. The laws relating to fee-splitting also vary from state to state and are not fully developed or uniformly enforced. Generally, these laws restrict business arrangements that involve a physician sharing professional fees with a non-professional source, but in some states, these laws have been interpreted to extend to other agreements between physicians and business entities under some circumstances.

Our test reports delivered to physicians provide information regarding solutions that oncologists and other physicians may use in making treatment decisions for their patients. We also employ pathologists and other medical professionals that interpret results of our solutions and sign our profiling results. These pathologists, physicians and other medical professionals are employed through our subsidiary non-profit corporation, Caris Molecular Pathology, which we believe complies with state corporate practice prohibitions and professional fee-splitting prohibitions. A governmental authority or other parties could allege that the business practices and services we provide constitute the practice of medicine or violate professional fee-splitting prohibitions and that our structure and arrangements are not compliant. A state may seek to have us discontinue the related services we provide, or subject us to fines, penalties, or other sanctions. Any determination that we are practicing medicine without a license may result in significant liability to us, and our business and reputation would be harmed.

Obtaining and maintaining regulatory authorization of our solutions in one jurisdiction does not mean that we will be successful in obtaining regulatory authorization of our solutions in other jurisdictions.

Obtaining and maintaining regulatory authorization of solutions in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory authorization in any other jurisdiction, but a failure or delay in obtaining regulatory authorization in one jurisdiction may have a negative effect on the regulatory authorization process in others. For example, even if the FDA or a comparable foreign regulatory authority grants marketing authorization for our solutions, comparable regulatory authorities in foreign jurisdictions may also need to authorize the solutions in those countries. Premarket authorization processes vary among jurisdictions and can involve requirements and administrative

review periods different from those in the United States, including additional clinical trials, because clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions or the data may not be considered applicable to the jurisdiction's intended patient population. For example, while we have obtained a PMA approval from the FDA for MI Cancer Seek, we do not have any non-U.S. approvals for this solution, and there can be no assurance that we receive any such approvals in the future. In some cases, the price that we intend to charge for our solutions may also be subject to approval. In addition, NY CLEP approval is required in order to market LDTs in New York State. We have not received NY CLEP approval for Caris Assure.

Obtaining foreign regulatory authorization and maintaining compliance with foreign regulatory requirements could result in significant delays, difficulties, and costs for us and could delay or prevent the introduction of our solutions in certain countries. If we fail to comply with the regulatory requirements in other jurisdictions, or we fail to receive necessary or desirable marketing authorizations in other jurisdictions, our target market will be reduced and our ability to realize the full market potential of our solutions will be harmed.

Our employees, independent contractors, consultants, commercial partners, customers, and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of fraud, misconduct, or other illegal activity by our employees, independent contractors, consultants, commercial partners, customers, and vendors. Misconduct by these parties could include intentional, reckless and negligent conduct that fails to: comply with the rules and regulations of the CMS, the FDA, and other comparable foreign regulatory authorities; provide true, complete and accurate information to such regulatory authorities; comply with manufacturing and clinical laboratory standards; comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws; or report financial information or data accurately or to disclose unauthorized activities to us. Since we began commercializing MI Profile, Caris Assure and our earlier solutions in the United States, our potential exposure under such laws has increased significantly, and our costs associated with compliance with such laws have, and will likely continue to, increase. In particular, research, sales, marketing, education, and other business arrangements in the healthcare industry are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing, and other abusive practices, as well as off-label product promotion. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, educating, marketing and promotion, sales and commission, certain customer incentive programs, and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of participant recruitment for clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a Corporate Compliance Program, but it is not always possible to identify and deter misconduct by employees and third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions. Even if it is later determined after an action is instituted against us that we were not in violation of these laws, we may be faced with negative publicity, incur significant expenses defending our actions, and have to divert significant management resources from other matters. We expect our exposure to and costs associated with compliance with healthcare fraud and abuse laws to increase significantly if we commercialize additional solutions in the future.

We use medical and hazardous materials that require considerable expertise and expense for handling, storage, or disposal and may result in claims against us.

We and our facilities are subject on an ongoing basis to federal, state, and local laws and regulations governing the use, storage, handling, and disposal of regulated medical waste, hazardous waste, and biohazardous waste, including chemicals, biological agents and compounds and blood and other tissue specimens. We cannot eliminate the risk of accidental contamination or injury to employees, consultants, or third parties from the use, storage, handling, or disposal of these materials. Typically, we use licensed or otherwise qualified outside vendors to dispose of this waste. However, many of these laws and regulations provide for strict liability, holding a party potentially liable without regard to fault or negligence. As a result, we could be held liable for damages and fines if our, or others', business operations or other actions result in contamination of the environment or personal injury due to exposure to hazardous materials. Our costs for complying with these laws and regulations cannot be estimated or predicted with accuracy and depends on a number of factors, including the amount and nature of waste we produce, which depends in part on the number of tests we perform, and the terms we negotiate with our waste disposal vendors.

We have been, are currently, and in the future may be the subject of government investigations, claims, audits, whistleblower and payer audits, overpayment and recoupment efforts and other litigation in the course of our business that could adversely affect our business and financial results.

Healthcare companies are subject to various criminal, civil, and administrative investigations and audits by governmental authorities. Both federal and state government agencies have heightened civil and criminal enforcement efforts in recent years and expanded collaborative program integrity initiatives. These efforts have led to a number of investigations, prosecutions, convictions, and settlements in the healthcare industry involving federal civil and criminal false claims laws, other healthcare fraud and abuse laws, and civil monetary penalties laws, including the FCA. Further, under the FCA, private parties may bring qui tam, or "whistleblower," lawsuits on behalf of the government in connection with alleged false claims for payments submitted to the government or improper retention of overpayments, and these types of actions can be "under seal" for a long period of time while regulatory authorities investigate. The private parties who bring FCA lawsuits are entitled to share in any amounts recovered by the government. When an entity is determined to have violated the FCA and other criminal healthcare fraud laws, the government may impose substantial civil and criminal fines and penalties for each false claim, plus up to treble damages, and exclude the entity from participation in Medicare, Medicaid, and other federal healthcare programs. In addition, a number of states have adopted their own false claims and whistleblower provisions.

We have been, are currently, and may in the future be subject to lawsuits, qui tam actions, CIDs, subpoenas, investigations, audits, and other inquiries related to our operations. We have also been, are currently, and may be in the future, subject to subpoenas, CIDs, actions, or investigations relating to our arrangements and interactions with third parties such as healthcare professionals, healthcare institutions, market participants, or patients.

For example, in March 2025, we received a CID from the DOJ in connection with an investigation under the False Claims Act regarding our compliance with Medicare's date of service rule (also referred to as the 14-day rule), particularly focused on patients of certain health care providers, and our policies, procedures, and training related to compliance with the 14-day rule. The related investigation continues to evolve and is in too early a stage to assess potential outcomes. We are cooperating with the investigation. We have implemented compliance policies, procedures, and training designed to foster compliance with the 14-day rule, but there can be no certainties regarding the outcome of the CID. In June 2022, we entered into a settlement agreement with the United States in connection with a previous investigation into our compliance with the 14-day day rule. Pursuant to this settlement agreement, under which we admitted no fault or liability, we paid approximately $2.9 million in restitution and penalties and we obtained a nationwide release from all 14-day rule claims prior to January 1, 2018. For additional information see Part II, Item 1. "Legal Proceedings." These interactions could result in the government or other parties pursuing legal claims against us that may result in liabilities, including damages penalties, the potential for exclusion from participation in federal healthcare programs, or the imposition of additional compliance and reporting requirements as part of a corporate integrity agreement, any of which could have an adverse effect on our business, financial condition, reputation, and results of operations.

We are subject to audits and investigations of the ordering, billing, and coding of our solutions, including whether these services were properly ordered, billed, and coded or otherwise compliant with requirements for coverage and payment. In particular, as a result of our participation in the Medicare and Medicaid programs, we face and are currently subject to various governmental reviews, audits, and investigations to verify our compliance with these program requirements and applicable laws and regulations. Government agencies and their agents, such as the MACs and Recovery Audit Contractors, as well as the OIG, CMS, and state Medicaid programs, conduct audits of post-payment reviews to detect and correct improper payments in the Medicare program. Private third-party payers conduct similar reviews, audits and pre-payment and post-payment audits. Government agencies and their contractors and other third-party payers regularly conduct audits and request documentation to support claims submitted for payment of services rendered and compliance with claim submission requirements. We are routinely subject to audits under various government programs and third-party payers, and any delays timely providing requested records, negative audit findings or allegations of fraud or abuse may subject us to liability, such as overpayment liability, refunds or recoupments of previously paid claims, payment suspension or the revocation of billing or payment privileges in governmental healthcare programs or other third-party payer programs. Such actions, if imposed on us or our subsidiaries, could adversely impact our business, financial condition, and results of operations. In addition, we perform internal audits and monitoring. Depending on the nature of the conduct uncovered in such audits, and whether the underlying conduct could be considered systemic, the resolution of these audits could have an adverse effect on our business, financial condition, and results of operations.

Responding to government investigations, qui tam lawsuits, payer audits, subpoenas, CIDs, or other legal and administrative proceedings can be time- and resource-consuming and can divert management's attention from the

business. Even an unsuccessful challenge or investigation into our practices could cause unfavorable publicity and require us to incur significant costs, resulting in an adverse effect to our reputation and business. If our operations are found to be in violation of applicable laws or regulations, we may be subject to civil and criminal penalties, including significant fines or damages or other sanctions, including exclusion from government healthcare programs. Settlements of lawsuits involving Medicare and Medicaid issues routinely require both monetary payments and corporate integrity agreements that require the imposition of substantial compliance and reporting requirements, any of which could have an adverse effect on our business, financial condition, and results of operations.

Healthcare reform measures or changes in policy or government spending could cause significant harm to our business, financial condition, and results of operations.

Healthcare systems are subject to ongoing reform in the United States and abroad. Federal and state governments have made, and continue to make, significant modifications to the Medicare and Medicaid programs through statutory and regulatory changes, administrative rulings and other interpretations and determinations. For example, in the United States, the ACA made a number of substantial changes to the way healthcare is financed both by government and private insurers. The ACA, among other things, included provisions governing enrollment in federal and state healthcare programs, reimbursement matters, and fraud and abuse. We expect these and other provisions will influence our industry and our operations in ways that we cannot currently predict. Since its enactment, there have been judicial and congressional challenges to certain aspects of the ACA. For example, on June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. In addition, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (the "IRA") into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. The One Big Beautiful Bill Act (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 our solutions and limit the number of patients receiving procedures associated with the use of our solutions. Although the effect on our business cannot yet be predicted, a decrease in the number of insured patients or reimbursement levels for any future solutions could affect our revenue. It is also possible that efforts to reform, modify, or repeal parts of the ACA may continue.

In recent years, legislative and regulatory changes have resulted in limitations and reductions in reimbursement levels and payments to healthcare providers for certain services under the Medicare program. For example, In April 2014, Congress passed PAMA, which included substantial changes to the way in which clinical laboratory services are paid under Medicare. In addition, Congress established automatic spending reductions under the Budget Control Act of 2011 (the "BCA"), resulting in a 2% reduction in Medicare payments that began in 2013, and due to subsequent legislative amendments, will remain in effect until 2032, unless additional Congressional action is taken. In addition, as a result of the American Rescue Plan Act of 2021 ("ARPA"), an additional Medicare payment reduction of up to 4% was required to take effect in January 2022 based on statutory triggers if legislation increased the federal deficit. As a result of the OBBBA, an additional Medicare payment reduction of up to 4% may take effect in January 2026 based on Statutory Pay-As-You-Go-Act triggers if Congress does not act to waive the sequester. The effects of these laws would result in Medicare payment reductions capped at 4% total under current law. Historically, Congress has consistently waived PAYGO sequestration when triggered, including after ARPA, but there is no guarantee of future waivers and such waivers may not occur in the present term due to negotiations during the ongoing government shutdown. In addition, various bills have been introduced to amend PAMA, including the Results Act. It is difficult to predict whether, when or what other deficit reduction initiatives may be proposed by Congress. We anticipate that the federal budget deficit will continue to place pressures on government healthcare programs and impose additional spending reductions, which reductions could potentially lower the price that we receive for future solutions.

In addition to changing federal policy and regulatory oversight, states and third-party payers may also introduce proposals and polices to reduce costs while expanding individual healthcare benefits. Certain of these proposals may limit the prices we will be able to charge for our solutions or limit coverage of or lower reimbursement for the procedures associated with the use of our solutions. Healthcare reform and pricing of prescription drugs and medical devices, including clinical laboratory tests, are and will remain a key bipartisan issue. Policies to be pursued in the future may be more aggressive, regardless of which party controls the White House or houses of Congress. Uncertainty surrounding future changes may adversely affect our operating environment and therefore our business, financial condition, results of operations, and growth prospects.

We cannot predict whether or when these or other recently enacted healthcare initiatives will be implemented at the federal or state level or in foreign jurisdictions, or the full impact of current or future healthcare reform measures on our business. For example, the payment reductions imposed by the ACA and the changes to the reimbursement amounts paid by Medicare for tests based on the procedures set forth in PAMA, or other future federal or state measures, could limit the prices we are able to charge or the amount, if any, of available reimbursement or coverage for our solutions, which would reduce our revenue. Additionally, these healthcare policy changes could be amended or additional healthcare initiatives could be implemented in the future.

Further, the impact on our business of the expansion of the federal and state governments' role in the U.S. healthcare industry generally, including the social, governmental, and other pressures to reduce healthcare costs while expanding individual benefits is uncertain.

Statutory, regulatory, and policy changes, or government budget and funding levels, may also impact the ability of the FDA, the Department of Health and Human Services (including CMS) and other regulatory authorities to perform their regulatory functions. Inadequate funding or staffing for such organizations and/or potentially shifting priorities, including under the new administration, could prevent or delay regulatory reviews and approval processes on which certain of our initiatives may rely, adversely affect agencies' ability to hire and retain key personnel, or otherwise prevent those agencies from timely performing normal business functions on which the operation of our business may rely, any of which could negatively impact our business.

The current Trump administration is pursuing policies to reduce regulations and expenditures across government including at HHS, the FDA, CMS, and related agencies, including the recent layoffs across HHS, including the FDA. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business, including disruptions and delays in FDA guidance, review and approval of our solutions. See "—Changes in funding or disruptions at the FDA and other government agencies caused by funding shortages, staffing limitations, or global health concerns could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could adversely impact our business." Further, in June 2024, the U.S. Supreme Court reversed its longstanding approach under the Chevron doctrine, which provided for judicial deference to regulatory agencies' interpretation of statutes that are silent or ambiguous, including the FDA and CMS. As a result of this decision, we cannot be sure whether there will be increased challenges to existing agency regulations or how lower courts will apply the decision in the context of other regulatory schemes without more specific guidance from the U.S. Supreme Court. For example, this decision may result in more companies bringing lawsuits against the regulatory agencies to challenge current regulations and longstanding decisions and policies of the FDA or CMS, which could lead to uncertainties in the industry. We cannot predict the full impact of this decision, future judicial challenges brought against the FDA, CMS, or other regulatory agencies, or the nature or extent of government regulation that may arise from future legislation or administrative action.

The marketing authorization processes of the FDA and comparable foreign regulatory authorities are lengthy, time-consuming, and unpredictable. If we are ultimately unable to obtain any necessary or desirable marketing authorizations, or if such marketing authorizations are significantly delayed, our business will be substantially harmed.

Except for MI Cancer Seek, for which we have obtained a PMA approval from the FDA, we currently offer our NGS solutions, MI Tumor Seek Hybrid and Caris Assure, and our AI solutions, such as GPSai and FOLFIRSTai, as LDTs. See "—We have current solutions marketed as LDTs and plan to launch future solutions as LDTs. The regulation of LDT products in the United States remains subject to significant uncertainty, and if we fail to comply with any new or existing legal requirements with respect to our LDT solutions, our business, financial condition, and results of operations could be adversely affected." We currently anticipate seeking FDA approval for Caris Assure and additional solutions. The time required and ability to obtain marketing authorization from the FDA and comparable foreign regulatory authorities is unpredictable and typically takes several years following the commencement of clinical trials, and depends upon numerous factors, including the type, complexity, and novelty of our solutions. In addition, policies, laws, regulations, or the type and amount of clinical data necessary to gain marketing authorization may change during the course of a test's clinical development and may vary among jurisdictions, which may cause delays in the marketing authorization of, or the decision not to approve, an application. Regulatory authorities have substantial discretion in the premarket review process and may refuse to accept any application, decide that our data are insufficient for marketing authorization, require additional clinical or other data, or determine that our manufacturing and quality systems are insufficient or in violation of applicable requirements. Even if we believe our data are sufficient to support marketing authorization,

regulatory authorities may disagree, or may require the generation and submission of additional data or analyses, which could significantly delay or preclude marketing authorization.

Before a new medical device can be marketed in the United States, a company must first submit a premarket notification to FDA and receive clearance by FDA under Section 510(k) of the FDCA, a PMA application and receive approval by FDA under Section 515 of the FDCA, or a de novo classification request and receive a grant of the request from the FDA under section 513(f)(2) of the FDCA, unless an exemption applies. In the 510(k) clearance process, before a device may be marketed, the FDA must determine that a proposed device is "substantially equivalent" to a legally-marketed "predicate" device, which includes a device that has been previously cleared through the 510(k) process, a device that was legally marketed prior to May 28, 1976 (pre-amendments device), a device that was originally on the U.S. market pursuant to an approved PMA and later down-classified, a device that was classified under the de novo classification pathway, or a 510(k)-exempt device. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device and performance data show that the proposed device is as safe and effective as the predicate device. Clinical data are sometimes required to support substantial equivalence. In the process of obtaining PMA approval, the FDA must determine that a proposed device is safe and effective (which means analytically valid and clinically valid in the case of tests) for its intended use based, in part, on extensive data, including, but not limited to, technical, pre-clinical, clinical trial, manufacturing and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices. In the de novo classification process, a manufacturer whose novel device under the FDCA would otherwise be automatically classified as Class III and require the submission and approval of a PMA prior to marketing is able to request down-classification of the device to Class I or Class II on the basis that the device presents a low or moderate risk. If Class II, new special controls will be required to provide reasonable assurance of safety and effectiveness of the device. If the FDA grants the de novo classification request, the applicant will receive authorization to market the device. This device type may be used subsequently as a predicate device for future 510(k) submissions.

The PMA approval, 510(k) clearance and de novo classification processes can be expensive, lengthy, and uncertain. The FDA's 510(k) clearance process usually takes from three to 12 months, but can take longer. The process of obtaining a PMA approval or de novo classification is much more costly and uncertain than the 510(k) clearance process and the FDA has 180 days from the day of filing under the FDC Act to complete its review of the PMA and FDA endeavors to review de novo classification requests within 150 days, although, in practice, the FDA's review often takes significantly longer. In addition, a PMA generally requires the performance of one or more clinical trials. Despite the time, effort and cost, a device may not obtain marketing authorization by the FDA. Any delay or failure to obtain necessary marketing authorizations could harm our business. Furthermore, even if we are granted such marketing authorizations, they may include significant limitations on the indicated uses for the solution, which may limit the potential commercial market for the solution.

In the United States, any modification to a product for which we receive marketing authorization may require us to submit a new 510(k) notification and obtain clearance, to submit a supplemental PMA and obtain FDA approval, or to submit a de novo request prior to implementing the change. For example, any modification to a 510(k)-cleared device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design, or manufacture, generally requires a new 510(k) clearance or other marketing authorization. The FDA requires every manufacturer to make such determinations in the first instance, but the FDA may review any manufacturer's decision. The FDA may not agree with a manufacturer's decisions regarding whether new marketing authorizations is necessary. If we obtain market authorizations from the FDA, we may make modifications or add additional features in the future that we believe do not require a new 510(k) clearance, de novo request or approval of a PMA or supplement. If the FDA disagrees with our determination and requires us to seek new marketing authorizations for the modifications for which we have concluded that new marketing authorizations are unnecessary, we may be required to cease marketing and/or to recall the modified product until we obtain such marketing authorization, and we may be subject to significant regulatory fines or penalties. If the FDA requires us to go through a lengthier, more rigorous examination for future solutions or modifications to existing solutions than we had expected, solution introductions or modifications could be delayed or canceled, which could adversely affect our business.

The FDA or other regulators can delay, limit, or deny marketing authorization of a product for many reasons, including but not limited to the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design, implementation, or results of, or interpretation of the data from, our clinical trials;

- the FDA or comparable foreign regulatory authorities may determine that our solution has not been shown to be safe and effective or substantially equivalent to a predicate device, or has other characteristics that preclude us from obtaining marketing authorization or prevent or limit its commercial use (for example, a narrowed indication for use claim);
- the population studied in the clinical program may not be sufficiently broad, generalizable, or representative of the intended target population of our solution to assure effectiveness and safety in the population for which we seek approval or clearance;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from clinical trials or may fail to accept data from clinical trials (or clinical sites), including if we fail to establish the integrity of our data;
- the FDA or comparable foreign regulatory authorities may determine that our clinical trials otherwise fail to comply with applicable regulations;
- serious or unexpected adverse effects or other performance issues are identified with our solutions;
- the FDA or comparable foreign regulatory authorities may determine that our manufacturing or quality system fails to comply with applicable regulations or otherwise fails to meet the standards necessary to support approval; 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.

There can be no assurance that our solutions for which we may seek marketing authorization will receive such marketing authorization from by the FDA or a comparable foreign regulatory authority on a timely basis, if at all, nor can there be assurance that labeling claims will be consistent with our anticipated claims or adequate to support continued adoption of, and reimbursement for, our solutions. If our solutions receive marketing authorization but there is uncertainty about such solutions among providers or payers, or if the approved or cleared indication or other labeling claims the FDA or a comparable foreign regulatory authority has authorized us to make are more limited than we expect, reimbursement may be adversely affected and we may not be able to sell our solutions. Compliance with FDA or comparable foreign regulatory authority regulations will require substantial costs, and subject us to heightened scrutiny by regulators and substantial penalties for failure to comply with such requirements or the inability to market our solutions, if authorized. The lengthy and unpredictable marketing authorization processes, as well as the unpredictability of the results of our clinical trials, may result in our failing to obtain marketing authorization to market our solutions, which would significantly harm our business, results of operations, reputation, and prospects.

Ethical, legal, and social concerns related to the use of genomic information could reduce demand for our solutions.

Genomic testing, like that conducted using our solutions, has raised ethical, legal, and social issues regarding privacy and the appropriate uses of the resulting information. Governmental authorities could, for social or other purposes, limit or regulate the use of genomic information or genomic testing or prohibit testing for genetic predisposition to certain conditions, particularly for those that have no known cure. Similarly, these concerns may lead patients to refuse to use genomic and somatic profiling tests even if permissible.

Ethical and social concerns may also influence U.S. and foreign patent offices and courts with regard to patent protection for technology relevant to our business. These and other ethical, legal, and social concerns may limit market acceptance of our solutions or reduce the potential markets for services enabled by our platform, either of which could have an adverse effect on our business, financial condition, and results of operations.

If the validity of an informed consent from patients regarding our solution was challenged and proven invalid, unlawful, or otherwise inadequate for our purposes, we could be forced to stop offering our solutions or using our resources, our business, financial condition, and results of operations will be adversely affected.

We offer our solutions to physicians and to biopharma companies in connection with clinical trials. We generally rely on treating physicians to obtain required informed consent under applicable state laws, but we have also recently implemented measures to ensure that data and biological samples that we receive have been collected from subjects who have provided appropriate informed consent. We also conduct validation studies, or act as a sponsor of clinical trials in connection with the development and validation of our solutions, which are frequently conducted in collaboration with different parties. We submit for projects that meet the definition of "human subjects research," to the IRB, or other reviewing body for review and approval of processes for subject informed consent and authorization for use of personal information or waivers thereof. We and our biopharma partners could conduct clinical trials in a number of different countries. When we are acting as a vendor in connection with a clinical trial sponsored by our biopharma partners, we

rely upon them to comply with the requirements to obtain the subject's informed consent and to comply with applicable laws and regulations. The collection of data and samples in many different countries results in complex legal questions regarding the adequacy of informed consent and the status of genetic material under a large number of different legal systems. Those informed consents could be challenged and proven invalid, unlawful, or otherwise inadequate for our purposes. Any such findings against us, or our biopharma partners, could force us to stop accessing or using data and samples or servicing or conducting clinical trials, which would hinder our product offerings or development. We could also become involved in legal actions, which could consume our management and financial resources.

If we fail to comply with applicable data interoperability and information blocking rules, our business, financial condition, and results of operations could be adversely affected.

The 21st Century Cures Act (the "Cures Act"), which was passed and signed into law in December 2016, includes provisions related to data interoperability, information blocking and patient access. In March 2020, the HHS Office of the National Coordinator for Health Information Technology ("ONC") finalized and issued complementary rules that are intended to clarify provisions of the Cures Act regarding interoperability and information blocking, and include, among other things, requirements surrounding information blocking and changes to ONC's health IT certification program. The companion rules will transform the way in which healthcare providers, health IT developers, health information exchanges/health information networks and health plans share patient information, and create significant new requirements for healthcare industry participants. For example, the ONC rule, which went into effect on April 5, 2021, prohibits healthcare providers from engaging in practices that are likely to interfere with, prevent, materially discourage, or otherwise inhibit the access, exchange, or use of electronic health information ("EHI"), also known as "information blocking." To further support access and exchange of EHI, the ONC rule identifies eight "reasonable and necessary activities" as exceptions to information blocking activities, as long as specific conditions are met. On July 3, 2023, the HHS Office of the Inspector General ("HHS-OIG") published its final rule implementing information blocking penalties for "actors," which is supplemented by ONC's January 9, 2024 final rule enhancing certain information blocking requirements, under which HHS-OIG may impose penalties for information blocking that has occurred after September 1, 2023. In addition, ONC and HHS proposed a rule on November 1, 2023, listing "appropriate disincentives" for noncompliance by healthcare providers. If we fail to comply with the requirements, it may negatively impact our business operations. The goals of increased use of electronic health data and interoperability are improved quality of care and lower healthcare costs generally. However, increased use of electronic health data and interoperability inherently magnifies the risk of security breaches involving that data and information systems used to share it. For additional information, see "—Risks Related to Our Business and Industry—If our information technology systems or those of third parties with whom we work, or our data are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences." Any failure to comply with these rules could adversely affect our business, financial condition, and results of operations.

If we or our partners fail to comply with federal, state, and foreign laboratory and other applicable licensing and registration requirements, we could be prevented from performing our solutions or experience disruptions to our business.

CLIA is a federal law that regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention, or treatment of disease, or impairment of, or the assessment of the health of, human beings. CLIA regulations require, among other things, clinical laboratories to obtain a certificate and mandate specific standards in the areas of personnel qualifications, administration, participation in proficiency testing, test management, and quality assurance. CLIA certification is also required for us to be eligible to bill state and federal healthcare programs, if such reimbursement is otherwise available, as well as many private third-party payers, for our solutions. Certain product additions to our solution menu require notification to regulatory and accrediting bodies that regulate our laboratories. To renew these certifications, we are subject to routine surveys and inspections. Moreover, CLIA inspectors may make random or "for cause" inspections of our clinical laboratories.

We currently have two commercial clinical laboratory facilities in Phoenix, Arizona, and we are in the process of building out our newest clinical laboratory in Irving, Texas. Both of the Phoenix laboratory facilities hold independent CLIA Certificates of Accreditation. A CLIA Certificate of Accreditation is issued to a laboratory facility that performs moderate and/or high complexity testing after an accreditation organization conducts a survey and determines that the laboratory is in compliance with the CLIA regulations. Our laboratory facility in Irving, Texas will seek a CLIA Certificate of Registration from CMS, and upon required inspection, anticipate receiving a CLIA Certificate of Accreditation. The CLIA Certificate of Registration allows the laboratory facility to begin conducting moderate and/or high complexity testing, subject to a survey to determine compliance with the CLIA regulations. After a laboratory obtains a Certificate of

Registration, CLIA begins scheduling regular, routine inspections. Once the inspection process for the laboratory facility is successfully completed, the facility qualifies for a CLIA Certificate of Accreditation and thereafter is inspected every two years.

Both of our Phoenix laboratories hold CAP accreditations upon which our CLIA Certificate of Accreditation are based. CAP typically conducts biannual surveys of each facility. Any failure to pass inspections, maintain our CAP accreditation, CLIA Certificate of Registration, CLIA Certificate of Accreditation, or state licenses, or add new validated solutions to our laboratory offerings could significantly harm our business, results of operations, and prospects.

In addition to obtaining federal certification for a laboratory under CLIA, we are also required to obtain and maintain state licenses to conduct profiling in our laboratories. Neither Arizona (where we currently operate two clinical laboratories) nor Texas (where we are completing the build-out of our newest clinical laboratory) requires us to obtain and maintain state licenses to conduct profiling in our laboratories. However, some states require out-of-state licensure if we test specimens originating from those states and return patient-specific results. Our tissue-based Arizona facility has obtained licenses from California, Rhode Island, Maryland, New York, and Pennsylvania, and our blood-based Arizona facility has obtained licenses from California, Maryland, Pennsylvania, and Rhode Island. If we have a blood-based profiling solution approved by New York state, we will also obtain a New York license for our blood-based facility.

For example, to be able to receive specimens originating from New York, we must obtain and maintain a New York State Department of Health clinical laboratory permit. We have a New York State Department of Health clinical laboratory permit for our tissue-based Arizona facility, and we intend to apply for such a permit for our other commercial facilities. Research testing (which we conduct at our R&D laboratory in Tempe, Arizona), however, does not require licensure if patient-specific results are not generated and/or returned for diagnostic purposes. As our blood-based Arizona facility does not currently operate in New York, we have not sought a New York laboratory permit. We cannot guarantee that the New York State Department of Health will issue a clinical laboratory permit for our Texas facility or our blood-based Arizona facility, and if we do not receive this permit, our business may be adversely impacted. In addition, New York laws and regulations establish rigorous standards for day-to-day operation of a clinical laboratory, including training and skill levels required of laboratory personnel, physical requirements of a facility, equipment, and validation and quality control, and we are required to abide by these laws and regulations as a permit holder. Failure to comply with these laws and regulations could result in various significant penalties, including loss of our New York permit, fines and other penalties, or limitations on our potential profiling population, which could adversely impact our business. New York also requires specific reporting for companies in the oncology space. Failure to comply with any established reporting requires could negatively impact our license.

The states that require us to hold an out-of-state license may change, and we are uncertain whether states will continue to grant or may require us to hold these licenses in the future. Any failure or inability on our part to obtain required state licensure may result in substantial penalties, including prohibition form billing certain payers and thus adversely affect our business.

In connection with CLIA certification and state laboratory licensing and permitting, we remain subject to a number of risks in the event of noncompliance. Any sanction imposed under CLIA, its implementing regulations, or state or foreign laws or regulations governing licensure or permitting, or our failure to renew or maintain a CLIA certificate, a state license or permit, or accreditation (including CAP), could adversely affect our business and reputation. CMS also has the authority to impose a wide range of sanctions, including suspension, limitation, or revocation of the CLIA certification, termination of Medicare and Medicaid participation, civil money penalties, and a bar on the ownership or operation of a CLIA-certified laboratory by any owners or operators of the deficient laboratory. If we fail to obtain any required state licensure, or lose CLIA certification, CAP accreditation, or licensure once obtained, we would not be able to operate our clinical laboratories and offer our solutions in full or in particular states, which would adversely impact our business, financial condition, and results of operations. Even if we were able to bring our laboratory back into compliance, we could incur significant expenses and potentially lose revenue in doing so.

In addition to state laboratory licensing laws, we may also be subject to foreign state registration and/or licensing requirements that apply to companies that manufacture medical devices. Certain states may require such registrations or licenses before the solutions are commercialized, including while manufacturers are evaluating the devices in clinical trials. Violations of these laws may result in a range of potential sanctions or penalties which could include the denial, suspension, limitation or revocation of the registration or license, as well as other fines and penalties, including imprisonment.

In addition, our pathologists are subject to individual medical licensure requirements and our pathologists, physicians, and geneticists could also be subject to in the future additional licensure requirements under state law. If the physicians and geneticists are not able to timely maintain, obtain or otherwise satisfy any new licensure requirements, this could have a negative impact on our operations.

Data from validation studies or clinical trials that we announce or publish from time to time before our trials are complete may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or topline data from our validation studies and clinical trials that we conduct ourselves or in partnership with other organizations, including on the application of Caris Assure in early detection, MRD tracking, and treatment monitoring, and Caris ChromoSeq, which disclosures are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data. We also make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results once additional data have been received and fully evaluated. Topline and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the topline or preliminary data we previously published. As a result, topline and preliminary data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our validation studies that we conduct or from our clinical trials. Interim data from these studies or trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as subject enrollment continues and more data become available. Adverse differences between interim data and top-line, preliminary, or final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions, or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, and our ability to receive coverage, marketing authorization or commercialize a particular solution and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding our business. If the data that we report differ from final results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to commercialize or obtain marketing authorization for, our solutions may be harmed, which could harm our reputation, business, financial condition, results of operations, and prospects.

Any solution for which we obtain marketing authorization will be subject to extensive ongoing regulatory requirements, and we may be subject to penalties if we or our partners fail to comply with regulatory requirements or if we experience unanticipated problems with our solutions.

Medical devices, along with the manufacturing processes, post-market surveillance, labeling, packaging, advertising, and promotion, distribution, storage, import, export, reporting, and recordkeeping for such solutions, are subject to continued regulatory review, oversight, requirements, and periodic inspections by the FDA and comparable foreign regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports; registration and listing requirements; requirements relating to quality control, quality assurance, cyber security, and corresponding maintenance of records and documents; requirements relating to recalls, removals, and corrections; and requirements relating to product labeling, advertising and promotion, and recordkeeping. It is uncertain whether our currently-marketed LDTs will become subject to these or any other requirements. See "—We have current solutions marketed as LDTs and plan to launch future solutions as LDTs. The regulation of LDT products in the United States remains subject to significant uncertainty, and if we fail to comply with any new or existing legal requirements with respect to our LDT solutions, our business, financial condition, and results of operations could be adversely affected." Regardless, the regulations to which we are subject are complex and have tended to become more stringent over time. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales. The FDA enforces these regulatory requirements through, among other means, periodic unannounced inspections. We do not know whether we will be found compliant in connection with any future regulatory inspections.

Marketing authorization of a test or device may be subject to limitations by the regulatory body as to the indicated uses for which the product may be marketed or to other conditions of marketing authorization. In addition, marketing authorization may contain requirements for costly post-marketing testing and surveillance to monitor the safety or effectiveness of the test or device. Discovery of problems with our solutions, suppliers, vendors, contract manufacturers, manufacturing processes (including software validation), and/or failure to comply with regulatory requirements, may result in actions such as:

- restrictions on operations of our laboratories;
- restrictions on manufacturing processes;
- restrictions on marketing of a product;
- Untitled or Warning letters;
- withdrawal or recall of the product from the market or seizure of the product;
- refusal to approve applications or supplements to approved applications that we may submit;
- fines, restitution or disgorgement of profits or revenue;
- suspension, limitation, or withdrawal of marketing authorization;
- exclusion from participation in U.S. federal or state healthcare programs, such as Medicare and Medicaid;
- safety communications;
- refusal to permit the import or export of our solution;
- injunctions; or
- imposition of civil or criminal penalties.

Any of these sanctions could result in higher than anticipated costs or lower than anticipated sales and adversely affect our reputation, business, financial condition, and results of operations.

In addition, the FDA may change its marketing authorization policies, adopt additional regulations or revise existing regulations, or take other actions. For example, in February 2024, the FDA issued a final rule to amend and replace the QSR, which sets forth the FDA's current good manufacturing practice requirements for medical devices, to align more closely with the International Organization for Standardization standards. Specifically, this final rule, which the FDA expects to go into effect on February 2, 2026, establishes the Quality Management System Regulation ("QMSR"), which among other things, incorporates by reference the quality management system requirements of ISO 13485:2016. Although the FDA has stated that the standards contained in ISO 13485:2016 are substantially similar to those set forth in the QSR, it is unclear the extent to which this final rule, once effective, could impose additional or different regulatory requirements on us that could increase the costs of compliance or otherwise adversely affect our business. If we are unable to comply with the QMSR, once effective, or with any other changes in the laws or regulations enforced by the FDA or comparable regulatory authorities, we may be subject to enforcement action, which could have an adverse effect on our business, financial condition, and results of operations.

For any solution we market that is or becomes subject to the FDA's medical device authority, we are or may become subject to the FDA's requirements to report to the FDA certain information about adverse medical events or malfunctions for any of our solutions, and if we fail to do so, we would be subject to sanctions that could harm our reputation, business, financial condition, and results of operations. The discovery of serious safety issues with our solutions, or a recall of our solutions either voluntarily or at the direction of the FDA or another governmental authority, could have a negative impact on us.

Any solution we market that is or becomes subject to the FDA's medical device authority and any solution for which we obtain FDA marketing authorization, including MI Cancer Seek, is or will become subject to the FDA's medical device reporting regulations and similar foreign regulations, which require us to report to the FDA when we receive or become aware of information that reasonably suggests that one or more of these solutions may have caused or contributed to a death or serious injury or malfunctioned in a way that, if the malfunction were to recur, it could cause or contribute to a death or serious injury. See "—We have current solutions marketed as LDTs and plan to launch future solutions as LDTs. The regulation of LDT products in the United States remains subject to significant uncertainty, and if we fail to comply with any new or existing legal requirements with respect to our LDT solutions, our business, financial condition, and results of operations could be adversely affected." The timing of our obligation to report is 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 of which we become aware within the prescribed timeframe. We may also fail to recognize 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 the product. If we fail to comply with our reporting obligations, the FDA could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of

civil monetary penalties, revocation of our device marketing authorization, withdrawal of our solutions from the market, seizure of our solutions, or delay in marketing authorization of future solutions.

The FDA and foreign regulatory bodies have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. The FDA's authority to require a recall must be based on a finding that there is reasonable probability that the device could cause serious injury or death. We may also choose to voluntarily recall a product if any material deficiency is found. A government-mandated or voluntary recall by us could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing defects, labeling or design deficiencies, packaging defects or other deficiencies, or failures to comply with applicable regulations. Product defects or other errors may occur in the future.

Depending on the corrective action we take to redress a product's deficiencies or defects, the FDA may require, or we may decide, that we will need to obtain new marketing authorizations for the device before we may market or distribute the corrected device. Seeking such marketing authorizations may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including FDA warning letters, product seizure, injunctions, administrative penalties or civil or criminal fines.

Companies are required to maintain certain records of recalls and corrections, even if they are not reportable to the FDA. We may initiate voluntary withdrawals or corrections for our solutions in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, it could require us to report those actions as recalls and we may be subject to enforcement action. A future recall announcement could harm our reputation with customers, potentially lead to product liability claims against us and negatively affect the adoption and use of our solutions. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results.

Our solutions will need to be manufactured and offered in accordance with federal and state regulations, and we could be forced to recall our devices or terminate production or offering our LDTs if we or our partners fail to comply with these regulations.

The methods used in, and the facilities used for, the manufacture of medical devices must comply with the FDA's QSR requirements, which is a complex regulatory scheme that covers the procedures and documentation of the design, testing, production, process controls, quality assurance, labeling, packaging, handling, storage, distribution, installation, servicing, and shipping of medical devices. Furthermore, we are required to verify that our suppliers maintain facilities, procedures and operations that comply with our quality standards and applicable regulatory requirements. The FDA enforces the QSR requirements through periodic announced or unannounced inspections of medical device manufacturing facilities, which may include the facilities of subcontractors. Our solutions are also subject to similar state regulations and various laws and regulations of foreign countries governing manufacturing.

Our third-party manufacturers may not take the necessary steps to comply with applicable regulations, which could cause delays in the delivery of our solutions. In addition, in February 2024, the FDA issued a final rule to amend and replace the QSR, as described above in "—Any solution for which we obtain marketing authorization will be subject to extensive ongoing regulatory requirements, and we may be subject to penalties if we or our partners fail to comply with regulatory requirements or if we experience unanticipated problems with our solutions." It is unclear the extent to which this final rule, once effective, could impose additional or different regulatory requirements on us that could increase the costs of compliance or otherwise negatively affect our business. Failure to comply with applicable FDA requirements or later discovery of previously unknown problems with our solutions or manufacturing processes could result in, among other things: warning letters or untitled letters; fines, injunctions or civil penalties; suspension or withdrawal of approvals; seizures or recalls of our solutions; total or partial suspension of production or distribution; administrative or judicially imposed sanctions; FDA's refusal to grant pending or future marketing authorizations for our solutions; clinical holds; refusal to permit the import or export of our solutions; and criminal prosecution of us, our suppliers, or our employees.

Any of these actions could significantly and negatively affect supply of our solutions. If any of these events occurs, our reputation could be harmed, we could be exposed to product liability claims and we could lose customers, experience reduced sales, and increased costs.

The misuse or off-label use of our solutions may harm our reputation in the marketplace, lead to product liability suits or result in costly investigations, fines, or sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business.

Any marketing authorization we may receive for our solutions will be limited to specified indications for use. We train our marketing personnel and direct sales force to not promote our solutions for uses outside of FDA cleared or approved indications for use, known as "off-label uses." We cannot, however, prevent a physician from using our solutions off-label, when in the physician's independent professional medical judgment, he or she deems it appropriate.

If the FDA or any foreign regulatory body determines that our promotional materials or training constitute promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance or imposition of an untitled letter, which is used for violators that do not necessitate a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action under other regulatory authority, such as false claims laws, if they consider our business activities to constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment of our operations.

In addition, physicians may misuse our solutions if they are not adequately trained, potentially leading to injury and an increased risk of product liability. If our solutions are misused, we may become subject to costly litigation by our customers or their patients. As described above, product liability claims could divert management's attention from our core business, be expensive to defend and result in sizeable damage awards against us that may not be covered by insurance.

Misleading, untruthful, or unsubstantiated labeling, advertising, marketing, or promotional practices could adversely impact our business, financial condition, and results of operations. The FTC has instituted enforcement actions against certain healthcare testing companies for making false or misleading advertising claims and for failing to adequately substantiate claims made in advertising. These enforcement actions may result in warning letters, consent decrees, and the payment of civil penalties and/or restitution by the companies involved. Should the FTC determine that our claims are false or misleading or unsubstantiated, we could be subject to FTC enforcement action and may face significant penalties which may adversely impact our business, financial condition, and results of operations.

The labeling, advertising, marketing, and promotional practices related to our solutions is governed by numerous state and federal regulators, including the FDA and the FTC, as well as subject to third-party claims. Any statements related to our solutions that could be construed as misleading, untruthful, or unsubstantiated, could subject us to regulatory enforcement action, third-party lawsuits, or plaintiffs' complaints. Any of these actions could significantly and negatively affect our reputation, expose us to liability claims, and we could lose customers and experience reduced sales and increased costs.

Our "research use only" and any potential "investigational use only" products could become subject to more onerous regulation by the FDA or other regulatory authorities in the future, which could increase our costs and delay our commercialization efforts, thereby materially and adversely affecting our business, financial condition, and results of operations.

In the United States, some of our products are currently available, or may become available, for research use only ("RUO"), or for investigational use only ("IUO"), depending on the proposed application. We make our RUO and IUO products available to a variety of parties, including pharmaceutical and biotechnology companies and research institutions. Because RUO and IUO products are not intended for use in clinical practice and cannot be advertised or promoted for clinical or diagnostic claims, they are exempt from many regulatory requirements otherwise applicable to medical devices. In particular, FDA regulations require that RUO products be labeled "For Research Use Only. Not for use in diagnostic procedures," and IUO products be labeled "For Investigational Use Only. The performance characteristics of this product have not been established," and such products are not subject to the FDA's pre- and post-market controls for medical devices.

A significant change in the laws governing RUO or IUO products or how they are enforced may require us to change our business model in order to maintain compliance. In addition, even under the current law and governmental policies, there is a risk that the FDA may disagree with our characterization of whether a product is appropriately considered an "RUO" product that is not subject to FDA's premarket review or marketing authorization. For instance, in November 2013, the FDA issued a guidance document entitled "Distribution of In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only" (the "RUO/IUO Guidance"), which indicates that distribution of RUO or

IUO products with written or verbal statements in any labeling, advertising or promotion suggesting that clinical laboratories can validate the test through their own procedures and subsequently offer it for clinical diagnostic use as an LDT would conflict with the RUO or IUO status. The RUO/IUO Guidance further indicates that any assistance offered in performing clinical validation or verification, or similar specialized technical support, to clinical laboratories, would conflict with the RUO or IUO status of the product. If we engage in any activities that the FDA deems to be in conflict with the RUO or IUO status held by any of our products so labeled, we may be subject to immediate, severe, and broad FDA enforcement action that would adversely affect our ability to continue operations. Accordingly, if the FDA finds that we are distributing our RUO or IUO products in a manner that is inconsistent with its RUO/IUO requirements and restrictions, we may be forced to stop distribution of our RUO/IUO tests until we are in compliance, which would reduce our revenue, increase our costs, and adversely affect our business, financial condition, and results of operations.

Changes in funding or disruptions at CMS, the FDA and other government agencies caused by funding shortages, staffing limitations, or global health concerns could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could adversely impact our business.

The ability of the FDA to review and provide marketing authorization of new products or changes to existing products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, federal government shutdowns, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund R&D activities is subject to the political process, which is inherently fluid and unpredictable. Decreases in government funding of research and development, including termination of federal employees and any reductions in funding to the U.S. National Institutes of Health may impact our business, as could changes in government programs that provide funding to research institutions and companies, including changes in the amount of funds allocated to different areas of research or changes that have the effect of increasing the length of time of the funding process. Disruptions at CMS, the FDA and other government agencies may also slow the time necessary for new medical devices or modifications to FDA cleared or approved medical devices to be reviewed and/or approved by necessary government agencies or delays in reimbursement approvals, which could adversely affect our business. For example, in recent years, the U.S. government has shut down several times (and a government shutdown began on October 1, 2025) and certain regulatory agencies, such as CMS and the FDA, have had to furlough critical 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 CMS and the FDA, and it remains unclear the degree to which these efforts may limit or otherwise adversely affect CMS's and the FDA's ability to conduct routine activities.

In addition, during the COVID-19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. If the current government shutdown continues on a prolonged basis, a future prolonged shutdown occurs, or if funding shortages, staffing limitations or renewed global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other routine activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could adversely affect our business.

The Federal Policy for the Protection of Human Subjects or related state regulations may be revised or altered in a way that negatively impacts our business.

The Federal Policy for the Protection of Human Subjects (typically referred to as the Common Rule) may be altered in a way that prevents or restricts us from using patient samples or clinical trial data to further develop or validate our solutions or future AI/ML algorithms which rely upon identifiable data. The revised Common Rule, effective as of July 19, 2018, allows the use of prospective consent to unspecified future research (i.e., "broad consent") from a human subject for the storage, maintenance, and secondary use of identifiable private information and identifiable biospecimens in research activities. We obtain both identifiable and de-identified data which we use to develop our solutions through biospecimen repositories and from our biopharma partners. If regulations allowing broad consent or the regulatory definition of "research" changes in a way that excludes our research activities, our business may be negatively impacted. State laws governing clinical research may complicate our compliance efforts and add costs and delay to our R&D activities.

Our business activities are subject to the FCPA and similar anti-bribery and anti-corruption laws, as well as export and import controls and economic sanctions laws and regulations of the United States and other jurisdictions.

Our business activities are subject to the Foreign Corrupt Practices Act of 1977, as amended (the "FCPA"), and similar anti-bribery or anti-corruption laws, regulations, or rules of other countries, such as the U.K. Bribery Act. The FCPA generally prohibits offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many countries, the healthcare providers who administer diagnostic tests are employed by their government, and the purchasers of diagnostics tests are government entities; therefore, our dealings with these providers and purchasers are subject to regulation under the FCPA. The Securities and Exchange Commission ("SEC") and DOJ have increased their FCPA enforcement activities with respect to life sciences companies. There is no certainty that all of our employees, agents, contractors, or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Filing of FCPA enforcement actions have been temporarily paused. Once enforcement resumes, companies may incur additional damage due to delayed prosecution.

Our business is also subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. customs regulations, and various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Control. Export controls and trade sanctions laws and regulations may restrict or prohibit altogether the provision, sale, or supply of our products to certain governments, persons, entities, countries, and territories, including those that are the target of comprehensive sanctions or an embargo. In particular, there is currently significant uncertainty about the future relationship between the United States and various other countries, including, without limitation, China, Mexico, and Canada, with respect to trade policies, treaties, tariffs, taxes, and other limitations on cross-border operations.

Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of our facilities, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our solutions in one or more countries and could harm our reputation, brand, international expansion efforts, and ability to attract and retain employees, which could have an adverse effect on our business, financial condition, and results of operations.

Risks Related to Intellectual Property

If we are unable to obtain and maintain intellectual property protection for our technology, or if the scope of the intellectual property protection we obtain is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to our solutions, and our ability to successfully commercialize our solutions may be impaired.

Our success and ability to compete successfully will depend in part on our ability to obtain, maintain, and enforce issued patents, trademarks, and other intellectual property rights and proprietary technology protection for our solutions, preserve our trade secrets, and operate without infringing the intellectual property rights of third parties. Filing, prosecuting, enforcing, and defending patents on our solutions and other technologies in all countries throughout the world would be prohibitively expensive and time-consuming, and the laws of some foreign countries may not protect our rights to the same extent as the laws of the United States. We may not, and our international distributors may not, be able to file, prosecute, maintain, enforce, or license all necessary or desirable patents or patent applications at a reasonable cost or in a timely manner, or in all jurisdictions, or at all, or may choose not to do any of the foregoing. Furthermore, in some cases, we have only filed provisional patent applications on certain aspects of our products and technologies and each of these provisional patent applications, or any future provisional patent application on certain aspects of our products and technologies, is not eligible to become an issued patent until, among other things, we file a non-provisional patent application within 12 months of the filing date of the applicable provisional patent application. In cases where we have not obtained, or decided not to obtain, patent protection for certain of our inventions, we may not be able to prevent third parties from practicing our inventions or from selling or importing tests made using our inventions in and into the United States or other jurisdictions.

The patent positions of companies, including our patent position, may involve complex legal and factual questions that have been the subject of much litigation in recent years, and, therefore, the scope of any patent claims that we have or may obtain cannot be predicted with certainty. Accordingly, we cannot provide any assurances about which of our patent applications will issue, the breadth of any resulting patent, whether any of the issued patents will be found to be infringed, that any of our issued patents have, or that any of our currently pending or future patent applications that mature into issued patents will include, claims with a scope sufficient to protect our solutions and services. Our pending and future patent applications may not result in the issuance of patents or, if issued, may not issue in a form that will be advantageous to us. The coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. We cannot offer any assurances that the breadth of our granted patents will be sufficient to prevent a competitor from developing, manufacturing, and commercializing a solution or technologies in a non-infringing manner that would be competitive with one or more of our solutions or technologies, or otherwise provide us with any competitive advantage.

Moreover, although we have applied for patents covering aspects of our technology in the United States and several other countries, we cannot be certain that our owned and exclusively licensed patents will not be challenged, or that all patents for which we have applied, or that are covered by our exclusive in-licenses, will be issued on a timely basis or at all, or that such patents will protect our technology, in whole or in part, or be issued in a form that will provide us with meaningful protection, prevent competitors from competing with us, or otherwise provide us with any competitive advantage. As further described below, the enforceability of issued patents may be challenged on a number of fronts, including inventorship, scope, or validity, and certain of our owned or exclusively in-licensed patents have been, and others in the future may be, challenged in the courts or patent offices in the United States and abroad. As a result of such challenges, our issued patents may be held invalid or unenforceable and the scope of existing or future patents may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. For additional information, see "—Issued patents covering our solutions and other technologies could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States and abroad." We may fail to identify patentable technologies in a timely fashion, which could impair our ability to obtain patent protection on such technology at all. If we fail to timely file for patent protection in any jurisdiction, we may be precluded from doing so at a later date. Our competitors may be able to circumvent our owned or exclusively in-licensed patents by developing similar or alternative technologies or tests in a non-infringing manner. In addition, to the extent we have granted, or may grant in the future, licenses, or sublicenses of our intellectual property rights to third parties, we cannot be certain that such intellectual property rights will not be used by those third parties in a manner that could compete with our business or otherwise negatively impact any competitive advantage provided by such intellectual property rights.

Publications of discoveries in scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are uncertain. Given the amount of time required for the development, testing, and regulatory review of biological tests, patents protecting or covering such tests might expire shortly after such solutions are commercialized. As a result, our owned or exclusively in-licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If a third party obtains an issued patent on a technology we use in our solutions, that party may be able to prevent us from using those inventions, and we may not be able to design around the third party's patents or obtain a license on commercially reasonable terms, if at all. Third-party patents or other intellectual property may exist that our current technology, manufacturing methods, solutions, platform, or future methods or tests will be alleged to infringe, which could result in litigation, the imposition of injunctions preventing our use of the foregoing, or require us to obtain licenses or pay royalties and/or other forms of compensation to third parties, which could be significant and could harm our results of operations.

Some of our patents and patent applications may in the future be co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products, services, and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us.

The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that:

- any of our patents, or any of our pending patent applications, if issued, will include claims having a scope sufficient to protect our solutions;
- any of our pending patent applications will issue as patents;
- we will be able to successfully manufacture and commercialize our solutions on a substantial scale, if approved, before relevant patents we may have expire;
- we were the first to make the inventions covered by each of our patents and pending patent applications;
- we were the first to file patent applications for these inventions;
- others will not independently develop, manufacture and/or commercialize similar or alternative or duplicative solutions of any of our technologies or products that do not infringe our patents;
- any of our challenged patents will be found to ultimately be valid and enforceable;
- any patents issued to us will provide a basis for an exclusive market for our commercially viable solutions or technologies, and will provide us with any competitive advantages or will not be challenged by third parties;
- we will develop additional proprietary technologies or solutions that are separately patentable;
- our pending patent applications or those that we may own in the future will lead to issued patents;
- our competitors will not conduct R&D activities in countries where we do not have patent rights and then use the information learned from such activities to develop, manufacture, and commercialize competitive products for sale in our major commercial markets;
- the patents of others will not harm our business;
- a third party does not subsequently file a patent covering trade secrets or know-how that we chose not to seek patent protection; or
- our commercial activities or solutions will not infringe upon the patents of others.

Third parties may allege that we infringe, misappropriate, or violate their intellectual property rights, and if they prevail, could block sales of our solutions and force us to pay damages and/or royalties, which could adversely affect the success of our business.

Our commercial success in part depends upon our ability, and the ability of our relevant commercial partners, to market, sell, and distribute our solutions and use our proprietary technologies and platform without infringing, misappropriating, or otherwise violating the intellectual property rights of third parties. There is considerable intellectual property litigation in the medical technology, biotechnology, diagnostic, and pharmaceutical industries, and companies in these industries have used intellectual property litigation to gain a competitive advantage. In addition, there is ongoing intellectual property litigation involving the analysis of circulating nucleic acid, the outcome of which could also impact future litigation involving our intellectual property or our ability to commercialize our solutions. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights. Third parties may assert infringement claims against us based on existing patents or patents that issue in the future.

If we are found to infringe, misappropriate, or otherwise violate a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing, marketing, selling, and distributing our solutions or platform, or to cease using the infringing technology. However, we may not be able to obtain any required license on commercially reasonable terms, if at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, we could be found liable for monetary damages, including treble damages if we are found to have willfully infringed a patent and attorneys' fees if the court finds the case to be exceptional. A finding of infringement, misappropriation, or other violation could prevent us from commercializing our solutions or force us to cease some of our operations or develop alternate technologies, which could materially harm our business, financial condition, results of operations, and prospects. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our reputation and business.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our personnel from their normal responsibilities. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can if they have greater financial resources and/or more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could adversely affect our ability to compete in the marketplace.

Issued patents covering our solutions and other technologies could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States and abroad.

In addition to allegations of infringement of a third party's intellectual property rights, a third party may also challenge the validity or enforceability of our owned or in-licensed patents in court or before administrative bodies in the United States or abroad. If we or one of our licensors were to initiate legal proceedings against a third party to enforce a patent covering a solution or a solution candidate, the defendant could counterclaim that the asserted patent is invalid and/or unenforceable. Though an issued patent is presumed valid and enforceable, defendant counterclaims alleging invalidity or unenforceability are commonplace in patent litigation in the United States. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements for patentability, including lack of novelty, obviousness, lack of subject matter eligibility, lack of written description, and non-enablement. Non-statutory grounds for unenforceability include inequitable conduct in obtaining the patent, such as an allegation that someone connected with prosecution of the patent withheld relevant information from the United States Patent and Trademark Office (the "USPTO"), or made a material misleading statement. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to validity, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. In addition, the patent laws or interpretation thereof by the USPTO and courts could result in some of the claims of our patents to become invalidated. A court may decide that a patent or other intellectual property right of ours is invalid or unenforceable, in whole or in part, construe the patent's claims or other intellectual property narrowly or refuse to stop a third party from using the technology at issue on the grounds that our patents or other intellectual property do not cover the technology in question and is therefore not infringed upon, violated, or misappropriated. For example, certain claims of five of our U.S. patents have previously been invalidated in inter partes review ("IPR") proceedings, two of our European patents were challenged but ultimately upheld in their entirety in opposition proceedings, and one of our European patents was held unpatentable in an opposition proceeding. As a result of such challenges, our issued patents may be held invalid or unenforceable and the scope of existing or future patents may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If a defendant were to prevail on its legal assertion of invalidity and/or unenforceability against our intellectual property related to a solution or a solution candidate, we could lose at least part, and perhaps all, of the patent protection on such solution or solution candidate. Such a loss of patent protection could adversely impact our business. Moreover, our competitors could counterclaim that we infringe their intellectual property, and some of our competitors have substantially greater intellectual property portfolios than we do. Even if our patents or other intellectual property rights are found to be valid and infringed, a court may refuse to grant injunctive relief against the infringer and instead grant us monetary damages and/or ongoing royalties. Such monetary compensation may be insufficient to adequately offset the damage to our business caused by the infringer's competition in the market. An adverse result in any litigation or administrative proceeding could put one or more of our patents or other intellectual property rights at risk of being invalidated or interpreted narrowly, which could adversely affect our competitive business position, financial condition, and results of operations. Moreover, even if we are successful in any litigation, we may incur significant cost and expense in connection with such proceedings, and the amount of any monetary damages may be inadequate to compensate us for damage from the infringement and proceedings.

In addition to infringement claims against us, third parties have raised, and in the future may raise, claims challenging the validity or enforceability of our owned or in-licensed patents before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms before the USPTO include re-examination, post grant review, IPR, derivation proceedings, interference proceedings, and equivalent proceedings in foreign jurisdictions (such as opposition proceedings in Europe). Such administrative proceedings could result in the revocation of, cancellation of, or amendment to our patents in such a way that they no longer cover our technologies or solutions. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel, and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity and/or unenforceability, we may lose at least part, and perhaps all, of the patent protection on our solutions or technologies. Such a loss of patent protection could adversely impact our business, financial condition, and results of operations.

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

We have entered into, and may further need to enter into, certain licenses or other collaboration agreements pertaining to the in-license of intellectual property rights from others to advance our research or allow commercialization

of our solutions and technologies. Some of these licenses are for a limited term and may include the right for the licensor to terminate upon notice. If any such arrangement is terminated by the licensor, or if we need to enter into any additional licensing arrangements, then we may be unable to obtain such licenses at a reasonable cost or on reasonable terms, if at all, and as a result, we may be required to expend significant time and resources to redesign our technology or to develop or license replacement technology, any of which may not be feasible on a technical or commercial basis. If we are unable to obtain or maintain applicable licenses, we may be unable to commercialize certain solutions or continue to use certain technology, which could harm our business, financial condition, and results of operations.

Our intellectual property in-licenses may impose various reporting, development, diligence, milestone payment, royalty, insurance, commercialization, and other obligations on us, and we expect that our future license or development agreements will contain similar types of obligations. If we fail to comply with any of these obligations, our licensor or collaboration partners may have the right to terminate the relevant license or collaboration agreement, in which event we would not be able to develop or market the solutions or technologies covered by such licensed intellectual property, or to pursue other reasonable or alternative arrangements. Despite our efforts, our licensors or collaborators might conclude that we have materially breached our obligations under such license agreements. If our licensors or collaborators were to terminate the license agreements or otherwise modify our rights under those agreements, our ability to develop and commercialize solutions and technology covered by these license agreements could be limited if not halted. This could adversely affect our competitive position, business, financial condition, results of operations, and prospects.

Agreements under which we license or otherwise obtain rights to intellectual property or technology from third parties may be complex, and certain provisions in such agreements may be susceptible to multiple interpretations, which could lead to disputes between us and our licensor, including:

- the scope of rights granted under the license agreement;
- the extent to which our solution and technology are alleged to infringe the licensor's intellectual property that is not subject to the license agreement;
- the right to sublicense patent and other rights under our collaborative development relationships;
- our diligence and other obligations under the license agreement;
- the priority of invention of patented technology; and
- the inventorship and ownership of inventions and know-how resulting from the collaboration with a licensor or joint invention of intellectual property by us and our licensors and our partners.

The resolution of any contract disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could adversely affect our business, financial condition, results of operations, and prospects. If we were required to engage in litigation to enforce or defend our rights under our license or development agreements, even if we were successful, such litigation could require significant financial resources, divert the attention of management, and harm our business. Moreover, if disputes over intellectual property rights that we have licensed or otherwise obtained rights to prevent or impair our ability to maintain our current arrangements on commercially acceptable terms, or at all, we may be unable to successfully commercialize the affected solution or technology, which could adversely affect our business, financial condition, results of operations, and prospects.

In addition, we may have limited control over the maintenance and prosecution of in-licensed patents and patent applications, or any other intellectual property that may be related to our in-licensed intellectual property. For example, we cannot be certain that such activities by any future licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. If any of our current or future licensors fail to obtain and maintain patent or other protection for the proprietary intellectual property we license from them, we could lose our rights to the intellectual property, or these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business and our competitors could market competing products using the intellectual property. In the event we breach any of our obligations related to such maintenance or prosecution, we may incur significant liability to our licensing partners, including loss of our right to the licensed patent applications or early termination of the license by our licensor. We also may have limited control over the manner in which our licensors initiate an infringement proceeding against a third-party infringer of the intellectual property rights, or defend certain of the intellectual property that is licensed to us. It is possible that the licensor's infringement proceeding or defense activities may be less vigorous than had we conducted such activities ourselves. Our ability to enforce in-licensed patents may be in question if our licensors refuse to join in such activities initiated by us.

Our technology licensed from third parties may be subject to retained rights.

Any license we may enter into could provide for the retention by the licensor of certain rights under their agreements with us, including for example, the right to use the underlying technology for noncommercial academic and research use, to publish general scientific findings from research related to the technology, and to make customary scientific and scholarly disclosures of information relating to the technology. It is difficult to monitor whether any future licensors will limit their use of the technology to these uses, and we may incur substantial expenses to enforce our rights to our licensed technology in the event of misuse.

In addition, the U.S. government retains certain rights in inventions produced with its financial assistance under the Patent and Trademark Law Amendments Act (the "Bayh-Dole Act"). The U.S. government retains a "nonexclusive, nontransferable, irrevocable, paid-up license" for its own benefit. The Bayh-Dole Act also provides federal agencies with "march-in rights." March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a "nonexclusive, partially exclusive, or exclusive license" to a "responsible applicant or applicants." If the patent owner refuses to do so, the government may grant the license itself. The Bayh-Dole Act also imposes other obligations, including the requirement that products covered by the government funded patents be manufactured in the United States. We sometimes collaborate with academic institutions to accelerate our R&D efforts. In the future, we may own or license technology which is critical to our business that is developed in whole or in part with federal funds subject to the Bayh-Dole Act. If the federal government exercises its rights under the Bayh-Dole Act, our ability to enforce or otherwise exploit patents covering such technology may be adversely affected.

We may become involved in lawsuits to protect or enforce or defend our patents or other intellectual property rights, which could be expensive, time-consuming, and unsuccessful.

Third parties, including our competitors, may currently, or in the future, infringe, misappropriate, or otherwise violate our issued patents or other intellectual property rights, and we may file lawsuits or initiate other proceedings to protect or enforce our patents or other intellectual property rights, which could be expensive, time-consuming, and unsuccessful. We monitor for unauthorized use of our intellectual property rights and, from time to time, analyze whether to seek enforce our rights against potential infringement, misappropriation, or violation of our intellectual property rights. However, the steps we have taken, and are taking, to protect our proprietary rights may not be adequate to enforce our rights as against such infringement, misappropriation, or violation of our intellectual property rights. In certain circumstances it may not be practicable or cost-effective for us to enforce our intellectual property rights fully, for example, in certain countries or where the initiation of a claim might harm our business relationships. We may also be hindered or prevented from enforcing our rights with respect to a government entity or instrumentality because of the doctrine of sovereign immunity. Our ability to enforce our patent or other intellectual property rights can depend on our ability to detect infringement. It may be difficult to detect infringers who do not advertise the components or methods that are used in connection with their products or technologies. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's product or technologies. Thus, we may not be able to detect unauthorized use of, or take appropriate steps to enforce, our intellectual property rights. Any inability to meaningfully enforce our intellectual property rights could harm our ability to compete and reduce demand for our solutions.

In addition, these lawsuits or other proceedings could be costly and could affect our operations and divert the attention of our managerial, legal, and scientific personnel. There is a risk that a court or administrative body would decide that our owned or in-licensed patents are invalid or not infringed by a third party's activities, or that the scope of certain claims is more limited than we believe. An adverse outcome in a litigation or other proceeding involving our owned or in-licensed patents could limit our ability to enforce our patents against competitors, affect our ability to receive royalties or other licensing consideration, and may curtail or preclude our ability to exclude third parties from making, using, and selling similar or competitive products. We may become more susceptible to these types of lawsuits and proceedings given the proliferation of organizations pursuing intellectual property protections in the biomarker testing space, particularly as relates to cell free nucleic acids. Any of these occurrences could adversely affect our business, financial condition, results of operations, and prospects.

Intellectual property litigation may lead to public disclosures and unfavorable publicity that harms our reputation and causes the market price of our common stock to decline.

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 litigation. Further, during the course of any intellectual property litigation, there could be public announcements of the initiation of the litigation as

well as results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our existing solutions, programs or intellectual property could be diminished. Accordingly, the market price of shares of our common stock may decline. Such announcements could also harm our reputation or the market for our future solutions, which could adversely affect our business.

Patent terms may be inadequate to protect our competitive position on our solutions for an adequate amount of time.

Patents have a limited lifespan in all jurisdictions around the world. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the protection offered by a patent remains time limited. Once a patent covering our solutions expires, we may be subject to additional competition. Given the amount of time required for the development, testing and regulatory review of new products, patents protecting such products might expire before or shortly after such products are commercialized or receive regulatory approval. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing solutions similar or identical to ours for a meaningful amount of time, or at all. Such an inability to exclude competitors from commercializing similar or identical products could have adversely impact our reputation, business, financial condition, results of operations, and prospects.

If we do not obtain patent term extension and data or regulatory exclusivity for any solutions we may develop, our business may be materially harmed.

Depending upon the timing, duration, and specifics of any FDA marketing approval of any therapeutic solutions we may develop, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984 (the "Hatch-Waxman Amendments"). The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable legal requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our solution will be shortened and our competitors may obtain approval of competing products following our patent expiration and may take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data to launch their product earlier than might otherwise be the case.

Additionally, depending upon the timing, duration, and specifics of any FDA approval of biological products we may develop as part of Caris Discovery or otherwise, such products may be eligible for a period of regulatory exclusivity under the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), a subtitle of the Patient Protection and Affordable Care Act. The BPCIA created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a highly similar or "biosimilar" product may not be submitted to the FDA until four years following the date that the reference product was first approved 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 approved. 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 biologics license application 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.

Biological products we may develop, if any and if approved, could be considered reference products entitled to 12-year 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 a product candidate to be reference products for competing products, potentially creating the opportunity for competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. The FDA only approved the first interchangeable biosimilar in July 2021, and the law is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and

meaning are subject to uncertainty. If competitors are able to obtain marketing approval for biosimilars referencing any biological products we may develop, our products may become subject to competition from such biosimilars, which could adversely impact our competitive position.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and 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 application process to maintain patent applications and issued patents. In addition, periodic maintenance fees, renewal fees, annuity fees, and various other government fees on patents and applications must be paid to the USPTO and similar patent agencies outside of the United States over the lifetime of our owned and in-licensed patents and applications. In some cases, we rely on our licensing partners to pay such fees and to take the necessary actions to comply with other requirements to maintain such in-licensed patents during their term. While an unintentional lapse of a patent or patent application can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, in some cases non-compliance can result in abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, potential competitors might be able to enter the market with similar or identical tests or technology, which could adversely affect our competitive position.

Developments in patent law could have a negative impact on our business.

From time to time, the U.S. Supreme Court or other federal courts, the U.S. Congress, the USPTO, or similar governmental authorities in other jurisdictions may change the standards of patentability and any such changes could have a negative impact on our business.

Several decisions from the U.S. Supreme Court regarding patentable subject matter are of particular relevance in the medical diagnostics and computer-implemented applications space. The 2012 decision in Mayo Collaborative v. Prometheus Laboratories ("Mayo") concerns patent claims directed to optimizing the amount of drug administered to a specific patient based on certain metabolite levels in blood. The Supreme Court held that the applicable patent's claims were directed to a law of nature (i.e., a natural correlation between metabolite levels and efficacy or toxicity) and failed to incorporate a sufficiently inventive concept above and beyond routine and conventional method steps to allow the claimed methods of treatment to qualify as patent eligible. The 2014 decision in Alice Corporation Pty. Ltd. v. CLS Bank International ("Alice") concerns a computer-implemented, electronic escrow service for facilitating financial transactions. The Supreme Court held that an abstract idea could not be patented just because it is implemented on a computer. It is generally believed that Mayo and Alice, and subsequent cases interpreting these decisions, have made it more difficult to patent medical diagnostic and computer-implemented inventions. Our efforts to seek patent protection for such technologies and solutions may be negatively impacted by this jurisprudence, or guidance or procedures issued by the USPTO or authorities in other jurisdictions.

We cannot predict the impact of the changing landscape of patent eligible subject matter on our ability, or that of our competitors, to obtain or enforce patents relating to products and services involving genomic or biomarker related discoveries, or computer-implemented technologies, such as molecular tests that implement ML. Indeed, many believe that the contours of whether claims are patent eligible, or recite laws of nature, natural phenomena, natural products, or abstract ideas remain unclear despite a decade of interpretation at the USPTO and in the courts. Third parties holding patents issued prior to Mayo, Myriad and Alice could allege that we infringe these patents, even if these patents are not likely enforceable under current U.S. laws. We could be forced to defend against claims of patent infringement or obtain license rights, if available on commercially reasonable terms or at all, under these patents. In jurisdictions other than the United States, gene- and computer-related patent claims may remain valid and may be enforceable against us.

The U.S. Congress has periodically sought to pass laws concerning subject matter eligibility for patent protection, aimed in large part at abrogating the holdings of Mayo and Alice. To date, these efforts have been unsuccessful, but are ongoing. We cannot fully predict the impact that such new laws may have on our ability to obtain patent protection on our solutions and technologies, and our ability to operate in view of the patents controlled by third parties.

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

The laws of foreign countries may not protect intellectual property rights to the same extent as the laws of the United States. In some cases, companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to life sciences. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. For example, some foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties.

On June 1, 2023, the European Union implemented a unitary patent system with the goal of providing a single pan-European Unitary Patent and a new European Unified Patent Court ("UPC") for litigation involving European patents. As a result, all European patents, including those issued prior to ratification of the unitary patent system, now by default automatically fall under the jurisdiction of the UPC, although patent applicants and patent holders may elect to opt-out of the new system for a transitional period of at least seven years. It is uncertain how the UPC will impact European patents, including those in the biotechnology and pharmaceutical industries. If we do not opt-out, our European patents could be challenged in the UPC. Thus far, like many others, we have elected to opt-out of the UPC as it matures. We may continue to opt-out our future European patents, but doing so may preclude us from realizing its benefits. Moreover, if we do not meet all of the formalities and requirements for opt-out under the UPC, our future European patents could remain under the jurisdiction of the UPC. The UPC will provide our competitors with a new forum to centrally revoke our European patents, and allow for the possibility of a competitor to obtain a pan-European injunction. Such a loss of patent protection or injunction obtained by a competitor could adversely impact our business and our ability to commercialize our technology and solutions and, as a result, on our business, financial condition, prospects, and results of operations.

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. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our solutions. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain and enforce adequate intellectual property protection for our solutions and technology.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position could be harmed.

In addition to seeking patents for certain of our solutions and other technologies, we rely on trade secrets and confidentiality agreements to protect our unpatented know-how, technology, data, and other proprietary information and to maintain our competitive position. Trade secrets and know-how can be difficult to protect. Our trade secrets and know-how may over time become known to others through various means such as independent development, personnel movement, collaborative efforts or other intentional or unintentional disclosure.

We seek to protect our trade secrets and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with relevant parties, such as our employees, directors, corporate and scientific collaborators, contract research organizations, contract manufacturers, suppliers, service providers, consultants, advisors, and other third parties. We generally enter into confidentiality and invention assignment agreements with our employees and consultants upon their commencement of a relationship with us, and remind departing employees of their continuing confidentiality obligations. However, we may not be successful in entering into such agreements with all employees and consultants. Although we generally require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information, processes, or technology to enter into confidentiality agreements, we cannot provide any assurances that we have entered into confidentiality agreements with each person or party that had or may have had access to our proprietary know-how, information, processes, or technology. In addition, monitoring unauthorized use and disclosure of our proprietary know-how, information, processes or technology by employees, consultants and other third parties who have access can be difficult, and we cannot be certain whether the steps we have taken to protect our proprietary know-how, information, processes, or technology will be adequate. Therefore, we may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by such employees, consultants, advisors or third parties, despite the existence of confidentiality restrictions. These agreements may also not provide meaningful protection against the unauthorized use or disclosure of our trade secrets, know-how or other proprietary information in the event the unwanted use is outside the scope of the provisions of the contracts or in

the event of any unauthorized use, misappropriation, or disclosure of such trade secrets, know-how, or other proprietary information.

Despite our efforts, any of these persons or 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. Enforcing a claim that a person or party illegally disclosed or misappropriated a trade secret can be difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, some courts outside the United States may be less willing or unwilling to protect trade secrets. Further, agreement terms that address non-competition are difficult to enforce in many jurisdictions and might not be enforceable in certain cases. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. We may enter into collaboration, license, contract research and/or manufacturing relationships with contract organizations that operate in certain countries that are at heightened risk of theft of technology, data, and intellectual property through direct intrusion by private parties or foreign actors, including those affiliated with or controlled by state actors. If any of our trade secrets were to be misappropriated by, disclosed to, or independently developed by a competitor or other third party, our competitive position could be adversely harmed.

In addition to contractual measures, we try to protect the confidential nature of our proprietary information by maintaining physical security of our premises and electronic security of our information technology systems. Such security measures may not be adequate for all scenarios, for example, in the case of misappropriation of a trade secret by an employee, consultant, or other third party with authorized access. An employee, consultant or other third party who misappropriates our trade secrets may provide such information to a competitor, and any recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our solutions, platform, or services that we consider proprietary. Although we use commonly accepted security measures, trade secret violations are a matter of both federal and state law in the United States, and the criteria for protection of trade secrets can vary among different jurisdictions. If the steps we have taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. If any of our intellectual property rights or confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, it could adversely affect our competitive position, business, financial condition, results of operations, and prospects.

Accordingly, our efforts to protect and enforce our trade secrets, know-how and intellectual property rights around the world may be inadequate to obtain a significant commercial advantage, and we may be at heightened risk of losing our trade secrets, proprietary know-how and intellectual property rights around the world, to the extent such theft or intrusion destroys their secrecy or other proprietary nature.

We may be subject to claims by third parties asserting that we or our employees have infringed or misappropriated intellectual property rights, or to assertions by third parties or employees claiming ownership of what we regard as our own intellectual property.

Many of our former, current, and future employees, consultants and contractors have been previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors and strategic partners. Some of these employees, consultants and contractors have executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment or engagement. We train our employees, consultants, and contractors not to bring, or use in their work proprietary information or technology from former employers. Although we intend for such training and other measures to ensure that our employees do not use the proprietary information or know-how of others in their work for us, to the extent that our employees, consultants or contractors use intellectual property rights or proprietary information owned by others in their work for us, we may be subject to claims that an employee has used or disclosed intellectual property, including trade secrets or other proprietary information, of such employee's former employer. Litigation, which would be expensive, time-consuming, a distraction to management, and uncertain of outcome, may be necessary to defend against these claims.

In addition, we may be subject to claims from third parties challenging ownership interest in or inventorship of intellectual property rights we regard as our own, based on claims that our agreements with employees or consultants obligating them to assign their intellectual property rights to us are ineffective or in conflict with prior or competing contractual obligations to assign inventions and intellectual property rights to another employer, to a former employer, or to another person or entity. We are not aware of any threatened or pending claims related to these matters, but, in

the future, litigation may be necessary to defend against such claims should they arise, and it may be necessary or we may desire to obtain a license to such third party's intellectual property rights to settle any such claim. However, there can be no assurance that we would be able to obtain such license on commercially reasonable terms, if at all. If we fail in defending any such claims, in addition to paying monetary damages or a settlement payment, we may lose valuable intellectual property rights or personnel, or access to consultants and contractors. A court could prohibit us from using technologies, features or other intellectual property rights that are essential to our solutions or technologies, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of another person or entity, including another or former employers. An inability to incorporate technologies, features or other intellectual property rights that are important or essential to our solutions or technologies could adversely affect our business, financial condition, results of operations, and competitive position, and may prevent us from developing, manufacturing and/or commercializing our solutions or technologies. In addition, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and our employees. Any litigation or the threat of litigation may adversely affect our ability to hire employees or contract with independent sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to develop, manufacture and/or commercialize our solutions or services, which could adversely affect our business, financial condition, and results of operations.

In addition, we may be subject to claims that our former employees, contractors or collaborators, or other third parties have an ownership interest in our current or future patents, patent applications, or other intellectual property rights, including as an inventor or co-inventor. We may be subject to ownership or inventorship disputes in the future arising, for example, from conflicting obligations of employees, consultants or others who were or are involved in developing our solutions.

If we fail to prevail on any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, or be required to obtain a license, which may not be available to us on commercially reasonable terms or at all. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management, which could harm our business.

If our trademarks and trade names are not adequately protected, we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

We currently hold and/or have applied for a number of trademarks, covering Caris, MI Profile, MI Tumor Seek Hybrid, MI Cancer Seek, Caris Assure, and other solutions and services in certain jurisdictions. However, our pending or future trademark applications may not be approved or our registered or unregistered trademarks or trade names may be challenged, invalidated, infringed, or declared generic or determined to be infringing on other marks. If any of the foregoing occurs, we could be forced to re-brand our solutions or technologies, and we may not be able to protect our rights to these trademarks and trade names, which we view as valuable to building name recognition among partners and customers in our markets of interest. At times, competitors or other third parties have adopted or may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion and/or litigation. In addition, there have been and could be trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. There can be no assurance that competitors will not infringe our trademarks or that we will have adequate resources to enforce our trademarks. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, we may be unable to compete effectively and our business may be adversely affected. Our efforts to enforce, protect, or defend our trademarks may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our competitive position, business, financial condition, results of operations, and prospects.

Our use of open-source software could subject our proprietary technology to unwanted open-source license conditions that could negatively impact our business.

We use open-source software in some of our technologies and solutions, and we may incorporate open-source software into future technologies and solutions. From time to time, companies that use third-party open source software have faced claims challenging the use of such open source software and requesting compliance with the open source software license terms. Accordingly, we may be subject to suits by parties claiming ownership of what we believe to be open source software or claiming non-compliance with the applicable open source licensing terms. Some open source software licenses require end users, who use, distribute, or make available across a network software and services that include open source software, to make publicly available or to license all or part of such software (which in some circumstances could include valuable proprietary code, such as derivative works of the open source software) under the

terms of the particular open source license. If a third party were to allege that we had not complied with the conditions of one or more of these licenses, we could be required to invest substantial time and resources to re-engineer some of our software or release certain portions of our proprietary source code, which could substantially help our competitors develop products that are similar to or improve upon ours and harm our business. We could also be required to incur significant legal expenses defending against such allegations. Further, the outcome of such litigation may be particularly uncertain because there are numerous open source software licenses which have not been tested in courts of law, and thus lack guidance regarding their proper legal interpretation. Any of the foregoing could disrupt and harm our business.

In addition, the use of third-party open source software typically exposes us to greater risks than the use of third-party commercial software because open source licensors generally do not provide warranties or controls on the functionality or origin of the software. Use of open source software may also present additional security risks because the public availability of such software may make it easier for hackers and other third parties to determine how to compromise platforms using such source code. Any of the foregoing could harm our business and could help our competitors develop products and services that are similar to or that improve upon ours.

The occurrence of any of these events could adversely affect our business, financial condition, results of operations, and prospects.

Risks Related to Our Indebtedness

We have incurred substantial indebtedness, and we may not generate sufficient cash flow from operations to meet our debt service requirements, continue our operations, and pursue our growth strategy, and we may be unable to raise capital when needed or on acceptable terms.

As of September 30, 2025, we and our subsidiaries had approximately $400.0 million aggregate principal amount of debt outstanding under the 2023 Term Loan. Our substantial level of indebtedness increases the risk that we may be unable to generate cash sufficient to pay amounts due in respect of our indebtedness, pay dividends and to fund our general corporate and capital requirements. The substantial indebtedness of us and our subsidiaries could have important consequences to our shareholders, including:

- a portion of our cash flow from operations must be dedicated to the payment of principal and interest on our debt, thereby reducing the funds available to us for other purposes;
- our ability to satisfy our obligations under the 2023 Term Loan Agreement may be adversely affected;
- our ability to make loans and investments or engage in acquisitions without issuing additional equity or obtaining additional debt financing may be impaired in the future;
- our ability to obtain additional financing for working capital, capital expenditures, acquisitions, debt service requirements or general corporate purposes may be impaired in the future;
- our ability to pay dividends or engage in share repurchases may continue to be restricted;
- our flexibility may be limited in planning for, or reacting to, changes or challenges relating to the business we conduct;
- we may be more vulnerable to general adverse economic and industry conditions;
- we may be at a competitive disadvantage compared to our competitors who have less debt or comparable debt at more favorable interest rates or terms and who, as a result, may be better positioned to withstand economic downturns or to finance capital expenditures or acquisitions; our costs of borrowing may increase; and
- we may be unable to refinance our debt on terms as favorable as our existing debt or at all.

The occurrence of any one of these events could have an adverse effect on our business, financial condition, results of operations, and ability to satisfy our obligations under the 2023 Term Loan Agreement. We may not be able to access capital on acceptable terms, raise additional capital in the future, or make effective capital allocation decisions, which could result in our inability to achieve operational objectives. Any disruption in access to capital could require us to take measures to conserve cash until alternative credit arrangements or other funding for business needs can be arranged. Such measures could include deferring capital expenditures, acquisitions or other discretionary uses of cash, or revising capital allocation decisions. Any of these risks could adversely affect our business, financial condition, and results of operations.

The agreements and instruments governing our debt contain restrictions and limitations that could significantly impact our management's flexibility and our financial and operational flexibility to operate our business.

Restrictive covenants in the 2023 Term Loan Agreement place limits on our ability to conduct our business. Covenants in the 2023 Term Loan Agreement include those that, subject to certain exceptions, restrict our ability to:

- materially alter the business we conduct;
- incur certain additional indebtedness and guarantee indebtedness;
- create or incur liens;
- purchase, make, incur, assume, or permit to exist certain investments;
- make any dividends, distributions, and certain other payments to our shareholders;
- sell, transfer, or otherwise dispose of assets, including capital stock of our subsidiaries;
- modify certain agreements that have an impact on our indebtedness;
- engage in certain transactions with our affiliates;
- enter into any restrictive agreements prohibiting (i) the creation of liens to secure our obligations under the 2023 Term Loan Agreement, (ii) our or our subsidiaries' modification of the 2023 Term Loan Agreement, or (iii) our or our subsidiaries' ability to pay dividends or make any other distributions on any capital securities;
- enter into sale and leaseback transactions;
- make changes to name, location, executive office, executive management, or fiscal years without prior notice; and
- incur any actual or potential liability on benefit plans or allow any employee benefit plans to cease to be tax qualified.

The 2023 Term Loan Agreement also imposes maintenance requirements on our liquidity and revenue base and restricts our ability to engage in certain mergers or consolidations. For additional information, see Part I, Item 2. "Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources—Indebtedness" and "—Risks Related to Our Business and Industry—Our business and results of operations will suffer if we fail to compete effectively." These restrictions may prevent us from taking actions that we believe would be in the best interest of our business and may make it difficult for us to execute our business strategy successfully or compete effectively with companies that are not similarly restricted. We may also incur future debt obligations that might subject us to additional restrictive covenants that could affect our financial and operational flexibility. Our ability to comply with the covenants and restrictions contained in the 2023 Term Loan Agreement may be affected by economic, financial and industry conditions beyond our control. The breach of any of these covenants or restrictions could result in a default under the 2023 Term Loan Agreement that would permit the applicable lenders or noteholders, as the case may be, to declare all amounts outstanding thereunder to be due and payable, together with accrued and unpaid interest. In addition, such a default or acceleration may result in the acceleration of any other debt to which a cross-acceleration or cross-default provision applies. Our obligations under the 2023 Term Loan Agreement are secured by our intellectual property. If we are unable to repay debt, lenders having secured obligations under the 2023 Term Loan Agreement could proceed against the collateral securing the debt. This could have serious consequences to our business, financial condition, and results of operations and could cause us to become bankrupt or insolvent.

We rely on cash generated from our financing and operating activities as our primary source of liquidity. To support our operations, execute our growth strategy as planned and pay dividends, if declared, we will need to continue generating significant amounts of cash from operations, including funds required to pay our employees, related benefits and other operating expenses, finance future acquisitions, invest in the growth of our business and pay for the increased direct and indirect costs associated with operating as a public company. If our business does not generate sufficient cash flow from operations to fund these activities, we may need to seek additional capital, including by incurring additional debt or equity capital. Additional capital may not be available to us on acceptable terms or at all. In addition, incurring indebtedness requires that a portion of cash flow from operating activities be dedicated to interest and principal payments. Debt service requirements could reduce our ability to use our cash flow to fund operations and capital expenditures, to capitalize on future business opportunities, including additional acquisitions, or to pay dividends. Any of these risks could adversely affect our business, financial condition, and results of operations.

Our variable rate debt subjects us to interest rate risk, which could cause our debt service obligations to increase significantly and affect our operating results.

The indebtedness under the 2023 Term Loan is at variable rates of interest, which exposes us to interest rate risk. In addition, our 2023 Term Loan references the Secured Overnight Financing Rate ("SOFR") as the primary benchmark rate for our variable rate indebtedness. If benchmark interest rates, including SOFR, were to increase, our debt service obligations on our variable rate indebtedness would increase even if the amount borrowed remains the same, and our net income and cash flows, including cash available for servicing our indebtedness, will correspondingly decrease. In addition, while our 2023 Term Loan will continue to be subject to SOFR, other factors may impact SOFR, including factors causing SOFR to cease to exist, new methods of calculating SOFR to be established, or the use of an alternative reference rate. Such circumstances are not entirely predictable, but could have an adverse impact on our financing costs and results of operations. As of September 30, 2025, we had $400.0 million outstanding principal amount

of variable rate debt subject to interest rate exposure. While we currently hedge the interest rate risk on $200.0 million principal amount of this outstanding variable rate debt with a purchased interest rate cap derivative with a strike rate of 6.0% and a February 2026 maturity, the remainder of the outstanding amount is not similarly hedged. Accordingly, a 1% increase in interest rates would increase annual interest expense by $4 million.

Despite our indebtedness level, we and our subsidiaries may incur substantially more debt, including secured debt. This could further exacerbate the risks associated with our substantial indebtedness.

We and our subsidiaries may incur substantial additional indebtedness in the future. Although the terms of the 2023 Term Loan Agreement contain restrictions on the incurrence of additional indebtedness, such restrictions are subject to a number of significant exceptions and qualifications and any additional indebtedness incurred in compliance with such restrictions could be substantial. These restrictions also will not prevent us from incurring obligations that do not constitute indebtedness. If we and our subsidiaries incur significant additional indebtedness or other obligations, the related risks that we face could increase, and we may not be able to meet all our debt obligations.

Risks Related to Ownership of Our Common Stock

An active, liquid, and orderly market for our common stock may not develop or be sustained. As a result, it may be difficult to sell shares of our common stock.

Prior to our IPO, there was no public trading market for our common stock. If an active, liquid, and orderly trading market for our common stock does not continue to develop or is not sustained, it may be difficult to sell shares of our common stock at the time or at the price you wish to sell them, if at all. It is possible that in one or more future periods our results of operations, regulatory approval process, and/or development of our platform and solutions may not meet the expectations of securities research analysts and investors. These and other factors could also significantly depress the market price of our common stock.

The market price of our common stock may be volatile, which could result in substantial losses for investors.

We cannot predict the prices at which our common stock will continue to trade, and the limited public float of our common stock may lead to increased price volatility. Securities markets worldwide experience significant price and volume fluctuations. This market volatility, as well as general economic, market, or political conditions, could reduce the market price of our common stock regardless of our operating performance. Some of the factors that may cause the market price of our common stock to fluctuate include:

- the timing or success of launch of our solutions, such as Caris Assure for early detection, MRD tracking, and treatment monitoring, as well as MI Cancer Seek or other solutions;
- the degree to which the launch and commercialization of our solutions meet the expectations of securities analysts and investors;
- changes in the structure of healthcare payment systems, including changes that would affect coverage and reimbursement by third-party or government payers;
- the success of, or perception of success of, our research and development efforts and our ability to develop new solutions and enhance our existing solutions, as well as our solutions' effectiveness or perceived effectiveness compared to those of our competitors;
- the timing and results of validation studies and clinical trials for our solutions and solutions from our competitors;
- commencement or termination of collaborations for our solution development and research programs;
- failure or discontinuation of any of our solution development and research programs;
- the success of existing or new competitive tests, services, or technologies;
- results of validation studies, clinical trials, or regulatory approvals of diagnostic or other cancer-related screening tests of our competitors, or announcements about new research programs or diagnostic or other cancer-related tests of our competitors;
- regulatory or legal developments in the United States and other countries affecting our solutions or competing products;
- developments or disputes concerning patent applications, issued patents, or other proprietary rights;
- the impact of public health crises on our business and on global economic conditions;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our research programs, clinical development programs or commercialization activities;
- actual or anticipated changes in our estimates as to our financial results or development timelines;

- whether our quarterly and annual financial results, forecasts, and development timelines meet the expectations of securities analysts or investors;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders, or other shareholders;
- expiration of lock-up agreements and market stand-off provisions;
- variations in our quarterly and annual financial results or those of companies that are perceived to be similar to us;
- changes in estimates or recommendations by securities analysts, if any, that cover our stock;
- changes in accounting standards, policies, guidelines, interpretations, or principles;
- market conditions in the healthcare sector;
- general economic, industry, and market conditions; and
- the other factors described in this "Risk Factors" section.

Stock markets in general, and the market for healthcare companies in particular (including companies in the precision oncology industry and broader precision medicine industry), experience significant price and volume fluctuations that are often unrelated or disproportionate to changes in the operating performance of the companies whose stock is experiencing those price and volume fluctuations. Broad market and industry factors may significantly affect the market price of our common stock, regardless of our actual operating performance. Following periods of such volatility in the market price of a company's securities, securities class action litigation has often been brought against that company. Because of the potential volatility of our stock price, we may become the target of securities litigation in the future. Securities litigation could result in substantial costs and divert management's attention and resources from our business.

If securities analysts do not publish, or cease to publish, research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.

The trading market for our common stock relies in part on the research and reports that industry or securities analysts publish about us or our business. If one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our common stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our common stock, which in turn could cause the price of our common stock to decline.

Sales of a substantial number of shares of our common stock in the public market, or the perception that such sales could occur, could cause the price of our common stock to decline.

Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur, could depress the market price of our common stock, and could impair our ability to raise capital through the sale of additional equity securities. Many of our existing equity holders have substantial unrecognized gains on the value of the equity they hold, and therefore, may take steps to sell their shares or otherwise secure the unrecognized gains on those shares. We are unable to predict the timing of or the effect that such sales may have on the prevailing market price of our common stock.

In connection with our IPO, we, our directors and executive officers, and holders of substantially all of our common stock and securities exercisable for our common stock, entered into lock-up agreements with the underwriters that restrict our and their ability to sell or transfer shares of our common stock, and securities exercisable for shares of our common stock, for a period of 180 days from the date of the prospectus related to our IPO, subject to certain customary exceptions and a potential earlier termination, as described in the section titled "Shares Eligible for Future Sale" in the prospectus related to our IPO. In addition, BofA Securities, Inc. and either J.P. Morgan Securities LLC or Goldman Sachs & Co. LLC, certain of the underwriters of our IPO, may, in their sole discretion, release certain shareholders from the lock-up agreements prior to the end of the lock-up period. If not earlier released, all of our shares of common stock, other than those sold in our IPO, substantially all of which are freely tradable, will become eligible for sale upon expiration of the lock-up period, expected to expire on December 1, 2025, except for any shares held by our affiliates as defined in Rule 144 under the Securities Act of 1933, as amended (the "Securities Act").

In addition up to 22,906,854 shares of our common stock and 4,132,565 shares of our common stock may be issued upon exercise of outstanding stock options or vesting and settlement of outstanding RSUs under our 2020 Plan and 2025 Plan, respectively, in each case as of September 30, 2025, and up to approximately 14,114,397 shares of our common stock remained available for future issuance under our 2025 Incentive Plan ("2025 Plan") and our Employee Stock Purchase Plan ("ESPP") as of September 30, 2025, and will become eligible for sale in the public market to the

extent permitted by the provisions of various vesting schedules, exercise limitations, the lock-up agreements, and Rule 144 and Rule 701 under the Securities Act. We have filed a registration statement to register all of the shares of common stock issuable upon exercise of options or other equity incentive awards granted under our 2025 Plan or issued pursuant to our ESPP and with respect to our 2020 Plan, all shares of common stock issuable upon the exercise of stock options or RSUs granted under our 2020 Plan that were outstanding as of the IPO. If any of these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

Further, holders of approximately 245.9 million shares as of September 30, 2025 have rights, subject to some conditions and the lock-up agreements described above, to require us to file registration statements covering the sale of their shares or to include their shares in registration statements that we may file for ourselves or other shareholders.

Raising additional capital may cause dilution to our existing shareholders, restrict our operations, or require us to relinquish rights to our technologies or our solutions.

We may need or determine to raise additional capital through a combination of public and private equity offerings, debt financings, strategic partnerships, and alliances and licensing arrangements. We, and indirectly, our shareholders, will bear the cost of issuing and servicing securities issued in any such transactions. Because our decision to issue debt or equity securities in any future offering will depend on market conditions and other factors beyond our control, we cannot predict or estimate the amount, timing, or nature of any future offerings. If we incur debt, debt holders would have rights senior to holders of our common stock to make claims on our assets, and any debt financing we secure would result in increased fixed payment obligations and could involve restrictive and financial covenants, such as 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. If we issue additional equity securities, shareholders will experience dilution, and the new equity securities could have rights senior to those of our common stock. Additionally, any future collaborations we enter into with third parties may provide capital in the near term but limit our potential cash flow and revenue in the future. If we raise additional funds through strategic partnerships, alliances, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or our solutions, or grant licenses on terms unfavorable to us.

Our executive officers, directors, and principal shareholders, including, in particular, David D. Halbert, our Founder, Chairman, and Chief Executive Officer, have the ability to control or significantly influence matters submitted to shareholders for approval, which could limit the ability of our other shareholders to affect the outcome of key corporate decisions and transactions, including a change of control.

As of September 30, 2025, David D. Halbert, our Founder, Chairman, and Chief Executive Officer, beneficially owns approximately 44.0% of our outstanding common stock. As a result, Mr. Halbert will be able to significantly influence all matters submitted to our shareholders for approval, including the election of directors, amendments to our certificate of formation and bylaws, and the approval of significant corporate transactions, regardless of whether others believe that any such transaction is in our best interests.

This concentration of ownership may have the effect of delaying, deferring, or preventing a change in control, impeding a merger, consolidation, takeover, or other business combination involving us, or discouraging a potential acquiror from making a tender offer or otherwise attempting to obtain control of our business, even if such a transaction would benefit other shareholders. Moreover, it could deprive shareholders of an opportunity to receive a premium for their common stock as part of a sale of our company and may adversely affect the trading price for our common stock because some investors perceive disadvantages in owning shares in companies with concentrated equity ownership.

We have identified a material weakness in our internal control over financial reporting. If our remediation of such material weakness is not effective, or if we experience additional material weaknesses in the future or otherwise fail to develop and maintain effective internal control over financial reporting, our ability to produce timely and accurate financial statements or comply with applicable laws and regulations could be impaired, investors may lose confidence in our financial reporting, and the trading price of our common stock may decline.

In connection with the audit of our consolidated financial statements for the year ended December 31, 2024, we identified a material weakness in our internal control over financial reporting. A material weakness, as defined by Rule 12b-2 under the Exchange Act, is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

The material weakness identified pertained to a lack of sufficient qualified accounting resources, including those with technical expertise necessary to account for and disclose accounting transactions which require complex calculations or thorough evaluation of the accounting literature.

We have taken and will continue to take action to remediate the material weakness, including:

- implementation of controls to enhance our review of significant accounting transactions and other new technical accounting and financial reporting issues and the preparation and review of accounting memoranda addressing these issues;
- implementation of controls to enable an effective and timely review of account analyses and account reconciliations; and
- continued hiring of additional accounting and finance resources with public company experience and expanding the capabilities of the existing accounting and financial personnel through continuous training and education in the accounting and reporting requirements under GAAP and SEC rules and regulations.

Pursuant to SOX Section 404, our management will be required to report upon the effectiveness of our internal control over financial reporting beginning with the annual report for the year ending December 31, 2026. When we lose our status as an "emerging growth company" and do not otherwise qualify as a "smaller reporting company" with less than $100.0 million in annual revenue, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for our management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with these requirements, we may need to upgrade our information technology systems; implement additional financial and management controls, reporting systems and procedures; and hire additional accounting and finance staff. If we or, if required, our auditors are unable to conclude that our internal control over financial reporting is effective, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

We will not be able to fully remediate the material weakness until the steps detailed above have been completed and such controls have been operating effectively for a sufficient period of time. Additionally, we have not performed an evaluation of our internal control over financial reporting as permitted under the JOBS Act; accordingly, we cannot assure you that we have identified all, or that we will not in the future have additional, material weaknesses. Material weaknesses may still exist when we report on the effectiveness of our internal control over financial reporting as required under SOX Section 404, beginning with our annual report for the year ending December 31, 2026.

We cannot assure you that additional material weaknesses in our internal control over financial reporting will not arise in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC, or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

We are an emerging growth company and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an emerging growth company and, for so long as we remain an emerging growth company, we are permitted by SEC rules and plan to rely on exemptions from certain disclosure requirements that are applicable to other SEC-registered public companies that are not emerging growth companies. Under these exemptions, we are not required to comply with the auditor attestation requirements of SOX Section 404 or the auditor requirements to communicate critical audit matters in the auditor's report on the financial statements, have reduced disclosure obligations regarding executive compensation, and have exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. As a result, the information we provide shareholders will be different than the information that is available with respect to other public companies.

We will cease to be an emerging growth company upon the earliest of: (i) the end of the fiscal year following the fifth anniversary of our IPO (*i.e.* the fiscal year ending December 31, 2030), (ii) the first fiscal year after our annual gross revenues are $1.235 billion or more, (iii) the date on which we have, during the previous three-year period, issued more than $1.0 billion in nonconvertible debt securities or (iv) the end of any fiscal year in which the market value of our

common stock held by non-affiliates exceeded $700 million as of the end of the second quarter of that fiscal year. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and our stock price may be more volatile.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards, and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies, which may make comparison of our financials to those of other public companies more difficult.

We have incurred and expect to continue to incur increased costs as a result of operating as a public company, and our management is and will be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting, and other expenses that we did not incur as a private company. SOX Section 404, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq, and other applicable U.S. rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. We expect that we will need to hire additional accounting, finance, and other personnel in connection with our efforts to comply with the requirements of being a public company, and our management and other personnel will need to devote a substantial amount of time towards maintaining compliance with these requirements. These requirements have increased and will further increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, the rules and regulations applicable to us as a public company have made it, and may in the future, make it more difficult and more expensive for us to obtain director and officer liability insurance, which could make it more difficult for us to attract and retain qualified members of our board of directors. We cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are required to maintain disclosure controls and procedures to support compliance with the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to provide reasonable assurance that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC. Even if we are successful in remediating our material weaknesses described above, we believe that any disclosure controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

If our estimates or judgments relating to our critical accounting policies are based on assumptions that change or prove to be incorrect, our results of operations could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of our common stock.

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in our financial statements and accompanying notes. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets, liabilities, equity, revenue, and expenses that are not readily apparent from other sources. For example, as we adopted and implemented the new revenue accounting standard, management made judgments and assumptions based on our

interpretation of the new standard. The new revenue standard is principles-based and interpretation of those principles may vary from company to company based on their unique circumstances. It is possible that interpretation, industry practice and guidance may evolve as we continue to use these new accounting standards. If our assumptions change or if actual circumstances differ from our assumptions, our results of operations may be adversely affected and could fall below our publicly announced guidance or the expectations of analysts and investors, resulting in a decline in the market price of our common stock.

We do not intend to pay dividends for the foreseeable future, and our investors may never obtain a return on their investment.

We have never declared or paid any cash dividends on our capital stock, and we do not intend to pay any cash dividends in the foreseeable future. We expect to retain all available funds and future earnings, if any, to support our operations and to finance the growth and development of our business. Any future determination to pay dividends on our capital stock will be at the discretion of our board of directors subject to applicable laws and dependent on factors our board of directors deems relevant. In addition, our ability to pay dividends on our capital stock is limited by the terms of the 2023 Term Loan Agreement and may be further restricted under the terms of any future debt or preferred securities or future credit facility. Accordingly, you must rely on the sale of your common stock after price appreciation, which may never occur, as the only way to realize any future gain on your investment.

Texas law and provisions in our amended and restated certificate of formation and bylaws might discourage, delay, or prevent a change in control of our company or changes in our management and, therefore, depress the trading price of our common stock.

Provisions in our amended and restated certificate of formation and bylaws may discourage, delay, or prevent a merger, acquisition, or other change in control that shareholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares of our common stock. These provisions may also prevent or frustrate attempts by our shareholders to replace or remove our management. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our organizational documents:

- authorize our board of directors to issue shares of preferred stock and determine the price and other terms of those shares, including preferences and voting rights, without shareholder approval;
- 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, or by a sole remaining director, or by the affirmative vote of a majority of the voting power of our then-outstanding capital stock entitled to vote generally in the election of directors;
- provide that any action required or permitted to be taken at an annual or special meeting of shareholders may be taken by written consent in lieu of a meeting of shareholders only with the unanimous written consent of our shareholders entitled to vote on such action;
- provide that the written request of the holders of at least 50% of the voting power of our outstanding capital stock entitled to be voted at a special meeting is required for our shareholders to call a special meeting of shareholders; and
- require that shareholders give advance notice to nominate directors or submit proposals for consideration at shareholder meetings.

Further, as a Texas corporation, we are also subject to provisions of Texas law that may impair a takeover attempt that our shareholders may find beneficial. Any provision of our amended and restated certificate of formation, bylaws, or Texas law that has the effect of delaying or preventing a change in control could limit the opportunity for our shareholders to receive a premium for their shares of our capital stock and could also affect the price that some investors are willing to pay for our common stock.

Our amended and restated certificate of formation provides that the Business Court in the First Business Court Division of the State of Texas will be the exclusive forum for substantially all disputes between us and our shareholders (excluding claims under the federal securities laws), which could limit our shareholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Our amended and restated certificate of formation provides that, unless we consent in writing to the selection of an alternative forum, the Business Court in the First Business Court Division of the State of Texas will be the exclusive forum for the following types of actions or proceedings under Texas statutory or common law:

- any derivative action or proceeding brought on our behalf (subject to the ownership requirements in our Amended and Restated Bylaws);

- any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees, or shareholders to us or our shareholders;
- any action asserting a claim arising pursuant to any provision of the Texas Business Organizations Code ("TBOC") or our amended and restated certificate of formation and bylaws; and
- any action asserting a claim governed by the internal affairs doctrine.

However, this provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Furthermore, our amended and restated certificate of formation also provides that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Any person purchasing or otherwise acquiring or holding any interest in shares of our capital stock is deemed to have received notice of and consented to the foregoing provisions. This choice of forum provision may limit a shareholder's ability to bring a claim in a judicial forum that it finds more favorable for disputes with us or with our directors, officers, other employees or agents, or our other shareholders, may discourage such lawsuits against us and such other persons, and may result in increased costs for a shareholder to bring a claim. Alternatively, if a court were to find this choice of forum provision inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business, financial condition, and results of operations.

General Risk Factors

The sizes of the markets for our current and future solutions have not been established with precision, and may be smaller than we estimate.

Our estimates of the total addressable markets for our current or future solutions are based on a number of internal and third-party estimates, including, without limitation, the number of new cancer cases, the market size of oncology testing, and the number of patients with advanced stage cancer. While we believe the assumptions and the data underlying these estimates are reasonable, these assumptions and estimates may not be correct and the conditions supporting these assumptions or estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors. As a result, these estimates of the total addressable market for our current or future solutions may prove to be incorrect. If the actual number of patients who would benefit from our solutions, the price at which we can sell our solutions, or the annual total addressable market for our solutions is smaller than estimated, it may impair our sales growth and have an adverse impact on our business, financial condition, and results of operations.

Adverse economic or market conditions may harm our business.

Worsening economic conditions, including heightened inflation, increasing interest rates, decreasing economic activity, volatility in equity and credit markets, or other changes in the economic environment, may adversely affect our business, financial condition, and results of operations. For example, we depend on third-party manufacturers and suppliers for some of our solutions, or components and materials used in our solutions, and the suppliers of these inputs may seek to raise prices in the current inflationary economic environment. If our costs increase and we are unable to successfully pass along those increased costs to our partners and patients, our revenue and or operating profitability may be adversely affected. In addition, we may in the future raise additional debt or refinance existing debt. Our cost of borrowing in the future may be higher than it has been to date because interest rates have risen and may continue to increase. An increased cost of borrowing may adversely affect our financial condition and results of operations.

Our business is subject to economic, political, regulatory, and other risks associated with international operations.

Some of our ordering physicians and biopharma partners are located outside of the United States. While we currently have limited international operations, international expansion could also become a key component of our future business strategy. Accordingly, our future results could be harmed by a variety of factors, including:

- challenges enforcing our contractual and intellectual property rights, especially in those foreign jurisdictions that do not respect and protect intellectual property rights to the same extent as the United States;
- trade protection measures, import or export controls and licensing requirements (including possible restrictions on licensing intellectual property to certain non-U.S. persons) or other restrictive actions by U.S. or non-U.S. governments;
- changes in non-U.S. laws, regulations and customs, tariffs, and trade barriers;

- exchange rate risk we may face from denominating a portion of our transactions in currencies other than the U.S. dollar;
- changes in a specific country's or region's political or economic environment, including inflation, including the United States;
- logistics and regulations associated with shipping samples, including infrastructure conditions and transportation delays;
- negative consequences from changes in tax laws;
- negative consequences from changes in U.S. national security laws, including those governing non-U.S. investors' ownership of U.S. biotech and other technology companies and U.S. companies' ability to enter into joint ventures with non-U.S. entities;
- compliance with tax, employment, immigration, and labor laws for employees living or traveling abroad;
- compliance challenges relating to the complexity of multiple, conflicting, and changing data protection laws and international data sharing and transfer restrictions globally. For additional information, see "—Risks Related to Regulation and Legal Compliance—We are subject to stringent and evolving U.S. and foreign privacy and data security laws, regulations, and rules, contractual obligations, industry standards, policies and other obligations related to privacy and data security. Our actual or perceived failure to comply with privacy and data security obligations could result in significant liability, administrative or governmental penalties, reputational harm and/or, other adverse business consequences";
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- adoption of new regulations, modification to existing regulations, or expiration of prior regulations that apply to the products we offer;
- difficulties associated with staffing and managing international operations, including differing labor relations;
- regulator and compliance risks that relate to maintaining and control over sales and distribution activities that may fall within the purview of the FCPA or comparable foreign laws;
- difficulties associated with the interpretation of laws and regulations in non-English speaking jurisdictions; and
- business interruptions resulting from geo-political actions, including war and terrorism, pandemics, or natural disasters, including earthquakes, typhoons, floods, and fires.

These and other risks associated with current and future international operations may adversely affect our business and prospects.

Our business is subject to risks arising from public health crises.

Widespread public health crises may pose the risk that our company, our personnel, courier delivery services, and other partners may be prevented from conducting business activities for an indefinite period of time, including due to spread of the disease within these groups or due to shutdowns that may be requested or mandated by governmental authorities. For example, the COVID-19 pandemic and mitigation measures have had an adverse impact on global economic conditions. Comparable future public health crises could have similar adverse effects on our business, financial condition, and results of operations, including impairing the ability to raise capital when needed.

Government-imposed quarantines and restrictions as a result of future public health crises may also require us to temporarily terminate our clinical sites. Furthermore, if we determine that our trial participants may suffer from exposure to such diseases as a result of their participation in our clinical trials, we may voluntarily terminate certain clinical sites as a safety measure until we reasonably believe that the likelihood of exposure has subsided. As a result, our expected regulatory submissions and development timelines for our solutions may be negatively impacted. Future public health crises may materially disrupt or delay our business operations, further divert the attention and efforts of the medical community to coping with such epidemics, reduce the number of patients getting physicals and physicians potentially ordering our solutions, disrupt the clinical sites on which we depend, and/or adversely affect our operations.

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

Our ability to utilize our net operating loss ("NOL") and R&D credit carryforwards is subject to certain conditions. For instance, we have experienced a history of losses and a lack of future taxable income would adversely affect our ability to utilize our NOL and R&D credit carryforwards. In addition, our federal NOL carryforwards generated in taxable years beginning before January 1, 2018, are permitted to be carried forward for only 20 years. Although our federal NOL carryforwards generated in taxable years beginning after December 31, 2017, may be carried forward indefinitely, they are permitted to be used in any taxable year to offset only up to 80% of taxable income, if any, in such year. For state income tax purposes, there may be periods during which the use of NOL carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. We also had R&D credit carryforwards of $2.8 million

that will begin to expire in 2031. Our ability to use our NOL and R&D credit carryforwards also may be subject to certain limitations due to prior or future ownership changes, if any, as defined in Section 382 of the U.S. Internal Revenue Code of 1986, as amended (the "Code") (generally a greater than 50% change, by value, in a corporation's equity ownership over a three-year period). Under Sections 382 and 383 of the Code, and corresponding provisions of state law, if a corporation undergoes an ownership change, the corporation's ability to use its pre-change NOL and R&D credit carryforwards to offset the corporation's post-change income or taxes may be limited. Although we have not experienced ownership changes in the past, we may experience ownership changes as a result of shifts in our stock ownership, some of which may be outside our control. As such, there can be no assurance that we will be able to utilize our NOL and R&D credit carryforwards, and we have established valuation allowances against our NOL and R&D credit carryforwards due to the uncertainty surrounding the realization of such assets.

Changes in tax laws or regulations may have an adverse effect on our business, financial condition, and results of operations.

New tax laws, statutes, rules, regulations, or ordinances could be enacted at any time. For example, the Tax Cuts and Jobs Act, the Coronavirus Aid, Relief, and Economic Security Act, and the Inflation Reduction Act made significant changes to U.S. tax laws. The recently enacted OBBBA introduced additional reforms, including by permanently extending certain provisions of the Tax Cuts and Jobs Act. Further, existing tax laws, statutes, rules, regulations, or ordinances could be interpreted differently, changed, repealed, or modified at any time. Any such enactment, interpretation, change, repeal, or modification could adversely affect us, possibly with retroactive effect.

We may seek acquisitions or other strategic transactions from time to time that could increase our capital requirements, dilute our shareholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

We may engage in various acquisitions and strategic partnerships in the future, including licensing or acquiring complementary intellectual property rights, technologies, or businesses. Any acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of indebtedness or contingent liabilities;
- the issuance of our equity securities that would result in dilution to our shareholders;
- assimilation of operations, personnel, intellectual property, and products of an acquired company;
- failure to achieve any expected synergies;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships; and
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or candidates and regulatory approvals, and the validity and enforceability of their intellectual property.

In addition, as our strategy evolves, we may opt to discontinue, deprioritize, or dispose of assets, technologies, or acquired businesses.

Evolving expectations regarding environmental, social, and governance ("ESG") matters could increase our costs, harm our reputation, and adversely impact our financial results.

There has been increasing and evolving public focus by investors, patients, environmental activists, the media, and governmental and nongovernmental organizations on a variety of environmental, social, and other sustainability matters. We may experience regulatory or commercial pressure to make commitments relating to sustainability matters, including the design and implementation of specific risk mitigation strategic initiatives relating to sustainability. If we are not effective in addressing environmental, social, and other sustainability matters affecting our business, or setting and meeting relevant sustainability goals, our reputation and financial results may suffer. If we fail to comply with new or existing laws, regulations or reporting requirements relating to ESG or sustainability matters, or we fail to provide complete and accurate information to our suppliers, customers or other business partners, we could be subject to penalties and our reputation and business could be adversely impacted.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Use of Proceeds

On June 20, 2025, we completed our initial public offering in which we issued and sold 23,529,412 shares of our common stock at a public offering price of $21.00 per share, and on June 25, 2025 we issued and sold an additional 3,529,411 shares of common stock pursuant to the underwriters' exercise in full of their option to purchase additional shares. We received net proceeds of $519.5 million after deducting underwriting discounts and commissions of $39.8 million and deducting offering expenses of $9.0 million. No payments for such expenses were made directly or indirectly to (i) any of our officers or directors or their associates, (ii) any persons owning 10% or more of any class of our equity securities or (iii) any of our affiliates.

All shares sold were registered pursuant to a registration statement on Form S-1 (File No. 333-287551), as amended (the "Registration statement"), declared effective by the SEC on June 17, 2025. The offering terminated after the sale of all securities registered pursuant to the Registration Statement. BofA Securities, Inc., J.P. Morgan Securities LLC, Goldman Sachs & Co. LLC, and Citigroup Global Markets Inc. acted as representatives of the underwriters for the IPO.

We expect to use a portion of the net proceeds from our IPO to satisfy tax withholding and remittance obligations related to the settlement of RSUs granted under our 2020 Plan that vested in connection with the initial public offering. There has been no material change in the expected use of the net proceeds from our IPO as described in the final prospectus dated as of June 17, 2025 and filed with the SEC pursuant to Rule 424(b)(4) on June 20, 2025.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

None.

Item 5. Other Information

Disclosure of Trading Arrangements

During the fiscal quarter ended September 30, 2025, none of our directors or officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted or terminated a "Rule 10b5-1 trading arrangement" or a "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408 of Regulation S-K, except as described in the paragraph below.

On August 19, 2025, Luke Power, our Senior Vice President, Chief Financial Officer and Chief Accounting Officer, entered into a pre-arranged stock trading plan. Such trading plan is intended to satisfy the affirmative defense of Rule 10b5-1(c) under the Exchange Act. Mr. Power's plan provides for, subject to certain market price limits set forth in the plan, the exercise of up to 62,250 vested stock options and the associated sale of shares remaining after the satisfaction of exercise price and tax withholding obligations between December 11, 2025 and June 11, 2026.

Item 6. Exhibits

Exhibit Number	Description of Exhibit	Incorporated by Reference				Filed or Furnished Herewith
		Form	File No.	Exhibit Number	Filing Date	
3.1	Amended and Restated Certificate of Formation of Caris Life Sciences, Inc.	8-K	001-42706	3.1	June 20, 2025	
3.2	Amended and Restated Bylaws of Caris Life Sciences, Inc.	8-K	001-42706	3.1	October 30, 2025	
10.1	Third Amendment, dated August 8, 2025, to Lease Agreement by and between WPT LAND 2 LP and Caris MPI, Inc.					X
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
32.1*	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
32.2*	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
101.INS	Inline XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document).					X
101.SCH	Inline XBRL Taxonomy Extension Schema Document.					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.					X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.					X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.					X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.					X
104	Cover Page formatted as Inline XBRL and contained in Exhibit 101.					X

* The certifications furnished in Exhibits 32.1 and 32.2 are not deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liability of that section, nor shall they be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended.

Signatures

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

CARIS LIFE SCIENCES, INC.

Date: November 05, 2025

By: /s/ David D. Halbert

David D. Halbert

Founder, Chairman, and Chief Executive Officer

(Principal Executive Officer)

Date: November 05, 2025

By: /s/ Luke Power

Luke Power

Senior Vice President, Chief Financial Officer, and Chief Accounting Officer

(Principal Financial and Accounting Officer)