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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2026

OR

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

Commission File Number: 001-42126

FREENOME, INC.

(Exact name of registrant as specified in its charter)

Delaware	**98-1783595**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
Genesis Marina **3300 Marina Blvd** **Brisbane** **CA** (Address of principal executive offices)	**94005** (Zip Code)

(650) 446-6630 (Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	FRNM	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, if any, 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	x	Smaller reporting company	x
Emerging growth company	x		

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 9, 2026, the registrant had 111,500,956 shares of common stock outstanding.

FREENOME, INC.

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Cautionary Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q, including the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations," contains forward-looking statements within the meaning of applicable securities laws. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These statements relate to, among other things, our future operating and financial performance, business and growth strategies, market opportunities, product development and commercialization, clinical trials and regulatory activities, reimbursement, collaborations and licensing arrangements, competition, capital requirements and expected cash runway.

Forward-looking statements are based on our current expectations, estimates, forecasts and assumptions and may be identified by words such as "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "plan," "potential," "predict," "project," "should," "will," "would" and similar expressions. Forward-looking statements contained in this Quarterly Report on Form 10-Q may include, but are not limited to, statements about:

- our growth rate and market opportunity;
- our ability to maintain the listing of our Common Stock on The Nasdaq Stock Market ("Nasdaq");
- the potential liquidity and trading of our Common Stock;
- the ability to realize the anticipated benefits of the business combination (the "Business Combination") with Perceptive Capital Solutions Corp. ("PCSC"), which closed on July 20, 2026, and which may be affected by, among other things, competition, our ability to grow and manage growth profitably, and our ability to retain our key employees;
- changes in applicable laws or regulations;
- our need to raise additional capital to fund our existing operations, develop our platform, commercialize new products or expand our operations;
- our expectations regarding our commercialization strategy, including the costs and timing of expanding our sales and marketing capabilities;
- our ability to support demand for our current and future products, including ensuring that we have adequate capacity to meet increased demand, or we are able to successfully manage our anticipated growth;
- estimates of the potential market opportunity and indications we intend to target;
- our ability to achieve market acceptance, obtain coverage and adequate reimbursement from third-party payers, and generate sufficient market share and revenue from approved products;
- our ability to advance our product candidates and expand our platform within our expected timelines, including the timing, results, and costs of our discovery activities, studies, and clinical trials for our current and future products and product candidates;
- our ability to maintain our existing collaboration agreements and identify and enter into future license agreements and collaborations;
- our ability to attract and retain qualified personnel, manage our future growth effectively and execute our business strategy;
- our ability to retain the services of our founder, our Chief Executive Officer, or other members of our senior management team;
- any changes in funding for, or disruptions caused by global health concerns impacting, the U.S. Food and Drug Administration (the "FDA") and other government agencies or notified bodies, which could hinder our ability to hire and retain key leadership and other personnel, or otherwise prevent new medical device products from being developed, authorized or commercialized in a timely manner;
- our financial performance, including the fact that we have incurred significant net losses in each period since our inception and anticipate that we will continue to incur net losses for the coming years;
- our ability to obtain and maintain intellectual property protection for our technologies and our product candidates; and
- potential liability lawsuits and penalties related to our technologies, product candidates and current and future relationships with third parties.

The absence of these words does not mean that a statement is not forward-looking. Forward-looking statements are subject to risks, uncertainties and other factors that could cause actual results, performance or events to differ materially from those expressed or implied by such statements. These risks and uncertainties include, among others, our ability to develop, obtain regulatory approval for and commercialize our products; achieve market acceptance and adequate reimbursement; successfully conduct clinical trials and validation studies; manage competition and anticipated growth; maintain relationships with suppliers, collaborators and licensees; protect our intellectual property; attract and retain key personnel; comply with applicable laws and regulations, including privacy and data security requirements; manage cybersecurity risks; realize the anticipated benefits of acquisitions, collaborations, licensing arrangements and cost-reduction initiatives; raise additional capital when needed; and respond to changing economic, regulatory and geopolitical conditions. Additional information regarding these and other risks is included in Part II, Item 1A, "Risk Factors," of this Quarterly Report on Form 10-Q.

Forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q. We undertake no obligation to update or revise any forward-looking statement as a result of new information, future events or otherwise, except as required by applicable law.

This Quarterly Report on Form 10-Q includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third-parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. We are responsible for all of the disclosure contained in this Quarterly Report on Form 10-Q, and we believe that these sources are reliable; however, we have not independently verified the information contained in such publications.

Risk Factors Summary

Below is a summary of the principal factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized below, and other risks that we face, can be found in "Item 1A. Risk Factors" and should be carefully considered, together with other information in this Quarterly Report on Form 10-Q and our other filings with the SEC, before making investment decisions regarding our common stock.

- We operate in a rapidly evolving field and have a limited operating history, which makes it difficult to evaluate our current business and predict our future performance.
- We have incurred significant net losses in each period since our inception and anticipate that we will continue to incur net losses for the coming years.
- We may need to raise additional capital to fund our existing operations, develop our platform, commercialize our product or new product candidates or expand our operations.
- If we cannot maintain our current collaborations or partnerships, including our arrangements with Exact and Roche, and enter into new collaborations or partnerships in a timely manner and on acceptable terms, our efforts to develop and commercialize our products could be delayed or adversely affected.
- Our approach to the development of multiple blood-based screening tests through the use of our technology platform is unproven, which makes it difficult to predict the time, cost of development and likelihood of successfully developing and launching additional tests.
- If we are unable to support demand for SimpleScreen CRC, SimpleScreen Lung or future products, if approved, including ensuring that we have adequate capacity to meet increased demand, or we are unable to successfully manage our anticipated growth, our business could suffer.
- We may experience challenges attracting and retaining qualified personnel due to competitive labor markets and we may be unable to manage our future growth effectively, all of which could make it difficult to execute our business strategy.
- If we lose the services of our founder, our Chief Executive Officer, or other members of our senior management team, we may not be able to execute our business strategy.
- We face intense competition from other companies and may not be able to compete successfully.
- Cybersecurity incidents such as security breaches, loss of data and other disruptions in relation to our information technology systems, as well as those of our third-party service providers, could compromise sensitive information related to our business, prevent us from accessing it and expose us to substantial liability, which could adversely affect our business and reputation.
- Failure of, or defects in, our machine learning algorithms, artificial intelligence, and cloud-based computing infrastructure, including interruptions of service through third-party service providers, or increased regulation in the machine learning or artificial intelligence space, could impair our ability to process our data, develop products, or provide test results, and harm our business and results of operations.
- Our current products and future products, if cleared or approved, may be subject to product recalls. A recall of our products, either voluntarily or at the direction of the FDA or another governmental authority, or the discovery of serious safety issues with our products, could have a significant adverse impact on us. In addition, recalls—whether required or voluntary—can trigger increased regulatory scrutiny of our quality systems, manufacturing processes, and post-market surveillance activities.
- The sizes of the markets for our current product and future products, if approved, have not been established with precision, and may be smaller than we estimate.
- The regulatory clearance, approval, or certification processes of the FDA and comparable foreign regulatory authorities or notified bodies are lengthy, time-consuming, and unpredictable. If we are ultimately unable to obtain any necessary or desirable regulatory approvals, clearances, or certifications, or if such approvals, clearances, or certifications are significantly delayed, our business will be substantially harmed.
- Changes in funding for, or disruptions caused by global health concerns impacting, the FDA and other government agencies or notified bodies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new medical device products from being developed, authorized or commercialized in a timely manner, which could negatively impact our business.
- Clinical development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies may not be predictive of future study results. In addition, regulatory authorities may require more extensive clinical evidence than we anticipate, and the standards for clinical data adequacy can evolve over time.
- Interim, "topline" and preliminary data from our clinical studies that we announce or publish from time to time 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.
- Our current products and, if cleared or approved, future products may fail to achieve the degree of market acceptance necessary for commercial success.
- Obtaining and maintaining regulatory authorization of our products in one jurisdiction does not mean that we will be successful in obtaining authorization of our products in other jurisdictions.
- Even if we receive regulatory authorization or certification of our products, we will continue to be subject to extensive regulatory oversight.
- The misuse or off-label use of our products may harm our reputation in the marketplace, result in injuries that 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.
- If our product, or any future products, if approved, result in direct or indirect participant or patient harm or injury, or otherwise involve errors that give rise to legal or regulatory exposure, we could be subject to significant reputational and liability risks.
- Our "research use only" and "investigational use only" products could become subject to more onerous regulation by the FDA or other regulatory agencies in the future, which could increase our costs and delay our commercialization efforts, thereby materially and adversely affecting our business and results of operations.

- If we fail to comply with healthcare and other applicable laws and regulations, we could face substantial penalties and our business, reputation, and operations and financial condition could be adversely affected.
- If third-party payers, including commercial payers and government healthcare programs, do not provide coverage of, or adequate reimbursement for, our tests, our business and results of operations will be negatively affected.
- The commercialization of our product and future products will depend heavily on payer coverage and reimbursement, and we may be unable to obtain or maintain adequate coverage or payment levels.
- We may be unable to obtain the coding necessary to secure appropriate payment for our future tests, and coding changes may adversely affect reimbursement.
- Commercial payer contracting is complex and uncertain, and failure to secure contracted status with key payers could limit adoption of our tests.
- If we or any third-party we engage now or in the future fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs or liabilities that could have a material adverse effect on our business.
- Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.
- Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.
- Patent terms may be inadequate, and developments in patent law could reduce the value of our patents.
- We may not be able to protect our intellectual property rights throughout the world.
- If we fail to comply with our obligations in the agreements under which we may license intellectual property rights from others or otherwise experience disruptions to our business relationships with our future licensors, we could lose license rights that are important to our business.
- Our use of open-source software could subject our proprietary technology to unwanted open-source license conditions, subject us to possible litigation or otherwise negatively impact our business.
- Future issued patents covering our products and other technologies could be found invalid or unenforceable if challenged in court or before administrative bodies in the U.S. and abroad.
- We may be subject to claims asserting that our employees or contractors have infringed, misappropriated or otherwise violated the intellectual property or proprietary rights of their former employers or claims asserting an ownership interest in what we regard as our own intellectual property.
- Intellectual property litigation may lead to unfavorable publicity that harms our reputation and causes the market price of our common stock to decline.
- We may become involved in lawsuits to protect, enforce or defend our intellectual property, which could be expensive, time-consuming and unsuccessful.
- Unfavorable global economic conditions could adversely affect our business, financial condition, stock price and results of operations.

The summary risk factors described above should be read together with the text of the full risk factors in the section titled “Risk Factors” and the other information set forth in this Quarterly Report on Form 10-Q, including our unaudited interim condensed financial statements and the related notes, as well as in other documents that we file with the Securities and Exchange Commission (“SEC”). The risks summarized above or described in full elsewhere in this Quarterly Report on Form 10-Q are not the only risks that we face. Additional risks and uncertainties not presently known to us, or that we currently deem to be immaterial may also materially adversely affect our business, financial condition, results of operations, and future growth prospects.

Part I — Financial Information

Item 1. Financial Statements

FREENOME, INC.
Condensed Consolidated Balance Sheets (unaudited)
(in thousands, except shares and par value data)

	September 30, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 180,379	$ 78,558
Marketable securities	249,593	138,106
Accounts receivable (includes $8,000 accounts receivable from a related party as of September 30, 2026)	8,821	1,307
Inventory	1,885	—
Prepaid expenses and other current assets	20,307	8,520
Total current assets	460,985	226,491
Property and equipment, net	154,537	155,776
Operating lease right-of-use assets, net	95,171	97,055
Intangible assets, net	2,486	3,300
Goodwill	10,513	10,513
Other long-term assets	279	4,800
Restricted cash	9,560	9,118
Total assets	$ 733,531	$ 507,053
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 8,279	$ 6,084
Accrued compensation and other related benefits	12,466	13,424
Accrued expenses and other current liabilities (includes $1,200 due to a related party as of September 30, 2026)	3,689	3,783
Deferred revenue, current	—	7,123
Current portion of lease liabilities	11,765	10,114
Total current liabilities	36,199	40,528
Long-term liabilities:		
Lease liabilities, net of current portion	189,894	199,015
Convertible note, at fair value	—	41,600
Convertible note, related party	—	60,895
Deferred revenue, non-current, related party (includes $24,594 due to a related party as of September 30, 2026)	24,594	49,138
Other long-term liabilities (includes $1,140 due to a related party as of September 30, 2026)	1,515	15,433
Total liabilities	252,202	406,609
Commitments and contingencies (Note 13)		
Stockholders' Equity:		
Preferred stock, $0.0001 par value – 10,000,000 shares authorized; zero shares issued and outstanding as of September 30, 2026 and December 31, 2025	—	—
Common stock, $0.0001 par value – 1,000,000,000 shares authorized; 110,870,300 and 67,944,192 shares issued and outstanding as of September 30, 2026, and December 31, 2025, respectively	11	7
Additional paid-in capital	1,901,263	1,447,410
Accumulated other comprehensive income (loss)	(362)	132
Accumulated deficit	(1,419,583)	(1,347,105)
Total stockholders' equity	481,329	100,444
Total liabilities and stockholders' equity	$ 733,531	$ 507,053

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

FREENOME, INC.
Condensed Consolidated Statements of Operations (unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Revenue:				
License and collaboration revenue	$ 182,547	$ —	$ 187,702	$ —
Service and other revenue	942	1,035	2,283	2,530
Total revenue	183,489	1,035	189,985	2,530
Operating costs and expenses:				
Cost of services	478	611	1,415	1,494
Research and development	68,417	50,627	174,804	145,486
General and administrative	44,628	15,055	71,252	41,070
Total operating costs and expenses	113,523	66,293	247,471	188,050
Income (loss) from operations	69,966	(65,258)	(57,486)	(185,520)
Other income (expense), net:				
Interest and investment income	2,969	1,420	5,698	5,137
Interest expense	(1,188)	(644)	(8,951)	(646)
Convertible note remeasurement loss	(11,631)	—	(11,731)	—
Other income (expense), net	(6)	13	(8)	(45)
Net income (loss)	$ 60,110	$ (64,469)	$ (72,478)	$ (181,074)
Net income (loss) per share:				
Basic	0.60	(0.95)	(0.92)	(2.66)
Diluted	0.58	(0.95)	(0.92)	(2.66)
Weighted-average shares outstanding used in computing net income (loss) per share:				
Basic	100,174,038	68,016,817	78,885,912	67,998,124
Diluted	103,221,841	68,016,817	78,885,912	67,998,124

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

FREENOME, INC.
Condensed Consolidated Statements of Comprehensive Income (Loss) (unaudited)
(in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Net income (loss)	$ 60,110	$ (64,469)	$ (72,478)	$ (181,074)
Other comprehensive income (loss):				
Unrealized gain (loss) on available-for-sale securities	(390)	18	(475)	(69)
Foreign currency translation adjustments	—	(29)	(19)	35
Other comprehensive loss	(390)	(11)	(494)	(34)
Comprehensive income (loss)	$ 59,720	$ (64,480)	$ (72,972)	$ (181,108)

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

FREENOME, INC.
Condensed Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (unaudited)
(in thousands, except share amounts)

	Nine Months Ended September 30, 2026							
	Redeemable convertible preferred stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance as of December 31, 2025, as previously reported	212,541,832	$ 1,363,580	26,267,598	$ 3	$ 83,834	$ 132	$ (1,347,105)	$ (1,263,136)
Retroactive application of recapitalization	(212,541,832)	(1,363,580)	41,676,594	4	1,363,576	—	—	1,363,580
Balance as of December 31, 2025, after effect of Business Combination	—	—	67,944,192	7	1,447,410	132	(1,347,105)	100,444
Stock-based compensation expense	—	—	—	—	2,903	—	—	2,903
Unrealized loss on available-for-sale securities	—	—	—	—	—	(87)	—	(87)
Foreign currency translation adjustment	—	—	—	—	—	(19)	—	(19)
Net loss	—	—	—	—	—	—	(63,559)	(63,559)
Balance as of March 31, 2026, after effect of Business Combination	—	—	67,944,192	7	1,450,313	26	(1,410,664)	39,682
Stock-based compensation expense	—	—	—	—	2,734	—	—	2,734
Unrealized gain on available-for-sale securities	—	—	—	—	—	2	—	2
Net loss	—	—	—	—	—	—	(69,029)	(69,029)
Balance as of June 30, 2026, after effect of Business Combination	—	—	67,944,192	7	1,453,047	28	(1,479,693)	(26,611)
Exercise of penny warrants	—	—	121,237	—	—	—	—	—
Vesting of restricted stock units, net of shares withheld for taxes	—	—	58,672	—	(1,096)	—	—	(1,096)
Stock-based compensation expense	—	—	—	—	41,944	—	—	41,944
Unrealized loss on available-for-sale securities	—	—	—	—	—	(390)	—	(390)
Issuance of common stock upon Business Combination to PCSC public shareholders and Sponsor, net of transaction costs	—	—	8,920,769	1	64,863	—	—	64,864
Issuance of common stock upon PIPE Financing, net of transaction costs	—	—	24,000,000	2	220,110	—	—	220,112
Issuance of common stock upon conversion of convertible notes	—	—	9,825,430	1	122,395	—	—	122,396
Net income	—	—	—	—	—	—	60,110	60,110
Balance as of September 30, 2026	—	$ —	110,870,300	$ 11	$ 1,901,263	$ (362)	$ (1,419,583)	$ 481,329

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

FREENOME, INC.
Condensed Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (unaudited)
(in thousands, except share amounts)

	Nine Months Ended September 30, 2025								
	Redeemable convertible preferred stock		Common Stock		Additional Paid-in Capital	Treasury Stock	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount					
Balance as of December 31, 2024, as previously reported	212,541,832	$ 1,363,580	25,973,713	$ 3	$ 75,259	$ (2,619)	$ 102	$ (1,127,762)	$ (1,055,017)
Retroactive application of recapitalization	(212,541,832)	(1,363,580)	41,887,527	4	1,363,576	—	—	—	1,363,580
Balance as of December 31, 2024, after effect of Business Combination	—	—	67,861,240	7	1,438,835	(2,619)	102	(1,127,762)	308,563
Retirement of treasury stock	—	—	—	—	(2,619)	2,619	—	—	—
Issuance of shares upon exercise of stock options	—	—	2,424	—	22	—	—	—	22
Stock-based compensation expense	—	—	—	—	2,276	—	—	—	2,276
Unrealized loss on available-for-sale securities	—	—	—	—	—	—	(82)	—	(82)
Foreign currency translation adjustment	—	—	—	—	—	—	15	—	15
Net loss	—	—	—	—	—	—	—	(57,874)	(57,874)
Balance as of March 31, 2025, after effect of Business Combination	—	—	67,863,664	7	1,438,514	—	35	(1,185,636)	252,920
Issuance of shares upon exercise of stock options	—	—	16,770	—	82	—	—	—	82
Stock-based compensation expense	—	—	—	—	2,738	—	—	—	2,738
Unrealized loss on available-for-sale securities	—	—	—	—	—	—	(5)	—	(5)
Foreign currency translation adjustment	—	—	—	—	—	—	49	—	49
Net loss	—	—	—	—	—	—	—	(58,731)	(58,731)
Balance as of June 30, 2025, after effect of Business Combination	—	—	67,880,434	7	1,441,334	—	79	(1,244,367)	197,053
Issuance of shares upon exercise of stock options	—	—	27,163	—	286	—	—	—	286
Stock-based compensation expense	—	—	—	—	2,831	—	—	—	2,831
Unrealized gain on available-for-sale securities	—	—	—	—	—	—	18	—	18
Foreign currency translation adjustment	—	—	—	—	—	—	(29)	—	(29)
Net loss	—	—	—	—	—	—	—	(64,469)	(64,469)
Balance as of September 30, 2025, after effect of Business Combination	—	—	67,907,597	$ 7	$ 1,444,451	$ —	$ 68	$ (1,308,836)	$ 135,690

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

FREENOME, INC.
Condensed Consolidated Statements of Cash Flows (unaudited)
(in thousands)

	Nine Months Ended September 30,	
	2026	**2025**
Cash flows from operating activities		
Net loss	$ (72,478)	$ (181,074)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	18,295	18,137
Noncash lease expense	1,884	3,407
Stock-based compensation expense	47,581	7,845
Net accretion and amortization of investments in marketable securities	(2,689)	(3,101)
Loss on fair-value remeasurement of convertible note	11,731	—
Loss from disposal of property and equipment	—	31
Non-cash interest expense and amortization of debt issuance costs	7,701	—
Changes in operating assets and liabilities:		
Accounts receivable	(7,514)	82
Inventory	(1,885)	—
Prepaid expenses and other current assets	(11,787)	(811)
Other long-term assets	—	269
Accounts payable	3,979	1,297
Accrued compensation and other related benefits	(958)	(2,084)
Accrued expenses and other current liabilities	30	1,026
Deferred revenue	(31,667)	8,400
Operating lease liabilities	(7,470)	4,894
Other long term liabilities	(13,449)	—
Net cash used in operating activities	(58,696)	(141,682)
Cash flows from investing activities		
Purchases of marketable securities	(271,573)	(119,210)
Proceeds from maturities of marketable securities	162,300	246,600
Purchases of property and equipment	(15,248)	(20,349)
Net cash (used in) provided by investing activities	(124,521)	107,041
Cash flows from financing activities		
Proceeds from issuance of common stock upon Business Combination and PIPE Financing	295,490	—
Payments made on finance leases	—	(159)
Proceeds from convertible note	—	41,600
Convertible note issuance costs	—	(294)
Payments for taxes on net settlement of equity awards	(1,096)	—
Payments of transaction costs related to the Business Combination	(8,895)	—
Proceeds from issuance of common stock upon exercise of stock options	—	390
Net cash provided by financing activities	285,499	41,537
Effect of exchange rate changes on cash and cash equivalents and restricted cash	(19)	35
Net increase in cash, cash equivalents and restricted cash	102,263	6,931
Cash, cash equivalents and restricted cash at beginning of period	87,676	76,170
Cash, cash equivalents and restricted cash at end of period	$ 189,939	$ 83,101

Reconciliation to amounts on the Condensed Consolidated Balance Sheets:		
Cash and cash equivalents	$ 180,379	$ 73,983
Restricted cash	9,560	9,118
Total cash, cash equivalents and restricted cash	$ 189,939	$ 83,101
Supplemental disclosures of cash flow information:		
Lease liabilities arising from obtaining right-of-use assets	—	$ 3
Supplemental disclosures of noncash investing and financing activities:		
Purchases of property and equipment in accounts payable and accrued expenses	$ 994	$ 77
Offering expenses included in accounts payable	$ 778	$ —
Deferred offering costs related to reverse recapitalization	$ 841	$ —
Issuance of common stock upon conversion of convertible notes	$ 122,396	$ —
Conversion of redeemable convertible preferred stock into common stock in connection with reverse recapitalization	$ 1,363,580	$ —

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

FREENOME, INC.

Notes to the Condensed Consolidated Financial Statements (unaudited)

Note 1—Organization and Business

Organization

Freenome, Inc. (together with its wholly-owned subsidiaries, the "Company") is a biotechnology company pioneering an early cancer detection platform. The Company's initial programs are focused on colorectal cancer with a pipeline of single-cancer and multi-cancer tests under development, including breast, cervical, liver, pancreatic and esophageal cancers. On October 20, 2026, subsequent to the balance sheet date, the Company launched SimpleScreen Lung, a laboratory-developed test for lung cancer screening. SimpleScreen Lung has not been reviewed, cleared or approved by the U.S. Food and Drug Administration (the "FDA").

The Company was incorporated in Delaware in 2016. The Company's headquarters are located in Brisbane, California.

Business Combination

On July 20, 2026, Freenome Holdings, Inc. ("Legacy Freenome") completed its business combination with Perceptive Capital Solutions Corp. ("PCSC") (the "Business Combination"). At closing, PCSC domesticated as a Delaware corporation and changed its name to Freenome, Inc. The Business Combination and concurrent private investment in public equity financing ("PIPE Financing") generated gross proceeds of approximately $310.7 million, consisting of approximately $70.3 million from PCSC's trust account after redemptions and $240.0 million from the PIPE Financing and $0.4 million cash held by PCSC at closing, before transaction expenses. The Company received net proceeds of approximately $295.5 million.

The Business Combination was accounted for as a reverse recapitalization, with Legacy Freenome as the accounting acquirer and PCSC as the acquired company for accounting purposes. Accordingly, the historical financial information presented for periods before the closing reflects Legacy Freenome's historical financial statements. PCSC's net assets were recognized at historical cost, and no goodwill or other intangible assets were recorded.

All issued and outstanding common stock, redeemable convertible preferred stock, stock awards, warrants, related capital accounts, and per-share amounts of Legacy Freenome for periods before the closing were retrospectively adjusted to reflect the 0.282895 exchange ratio ("Exchange Ratio"). Legacy Freenome's redeemable convertible preferred stock was retrospectively presented as common stock, and weighted-average shares outstanding and net loss per share were recast accordingly. These adjustments affected shares outstanding, par value, additional paid-in capital, and per-share information but did not affect Legacy Freenome's historical operating results or cash flows. See Note 10 for additional details.

Basis of Presentation and Principles of Consolidation

The accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with the United States generally accepted accounting principles ("U.S. GAAP") pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC") for reporting interim financial information. Any reference in these notes to applicable accounting guidance is meant to refer to the authoritative U.S. GAAP included in the Accounting Standards Codifications ("ASCs") and Accounting Standards Updates ("ASUs") issued by the Financial Accounting Standards Board ("FASB"). The unaudited interim condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

The condensed consolidated balance sheet as of December 31, 2025, included herein was derived from the audited consolidated financial statements as of that date. Certain information and footnote disclosures typically included in the Company's audited consolidated financial statements have been condensed or omitted. The accompanying unaudited interim condensed consolidated financial statements have been prepared on the same basis as the annual consolidated financial statements and reflect all adjustments of a normal and recurring nature that are necessary for the fair presentation of the Company's financial position, results of operations, and cash flows for the periods presented, but are not necessarily indicative of results to be expected for any future annual or interim period. These unaudited interim condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and footnotes for the year ended December 31, 2025, included in the proxy statement/prospectus filed with the SEC on June 17, 2026.

Use of Estimates

The preparation of unaudited interim condensed consolidated financial statements in conformity with U.S. GAAP requires the Company's management to make estimates and assumptions that affect the reported amounts of assets and liabilities as of the date of the unaudited interim condensed consolidated financial statements, the reported amounts of revenue and expenses during the reported periods, and the accompanying notes. The Company bases its estimates and judgments on historical experience and on various other assumptions that the Company believes are reasonable under the circumstances. These estimates are based on management's knowledge

about current events and expectations about actions the Company may undertake in the future. Actual results could differ materially from those estimates.

These judgments, estimates and assumptions made by management include, but are not limited to, the determination of:

- fair value of the Company's common stock prior to the Business Combination, including the valuation inputs used to determine the grant-date fair value of equity awards;
- impairment assessment of goodwill and intangible assets;
- impairment assessment and recoverability of long-lived assets;
- fair value of equity awards, including restricted stock units that vested in connection with the Business Combination, and the related stock-based compensation expense and assumptions;
- stock-based compensation expense and related assumptions;
- income tax uncertainties and valuation allowance for deferred tax assets;
- performance obligations within a contract and the determination of standalone selling price ("SSP") for each performance obligation;
- fair value of the license option liability under the Roche License and Option Agreement (as defined below) and the amortization of the related discount through conversion of the Roche Convertible Note (as defined below);
- allocation of transaction costs to the equity issued in the Business Combination and the PIPE Financing; and
- fair value of the convertible notes, including remeasurement immediately before conversion.

Summary of Significant Accounting Policies

The significant accounting policies used by the Company in its presentation of interim financial results are consistent with those described in Note 2 to the Company's audited consolidated financial statements for the year ended December 31, 2025, issued on March 30, 2026, except for the addition of the inventory policy described below. During the nine months ended September 30, 2026, there were no other significant changes in the Company's significant accounting policies from those disclosed in its consolidated financial statements for the year ended December 31, 2025.

Liquidity and Capital Resources

The Company has incurred losses and negative cash flows from operations since its inception. During the nine months ended September 30, 2026, the Company incurred a net loss of $72.5 million, used $58.7 million of cash in operations and had an accumulated deficit of $1.4 billion. As of September 30, 2026, the Company had approximately $430.0 million in cash, cash equivalents, and short-term marketable securities. Based on its current operating plan, the Company believes that its cash, cash equivalents, and short-term marketable securities as of September 30, 2026 will be sufficient to fund its anticipated operating expenses and capital expenditure requirements for at least the next 12 months from the date of issuance of these unaudited interim condensed consolidated financial statements.

The Company expects to incur additional losses in the future and may need to raise additional capital to further advance its research and development ("R&D") programs, prepare for potential regulatory submissions, commercialize tests that receive regulatory approval, operate its business, and meet its financial obligations. If its available funding is insufficient to meet working capital needs, the Company may need to modify, delay, or reduce the scope of research and development activities, terminate certain activities, or limit or cease operations. The Company may seek additional funding through equity or debt financings, grants, collaborations, or other strategic transactions. Such financing may be dilutive, may not be available on acceptable terms, or may not be available at all.

Risks and Uncertainties

The Company is subject to risks and uncertainties common to companies in the biopharmaceutical and diagnostic test industries, including, but not limited to, risks associated with failure or unsatisfactory results of nonclinical and clinical studies, the need for significant capital to fund clinical trials and development of its diagnostic test candidates, dependence on strategic relationships with collaboration partners and key personnel, the ability to develop, secure, and protect proprietary technology rights, compliance with government regulations, the development of technological innovations by competitors, and dependence on third-party service providers.

The Company relies on a limited number of third-party manufacturers and service providers, some of whom are sole suppliers or service providers, for a portion of the components, accessories, reagents, materials, and equipment that it uses in its operations. A disruption or interruption in supply from these suppliers, or in the operations of such suppliers, would negatively impact the Company's business, supply chain, and laboratory operations.

The Company's business and operations may be affected by worldwide economic conditions, which may continue to be impacted by global macroeconomic challenges, such as the effects of the ongoing geopolitical conflicts, tariffs, and uncertainty in the financial markets, including disruptions in the banking industry and inflationary trends.

Recently Adopted Accounting Pronouncements

In September 2025, the FASB issued ASU 2025-07, *Derivatives Scope Refinements and Scope Clarification for Share-Based Noncash Consideration from a Customer in a Revenue Contract*, which excludes from derivative accounting certain contracts whose payments are based on the operations or activities of one of the parties to the contract. The Company early adopted ASU 2025-07 on July 1, 2026 using the prospective transition method. The adoption did not have a material impact on the Company's condensed consolidated financial statements and related disclosures.

In May 2025, the FASB issued ASU No. 2025-03, Determining the Accounting Acquirer in the Acquisition of a Variable Interest Entity, which revises current guidance for determining the accounting acquirer for a transaction effected primarily by exchanging equity interests in which the legal acquiree is a variable interest entity that meets the definition of a business. The amendments require that an entity consider the same factors that are currently required for determining which entity is the accounting acquirer in other acquisition transactions. The standard is effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods within those annual reporting periods, with early adoption permitted. The standard is required to be applied prospectively. The Company early adopted ASU 2025-03 on July 1, 2026, the beginning of the third quarter of 2026. The adoption did not have a material impact on the Company's condensed consolidated financial statements and related disclosures.

Recently Issued Accounting Standards Not Yet Adopted

In November 2024, the FASB issued ASU 2024-03, *Income Statement (Subtopic 220-40): Reporting Comprehensive Income - Expense Disaggregation Disclosures*, which requires an entity to disclose on an annual and interim basis, disaggregated information about specific income statement expense categories. The standard will be effective for annual reporting periods beginning after December 15, 2026, and interim periods within annual periods beginning after December 15, 2027 with early adoption permitted. The guidance should be applied prospectively with the option to apply the standard retrospectively. The Company is currently evaluating the disclosure requirements related to this new standard.

In December 2025, the FASB issued ASU 2025-11, *Interim Reporting (Topic 270): Narrow-Scope Improvements*. ASU 2025-11 improves clarity for interim financial reporting requirements under the existing guidance within ASC 270, Interim Reporting. ASU 2025-11 is effective for public entities with annual periods beginning after December 15, 2027, with early adoption permitted. The Company is currently evaluating the impact of ASU 2025-11 on its financial statements and related disclosures.

Note 2—Certain Balance Sheet Components

Cash, Cash Equivalents, and Restricted Cash

Cash and cash equivalents include cash deposits in banks and highly liquid investments that are readily convertible to cash (maturity of three months or less at the time of purchase).

Restricted cash consists of funds held or designated to satisfy the requirements of certain agreements that are restricted in their use. As of September 30, 2026 and December 31, 2025, the Company's restricted cash consisted of cash deposits required to support irrevocable standby letters of credit provided to the landlord pursuant to certain lease agreements. The Company determines current or non-current classification of restricted cash on the consolidated balance sheets based on the expected duration of the restriction. The Company's restricted cash totaled $9.6 million and $9.1 million at September 30, 2026, and December 31, 2025, respectively.

Property and Equipment

Property and equipment, net consists of the following (in thousands):

	September 30, 2026	December 31, 2025
Leasehold improvements	$ 147,924	$ 147,924
Laboratory machinery and equipment	47,261	40,669
Machinery and equipment	7,514	7,514
Computer hardware and software	7,220	4,905
Furniture and fixtures	4,140	4,140
Construction in progress	7,451	847
Subtotal	221,510	205,999
Less: accumulated depreciation and amortization	(66,973)	(50,223)
Total property and equipment, net	$ 154,537	$ 155,776

Depreciation expense related to property and equipment was $5.7 million and $5.8 million for the three months ended September 30, 2026, and 2025, respectively, and $17.5 million and $17.3 million for the nine months ended September 30, 2026 and 2025, respectively, and were recorded in both R&D expenses and general and administrative ("G&A") expenses in the condensed consolidated statements of operations.

Accrued compensation and other related benefits

Accrued compensation and other related benefits consist of the following (in thousands):

	September 30, 2026	December 31, 2025
Accrued bonuses	$ 11,067	$ 12,141
Accrued payroll and related expenses	947	916
Accrued other compensation related benefits	452	367
Total accrued compensation and other related benefits	$ 12,466	$ 13,424

Intangible Assets, net

The following table presents details of intangible assets, net as of September 30, 2026 (in thousands):

	September 30, 2026			
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Remaining Weighted-Average Useful Life (in years)
Intangible assets acquired:				
Acquired developed technology	$ 5,509	$ (3,241)	$ 2,268	2.6
Customer relationships	529	(311)	218	2.6
Total intangible assets acquired	$ 6,038	$ (3,552)	$ 2,486	

The following table presents details of intangible assets, net as of December 31, 2025 (in thousands):

	December 31, 2025			
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Remaining Weighted-Average Useful Life (in years)
Intangible assets acquired:				
Acquired developed technology	$ 5,509	$ (2,498)	$ 3,011	3.4
Customer relationships	529	(240)	289	3.4
Total intangible assets acquired	$ 6,038	$ (2,738)	$ 3,300	

Amortization expense of finite-lived intangible assets was $0.2 million for the three months ended September 30, 2026 and 2025, respectively, and $0.8 million for the nine months ended September 30, 2026 and 2025, respectively.

The following table summarizes the Company's estimated future amortization expense of finite-lived intangible assets as of September 30, 2026 (in thousands):

Year Ending December 31,	Total
2026 (remainder of year)	$ 271
2027	1,006
2028	1,006
2029	203
Total	$ 2,486

Inventory

Inventory consists of raw materials and is stated at the lower of cost and net realizable value, with cost determined on a first-in, first-out basis. Costs capitalized to inventory consist of the purchase price of reagents used in commercial testing. Freight, duty and shipping, sales tax, storage and warehousing, consumables and plating costs are expensed as incurred. Before regulatory approval, the Company expensed pre-launch inventory costs as part of research and development expenses. Beginning in June 2026, in anticipation of FDA approval of SimpleScreen CRC, the Company began capitalizing the purchase price of reagents for commercial production because it determined that regulatory approval and future economic benefits were probable; the FDA approved SimpleScreen CRC in July 2026. Inventory used in research and development is expensed to research and development expense when consumed, and inventory used in commercial testing is expensed to cost of goods sold when the related test is performed. As of September 30, 2026 the Company had raw material inventory of $1.9 million.

Note 3—Fair Value Measurements

The preparation of the Company's unaudited interim condensed consolidated financial statements in accordance with U.S. GAAP requires certain assets and liabilities to be reflected at their fair value. Fair value is defined as the exchange price, or 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 on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The fair value hierarchy contains three levels of inputs that may be used to measure fair value, in accordance with ASC 820, *Fair Value Measurement*, the first two are considered observable and the last is considered unobservable. These levels are as follows:

- Level 1— inputs, which include unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access;
- Level 2 — inputs, which include observable inputs other than Level 1 inputs, such as quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the asset or liability; and

- Level 3 — inputs, which include unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the underlying asset or liability. Level 3 assets and liabilities include those whose fair value measurements are determined using pricing models, discounted cash flow methodologies, or similar valuation techniques, as well as significant management judgment or estimation.

To the extent the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. Marketable securities that are classified as available-for-sale are recorded at estimated fair value and are included in Level 1 or Level 2 of the fair value hierarchy. The Company classifies its money market funds and U.S. treasury securities, which are valued based on quoted market prices in active markets with no valuation adjustment, as Level 1 assets within the fair value hierarchy. The Company classifies its commercial paper, U.S. government agency bonds and corporate bonds as Level 2 assets because they are valued using observable inputs, such as quoted prices for similar securities, reported trades, broker and dealer quotes, benchmark yields and issuer credit spreads, obtained from third-party pricing services.

The categorization of a financial instrument within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement. The carrying value of cash, accounts payable, accrued expenses and other current liabilities and convertible note, related party approximate fair value.

The following table summarizes the Company's financial assets and liabilities measured at fair value on a recurring basis and their respective input levels based on the fair value hierarchy (in thousands):

	September 30, 2026			
	Level 1	**Level 2**	**Level 3**	**Total**
Assets:				
Cash equivalents:				
Money market funds	$ 40,221	$ —	$ —	$ 40,221
Commercial paper	—	25,955	—	25,955
U.S. treasury securities	14,944	—	—	14,944
Total cash equivalents	55,165	25,955	—	81,120
Short-term marketable securities:				
U.S. government agency bonds	—	34,886	—	34,886
U.S. treasury securities	84,816	—	—	84,816
Commercial paper	—	94,264	—	94,264
Corporate bonds	—	35,627	—	35,627
Total short-term marketable securities	84,816	164,777	—	249,593
Total assets subject to fair value measurements on a recurring basis	$ 139,981	$ 190,732	$ —	$ 330,713

	December 31, 2025			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 40,320	$ —	$ —	$ 40,320
U.S. treasury securities	29,638	—	—	29,638
Total cash equivalents	69,958	—	—	69,958
Short-term marketable securities:				
U.S. treasury securities	138,106	—	—	138,106
Total short-term marketable securities	138,106	—	—	138,106
Total assets subject to fair value measurements on a recurring basis	$ 208,064	$ —	$ —	$ 208,064
Liabilities:				
Convertible note, at fair value	$ —	$ —	$ 41,600	$ 41,600
Total liabilities subject to fair value measurements on a recurring basis	$ —	$ —	$ 41,600	$ 41,600

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

The Company elected to measure the convertible note originally issued to Exact Sciences Corporation (the “Exact Convertible Note”) using the fair value option before its automatic conversion. On September 8, 2026, approximately $50.5 million of principal and accrued and unpaid interest under the Exact Convertible Note automatically converted into 3,364,814 shares of the Company’s common stock at a conversion price of $15.00 per share. Accordingly, the Exact Convertible Note was not outstanding or subject to fair value measurement as of September 30, 2026.

The significant unobservable inputs used in the valuation of the Exact Convertible Note as of December 31, 2025 included the following:

	December 31, 2025
Estimated Stock Price	$ 2.44
Credit Spread	8.9%

During the nine months ended September 30, 2026, the fair value of the Exact Convertible Note increased by $12.2 million. Of this amount, $11.7 million was recognized as a convertible note remeasurement loss, including the remeasurement immediately prior to note’s conversion on September 8, 2026 and is included in convertible note remeasurement loss, and $0.5 million of interest accrued through the conversion date was included in interest expense in the condensed consolidated statements of operations. The remeasurement immediately prior to conversion was based on the quoted share price of the Company’s common stock of $15.99 on September 8, 2026, applied to the 3,364,814 shares issued upon conversion. The increase primarily reflects the appreciation in the Company’s stock price following the Business Combination.

The change in the fair value of the Exact Convertible Note is summarized in the following table for the nine months ended September 30, 2026 (in thousands):

Balance at December 31, 2025	$ 41,600
Change in fair value included in convertible note remeasurement loss	11,731
Accrued interest included in interest expense	472
Conversion into common stock	(53,803)
Balance at September 30, 2026	$ —

Note 4 — Investments in Marketable Securities

Investments in marketable available-for-sale securities consisted of the following (in thousands):

	September 30, 2026			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Estimated Fair Value
Cash equivalents:				
Money market funds	$ 40,221	$ —	$ —	$ 40,221
Commercial paper	25,959	—	(4)	25,955
U.S. treasury securities	14,946	—	(2)	14,944
Total cash equivalents	81,126	—	(6)	81,120
Short-term marketable securities:				
U.S. government agency bonds	34,983	—	(97)	34,886
U.S. treasury securities	84,892	—	(76)	84,816
Commercial paper	94,399	3	(138)	94,264
Corporate bonds	35,703	—	(76)	35,627
Total short-term marketable securities	249,977	3	(387)	249,593
Total assets measured at fair value	$ 331,103	$ 3	$ (393)	$ 330,713

	December 31, 2025			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Estimated Fair Value
Cash equivalents:				
Money market funds	$ 40,320	$ —	$ —	$ 40,320
U.S. treasury securities	29,631	7	—	29,638
Total cash equivalents	69,951	7	—	69,958
Short-term marketable securities:				
U.S. treasury securities	138,029	77	—	138,106
Total short-term marketable securities	138,029	77	—	138,106
Total assets measured at fair value	$ 207,980	$ 84	$ —	$ 208,064

As of September 30, 2026 and December 31, 2025, the Company has not realized any impairment charges on its marketable securities related to expected credit losses. As of September 30, 2026 the aggregate difference between the amortized cost and fair value of each security in an unrealized loss position was attributed to market interest rate changes and is not related to changes in credit. The Company does not intend to sell the investments and it is not more likely than not that the Company will be required to sell the investments before recovery of their amortized cost basis, which may be at maturity. None of the available-for-sale securities held as of September 30, 2026 and December 31, 2025 have been in an unrealized loss position for more than one year. See Note 3 for further information regarding the fair value of the Company's investments in marketable securities. Accrued interest receivable of $0.7 million as of September 30, 2026 is excluded from the amortized cost and estimated fair value amounts above and from the measurement of expected credit losses. As of September 30, 2026, all short-term marketable securities had contractual maturities of one year or less.

There were no long-term marketable securities as of September 30, 2026, and December 31, 2025.

Note 5—Taxes

The Company had no current or deferred income tax expense or benefit during the three and nine months ended September 30, 2026 and 2025. Deferred income taxes reflect the net tax effects of loss and credit carryforwards, as well as temporary differences between the carrying amounts of assets and liabilities for financial reporting and income tax purposes. The realization of these deferred tax assets is dependent upon future taxable income, the amount and timing of which are currently uncertain. All of the Company's deferred tax assets—which include net operating loss carryforwards, tax credits related primarily to research and development,

capitalized research and development costs, and operating lease liabilities—continue to have a full valuation allowance as of September 30, 2026. The Company will maintain this full valuation allowance until there is sufficient evidence to support the recoverability of its deferred tax assets.

Note 6—Revenue

Exclusive License Agreement with Exact Sciences Corporation ("Exact")

In August 2025, the Company signed an exclusive collaboration and license agreement (the "Exact Sciences License Agreement") with Exact Sciences Corporation ("Exact") to commercialize the Company's blood-based screening test for colorectal cancer ("CRC") in the United States ("U.S."). The Exact Sciences License Agreement was deemed effective for accounting purposes upon receipt of approval from the relevant governmental authority on November 7, 2025 (the "Antitrust Clearance Date"). On March 23, 2026, Abbott Laboratories ("Abbott") completed its acquisition of Exact, and Exact became a subsidiary of Abbott.

Pursuant to the Exact Sciences License Agreement, the Company granted Exact (a) a non-exclusive, fully paid, royalty-free, sublicensable (subject to certain restrictions) license under certain of the Company's intellectual property rights to develop in accordance with the development plan certain in vitro, blood-based products or services for diagnosis, screening or evaluation of CRC or colorectal pre-cancer (excluding certain multi-cancer tests) (each a "Collaboration Product") for all uses and purposes, excluding the diagnosis, screening or evaluation of measurable residual disease (the "Field"), (b) a co-exclusive, royalty-bearing, sublicensable (subject to certain restrictions) license under certain of the Company's intellectual property rights to commercialize Collaboration Products that are laboratory developed tests until the later of (i) the date of approval by the FDA of a premarket approval application for a class III medical device for CRC or colorectal pre-cancer that meets certain requirements for the first Collaboration Product and (ii) antitrust clearance, which occurred on November 7, 2025 and (c) upon approval by the FDA of a Collaboration Product, an exclusive, royalty bearing, sublicensable (subject to certain restrictions) license under certain of the Company's intellectual property rights to commercialize Collaboration Products in the Field in the U.S. In addition, the Company granted Exact Sciences a non-exclusive, worldwide license to manufacture Collaboration Products for purposes of developing and commercializing Collaboration Products as expressly permitted above. Collaboration Products exclude certain future CRC products for which Exact Sciences is granted a certain right of first negotiation in the U.S.

Pursuant to the Exact License Agreement, the Company received a one-time, non-refundable, non-creditable, upfront payment of $75.0 million from Exact on November 3, 2025 as partial consideration for the rights and license granted. The Company is also eligible to receive up to $700.0 million in certain development and regulatory milestones; annual development payments of up to $20.0 million per year over three years for funding of R&D development expenses leveraging the technology for those three years; and tiered royalties ranging from low to high double-digit percentages on U.S. sales of any commercial products that may result from the collaboration, subject to customary deductions under certain circumstances.

The Exact License Agreement is subject to termination by either party for the other party's uncured material breach or its insolvency. Subject to certain limitations, the Company and Exact both have certain termination for convenience rights, exercisable upon sufficient prior written notice. Specifically, the Company's right to terminate for convenience may be exercised if Exact ceases commercialization activities for all Collaboration Products; or if there is a patent challenge with respect to the Company's patent rights in the U.S.; or if Exact's licensees commercially launch, as a standalone product, the in vitro, blood-based product for the diagnosis, screening or evaluation of colorectal cancer in the U.S. that Exact is developing. Exact may terminate the agreement in its entirety, upon prior written notice to the Company, upon earlier of not meeting a certain development milestone event or by January 1, 2028.

Exact also has the right to terminate the collaborative activities under the Exact License Agreement at specified points during the collaboration term.

At the commencement of the arrangement, the Company concluded that Exact was a customer and that the Exact License Agreement should be accounted for under ASC 606. The performance obligations identified under the Exact License Agreement included the delivery of intellectual property and licenses related to development, co-exclusive commercialization, manufacturing, and data; research and development services; the exclusive commercialization license; technology transfers; and a material right to certain laboratory tests that the Company will bill at cost.

The promises related to the development license, co-exclusive commercialization license, manufacturing license, and data license were considered functional intellectual property and determined to be distinct from the remaining promises in the Exact Sciences License Agreement. These licenses were delivered at the same time, therefore, they are considered one performance obligation at contract inception.

The Company determined the transaction price under ASC 606 at the inception of the Exact License Agreement to be $143.4 million, consisting of the $75.0 million up front payment, $60.0 million reimbursement for development costs, and $8.4 million allocated to the Exact License Agreement from the proceeds received in the Exact Convertible Note. The reimbursement for development costs includes $20.0 million of variable consideration per year, that is expected to be paid by Exact over a three year period from the effective

date of the contract. The Exact Convertible Note converted into 3,364,814 shares of the Company's common stock on September 8, 2026 (see Note 8).

The Exact License Agreement includes $700.0 million milestone payments, of which $100.0 million is payable upon FDA approval of the Company's initial version of a Collaboration Product, $100.0 million is payable upon first-line FDA approval for the next-generation test contingent on meeting predefined performance benchmarks, and $500.0 million is payable if a Collaboration Product is rated as a first-line A or B test in the USPSTF guidelines or meets specified payer coverage requirements. The agreement provides for reductions to the applicable milestone payments if the performance benchmarks are not achieved or the Collaboration Product is rated as a second-line A or B test in the USPSTF guidelines. Because achievement depends on regulatory decisions and other conditions outside the Company's and licensee's control, the Company concluded that the milestones were not probable of achievement until the applicable approval, rating, or coverage condition occurred and constrained the related consideration. The Exact License Agreement also includes sales-based royalty payments, determined on a level of sales for which the license is deemed to be the predominant item to which the royalties relate. The Company will recognize revenue for these payments at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied or partially satisfied.

At contract inception, the Company allocated the transaction price to each performance obligation based on its relative SSP. The SSPs were estimated using an income approach based on discounted cash flows for the exclusive commercialization license; a replacement cost approach for the data, development, and manufacturing licenses; and a cost-plus margin approach for technology transfers, research and development services, and the material right for laboratory tests. For the latter items, estimates were based on expected costs and a market participant margin; for the material right, the estimate also considered the expected reimbursed cost of the laboratory tests.

The Company recognizes revenue allocated to the intellectual property licenses and technology transfers at a point in time when control of the related performance obligations transfers to the customer. It recognizes revenue allocated to research and development services over time using a cost input method as the services are performed. It recognizes revenue allocated to the material right over time using an output method as the laboratory tests are performed, which the Company believes best depicts the transfer of control to the customer.

During the three months ended September 30, 2026, FDA approval of the Company's initial version of a Collaboration Product made the exclusive commercialization license effective and transferred control of the license to Exact, resolving the constraint on the related $100.0 million milestone. The Company therefore satisfied the related performance obligation, and the associated milestone payment was determined to no longer be constrained. This resulted in immediate revenue recognition of $157.5 million related to the exclusive commercialization license and $22.5 million cumulative catch up related to the intellectual property licenses that were transferred at contract inception and development cost reimbursements that are recognized over time. The $100.0 million was included in the transaction price during the period and allocated to all the performance obligations in the Exact Sciences License Agreement. During the three months ended September 30, 2026, the Company recognized revenue of $182.5 million under the Exact Sciences License Agreement. Of the $182.5 million recognized as revenue, $157.5 million related to the exclusive commercialization license, $22.5 million related to the cumulative catch-up adjustment, and $2.5 million related to research and development services provided during the three-month period. At each reporting date the Company reviews the total costs incurred to date and the total expected costs necessary to fulfill the development cost reimbursement performance obligation. The Company recognized $2.5 million of revenue for research and development services performed during the quarter using the cost input method as the services are performed.

The following table summarizes the changes in deferred revenue (in millions):

Deferred revenue at December 31, 2025[1]	$	(56.3)
Additions related to development cost reimbursement received		(20.0)
Additions due to milestone achieved related to FDA approval		(100.0)
Recognized in revenue during the nine months ended September 30, 2026		187.7
Contract asset at September 30, 2026 (1)	$	11.4

(1) During the nine months ended September 30, 2026, the Company recognized $187.7 million of revenue and a contract asset of $11.4 million which the Company expects to bill in future periods as the contractual right to payment for collaboration services under the Exact Sciences License Agreement has not yet been raised. The contract asset was included as part of prepaid and other current assets on the condensed consolidated balance sheet. As of September 30, 2026, there was no deferred revenue under the agreement.

As of September 30, 2026, the aggregate transaction price allocated to unsatisfied performance obligations under the Exact Sciences License Agreement was $28.6 million. The Company expects to recognize $21.7 million as it performs research and development services (over approximately two years), $6.1 million as it performs laboratory tests under the material right, and $0.7 million when it completes certain technology transfers.

Service and Other Revenue

The Company derives revenue from diagnostic and research services performed under a research and services agreement with Roche, and from the sale and distribution of tests and services through its U.K.-based subsidiary, Freenome Ltd. Revenue is recognized at a point in time when the Company satisfies its performance obligations by transferring the related goods or services to customers.

The following table summarizes service and other revenue by type (in millions):

	Three Months Ended September 30,		Nine Months Ended September 30,	
Revenue type	2026	2025	2026	2025
Diagnostic and research services	$ —	$ 0.3	$ —	$ 0.3
EarlyCDT Lung royalties	0.5	0.3	1.3	0.7
EarlyCDT Lung test kits	0.3	0.3	0.8	1.1
EarlyCDT Lung test plates	0.1	0.1	0.2	0.4
Total revenue	$ 0.9	$ 1.0	$ 2.3	$ 2.5

Note 7—Exclusive License and Option Agreement with Roche

In November 2025, the Company entered into an exclusive license and option agreement with Roche Sequencing Solutions, Inc. (“Roche Sequencing”) and a promissory note agreement with Roche Holdings, Inc. (“Roche Holdings”) (the “Roche Promissory Note Agreement”) for a $75.0 million convertible promissory note (the “Roche Convertible Note”). The Company received total proceeds of $75.0 million under these agreements (collectively, the “Roche Agreements”) (see Note 8).

The exclusive license and option agreement with Roche Sequencing (the “Roche License and Option Agreement”) grants Roche Sequencing two rights: (a) an exclusive option (the “Option”) to obtain an exclusive, royalty-bearing, sublicensable (subject to certain restrictions) license to certain of the Company’s intellectual property rights for the manufacture and sale of kitted assays for cancer screening, including for colorectal cancer and lung cancer (the “Licensed Products”), outside the U.S.; and (b) in the event that the Company seeks to enter into a partnering transaction to offer centralized testing services for cancer screening outside the U.S., a preferred partner right to negotiate with the Company a definitive agreement for such partnering transaction. In addition, the Company agreed to conduct an evaluation of the Company’s cancer detection assays using Roche Sequencing’s sequencer (the “SBX Platform”) for no more than two years (the “Evaluation Period”).

Under the Roche License and Option Agreement, Roche Sequencing is obligated to pay the Company a $10.0 million option exercise fee within thirty (30) days of its written notice to exercise the Option.

If Roche Sequencing exercises the Option, the Company may receive up to $100.0 million in milestone payments as well as royalties on non-U.S. test sales that range from low single-digits to mid-teens, depending on sales of the Licensed Products.

The Option can be exercised anytime from November 14, 2025 (date of the Roche License and Option Agreement) through and until one year after the earlier of (i) Licensed Products for at least five separate indications, including CRC and lung cancer as two of such five separate indications, have been approved or cleared by the FDA, or (ii) (x) Licensed Products for CRC and lung cancer have been approved or cleared by the FDA, and (y) the Company has launched Licensed Products as laboratory developed tests under applicable regulatory requirements in the U.S., or Licensed Products have been approved or cleared by the FDA, for three additional separate indications other than CRC and lung cancer (such period, the “Option Term”). The agreement terminates upon the earlier of (i) the expiration of the royalty term for all Licensed Products outside the U.S. if Roche Sequencing exercises the Option, or (ii) if Roche Sequencing does not exercise the Option, three years after the Company has made all commercial assays of the Company available on the SBX Platform or the termination of the SBX evaluation and implementation plans. The Roche License and Option Agreement is subject to termination by either party for the other party’s uncured material breach. Additionally, both the Company and Roche Sequencing have certain specific termination rights, upon sufficient prior written notice. The Company may terminate if, following the exercise of the Option, Roche Sequencing engages in any patent challenge with respect to any licensed patent. The Company also has termination rights if, following receipt of regulatory approval for a licensed product, Roche Sequencing (i) does not initiate commercialization activities for at least one licensed product during the twelve (12) month period following the date of such regulatory approval, or (ii) ceases all commercialization activities for all licensed products for a continuous period of twelve (12) months. Conversely, Roche Sequencing may terminate the agreement if there is a Change of Control at the Company.

The Company evaluated the Roche Agreements together as a single arrangement because they were negotiated at the same time to achieve a single commercial objective. It allocated the $75.0 million of total proceeds first to the Roche Convertible Note at its

initial fair value of $60.0 million (see Note 8), with the residual $15.0 million allocated to the Roche License and Option Agreement. The Company recorded the $15.0 million in other long-term liabilities on the condensed consolidated balance sheet at December 31, 2025.

Upon delivery of the SBX Platform, the Company concluded that the agreement met the criteria for a contract under ASC 606. The $15.0 million of proceeds allocated to the Roche License and Option Agreement was recorded in other long-term liabilities as of December 31, 2025 and was reclassified to deferred revenue upon delivery of the SBX Platform on September 29, 2026.

The Company accounts for the Option under ASC 606 and applies ASC 606 by analogy to the SBX evaluation services. Roche Sequencing had not exercised the Option as of September 30, 2026, or through the date these condensed consolidated financial statements were issued.

The Company identified two distinct performance obligations: (i) the SBX evaluation services and (ii) a material right associated with the Option. Upon exercise of the Option, the material right would entitle Roche Sequencing to the underlying research and development services, preferred partner right, and technology transfer and development plan. The SBX implementation plan is not a performance obligation because the parties must mutually agree to proceed with it after the evaluation.

At the date of SBX Platform delivery, the transaction price of $35.0 million, consisted of $15.0 million of residual proceeds allocated to the Roche License and Option Agreement, and $20.0 million of both fixed and variable consideration for certain milestones and noncash consideration. The noncash consideration of $4.0 million comprised both a sample cohort and reagents that Roche Sequencing provided at no charge. The sample cohort was measured at fair value, based on negotiated pricing for similar samples and sample providers, and the reagents were measured at list price. The Company controls the reagents and samples and may use them in its own research and development beyond the SBX evaluation. The cost of the sample cohort was recorded as an asset upon receipt, as the samples may be used in research and development activities beyond the SBX evaluation, and was expensed to research and development as the samples were consumed. The sample cohort was fully consumed as of September 30, 2026.

Milestone #2 and Milestone #3 are variable consideration payable upon Roche Sequencing's acceptance of reports on the SBX evaluation. The Company included Milestone #2 in the transaction price because acceptance depends on completing specified evaluation activities, not on the evaluation's results, so it is probable that a significant reversal of cumulative revenue will not occur. The Company fully constrained and excluded Milestone #3 because it depends on favorable evaluation results that are subject to Roche Sequencing's review and acceptance and are outside the Company's control, and because the evaluation has only just begun. Milestone #3 is also payable only if Roche Sequencing does not terminate the SBX implementation plan after Milestone #2. The Company allocated Milestone #2 entirely to the SBX evaluation, and will allocate Milestone #3 to the material right and recognize the related revenue as it performs the SBX implementation plan. The Company applied the variable consideration allocation exception because the milestones relate specifically to its efforts to perform the evaluation, and the allocation is consistent with the allocation objective in ASC 606.

The Company allocated the fixed consideration to the SBX evaluation and the material right on a relative SSP basis.

Consideration allocated to the SBX evaluation is recorded as other current liabilities and recognized over time using a cost-to-cost input method, based on costs incurred relative to total estimated costs, over an expected period of approximately 24 months. Because the evaluation services are not outputs of the Company's ordinary activities, related amounts are presented in other income. Evaluation activities began in October 2026, after delivery of the SBX Platform on September 29, 2026. Accordingly, the Company did not recognize any amounts in other income for the evaluation during the three or nine months ended September 30, 2026. The amount allocated to the material right remains in deferred revenue until Roche Sequencing exercises the Option or the Option Term expires. If the Option expires unexercised, the Company will recognize the remaining balance at that time.

On September 29, 2026, the Company recorded $8.0 million receivable from Roche Sequencing, a related party, and the Company received $3.4 million non-cash consideration. As of September 30, 2026, the Company had $24.6 million of related-party deferred revenue related to the material right, and $2.3 million of related-party other liabilities related to the SBX evaluation, of which $1.2 million was classified as current and $1.1 million was classified as noncurrent. Roche Sequencing is a related party because it is an affiliate of Roche Holdings. Roche Holdings and an affiliate held an approximately 17% ownership interest in the Company as of September 30, 2026. As of September 30, 2026, the transaction price allocated to unsatisfied performance obligations under the Roche License and Option Agreement was $35.0 million. The Company expects to recognize the amount allocated to the SBX evaluation over approximately 24 months. The Company will recognize the amount allocated to the material right only if Roche Sequencing exercises the Option or when the Option Term expires. The timing is not currently estimable.

As of September 30, 2026, the transaction price allocated to unsatisfied performance obligations under the Roche License and Option Agreement was $34.9 million, of which $24.6 million relates to the material right and $10.3 million to the SBX evaluation, including $8.0 million for Milestone #2. The Company expects to recognize the amount allocated to the SBX evaluation over approximately 24 months. The Company will recognize the amount allocated to the material right only if Roche Sequencing exercises the Option or when the Option Term expires. The timing is not currently estimable.

Note 8—Debt

Exact Note Purchase Agreement with Exact

In August 2025, the Company entered into a Convertible Promissory Note Purchase Agreement (the "Exact Sciences Note Purchase Agreement") with Exact (now a subsidiary of Abbott), pursuant to which the Company issued the Exact Convertible Note with an aggregate principal amount of $50.0 million. On September 8, 2026, approximately $50.5 million of principal and accrued and unpaid interest (consisting of $50.0 million of principal and $0.5 million of accrued and unpaid interest from July 1, 2026 through September 8, 2026) under the Exact Convertible Note automatically converted into 3,364,814 shares of the Company's common stock at a conversion price of $15.00 per share.

The Company elected the fair value option to account for the Exact Convertible Note before its conversion. The conversion on September 8, 2026, was accounted for as a noncash financing transaction, except for the cash payment made in lieu of issuing a fractional share. The carrying value of the Exact Convertible Note was $41.6 million as of December 31, 2025, and no carrying value remained as of September 30, 2026. Immediately prior to conversion, the Exact Convertible Note was remeasured to its fair value of $53.8 million, on September 8, 2026, compared to a carrying value of $41.7 million as of June 30, 2026. The Company recognized a loss on remeasurement of $11.6 million and $11.7 million for the three and nine months ended September 30, 2026, respectively. These amounts exclude $0.5 million of accrued interest, which was recorded separately in the condensed consolidated statements of operations. Upon conversion, the $53.8 million fair value, inclusive of accrued interest, was reclassified to stockholders' equity, substantially all of which was recorded in additional paid-in capital, with the par value of the common stock issued recorded in common stock.

Promissory Note Agreement with Roche Holdings, a related party

In November 2025, the Company executed the Roche Promissory Note Agreement with Roche Holdings, a related party, for $75.0 million convertible promissory note, bearing an annual interest rate of 5%. The Roche Agreements were evaluated together as a single arrangement for revenue recognition because they were negotiated as a package with a single commercial objective and the consideration in one agreement depended on the price of the other. See Note 7 for the allocation of the $75.0 million of total proceeds. The $60.0 million allocated to the Roche Convertible Note represented its fair value at issuance.

Upon the July 20, 2026 closing of the Business Combination, the outstanding principal of $75.0 million and accrued interest of $2.5 million, or $77.5 million in total, under the Roche Convertible Note automatically converted into 6,460,616 shares of the Company's common stock at a conversion price of $12.00 per share. Interest expense was recognized using the interest method through the conversion date in accordance with ASC 835-30. The conversion was accounted for as a noncash financing transaction, and the carrying value of the Roche Convertible Note at conversion of $68.6 million, consisting of $75.0 million of principal and $2.5 million of accrued interest, net of $8.9 million of unamortized discount and debt issuance costs written off upon conversion, was reclassified to common stock and additional paid-in capital. No gain or loss was recognized on conversion because the Roche Convertible Note converted automatically in accordance with its original terms.

The Company recognized total interest expense of $0.8 million and $7.3 million related to the Roche Convertible Note for the three and nine months ended September 30, 2026, respectively, including coupon interest expense of $0.2 million and $2.1 million, respectively.

Note 9—Convertible Preferred Stock, Common Stock and Warrants

Immediately prior to the closing of the Business Combination, all 212,541,832 issued and outstanding shares of the redeemable convertible preferred stock of Legacy Freenome were converted into 213,907,881 shares of Legacy Freenome's common stock. Each share converted on a one-for-one basis, other than the Series D and Series E redeemable convertible preferred stock, which converted at ratios of 1.00252 and 1.05075 shares of common stock per preferred share, respectively, reflecting the anti-dilution adjustments triggered by the issuance of the Series F redeemable convertible preferred stock. The resulting shares of Legacy Freenome common stock were then converted into 60,513,413 shares of the Company's common stock based on the Exchange Ratio established in the Business Combination. The carrying amount of the redeemable convertible preferred stock of $1.4 billion was reclassified to common stock and additional paid-in capital upon conversion.

Common Stock and Preferred Stock

The Company's certificate of incorporation authorizes the issuance of 1,000,000,000 shares of common stock and 10,000,000 shares of preferred stock, each with a par value of $0.0001 per share. Holders of common stock are entitled to one vote per share. No shares of preferred stock were issued or outstanding as of September 30, 2026.

Warrants

Immediately prior to the closing, warrants to purchase 428,560 shares of Legacy Freenome common stock at $0.01 per share were exercised, resulting in 121,237 shares of the Company's common stock (see Note 10). As of September 30, 2026, a warrant to purchase 14,003 shares of the Company's common stock at an exercise price of $4.85 per share remained outstanding.

Note 10—Recapitalization

On July 20, 2026, PCSC consummated the Business Combination and PIPE Financing (see Note 1), and Legacy Freenome received net proceeds of $295.5 million, after deducting $15.2 million of transaction fees paid at closing. The cash consideration was comprised of $70.3 million in proceeds from issuance of common stock upon the closing of the Business Combination, representing cash released from PCSC's trust account after redemptions, $0.4 million cash held by PCSC at closing, and $240.0 million in proceeds from the PIPE Financing, in which investors purchased 24,000,000 shares of the Company's common stock at a purchase price of $10.00 per share. In connection with the Business Combination, PCSC domesticated from the Cayman Islands to the State of Delaware and changed its name to Freenome, Inc., and through a series of merger transactions Legacy Freenome became a wholly owned subsidiary of the Company. The Company incurred total transaction costs of $25.7 million, consisting of legal, accounting, advisory and other professional services directly related to the Business Combination and PIPE Financing, of which $15.2 million was paid at closing and $10.5 million was incurred directly by Legacy Freenome. All transaction costs were recorded as a reduction of additional paid-in capital in the unaudited condensed consolidated balance sheet. Net cash received in the Business Combination, including cash acquired from PCSC, was approximately $295.5 million. Legacy Freenome was deemed the accounting acquirer in the Business Combination and the Business Combination was accounted for as a reverse recapitalization based on the following predominant factors:

- Legacy Freenome's stockholders have the greatest voting interest in the Company, holding approximately 63% of the Company's common stock outstanding immediately following the closing;
- The Company's board and senior management are primarily composed of individuals associated with Legacy Freenome; and
- Legacy Freenome is the larger entity based on historical operating activity and has the larger employee base at the time of the Business Combination, and its operations comprise the only ongoing operations of the Company.

Accordingly, for accounting purposes, the reverse recapitalization was treated as the equivalent of Legacy Freenome issuing stock for the net assets of PCSC, accompanied by a recapitalization. PCSC had 8,920,769 shares of common stock outstanding prior to the Business Combination, consisting of 6,478,269 public shares remaining after redemptions and 2,442,500 shares held by its sponsor, and issued 24,000,000 shares of the Company's common stock in connection with the PIPE Financing, representing the total of 32,920,769 shares issued by Legacy Freenome in the reverse recapitalization. The net assets of PCSC are stated at historical cost, with no goodwill or other intangible assets recorded. Immediately following the closing, 107,446,814 shares of the Company's common stock were outstanding, consisting of 68,065,429 shares held by former Legacy Freenome equity holders, the 32,920,769 shares described above, and 6,460,616 shares issued upon conversion of the Roche Convertible Note.

Pursuant to the Business Combination Agreement, upon the closing of the Business Combination, (i) each share of redeemable convertible preferred stock of Legacy Freenome (on an as converted to common stock basis; see Note 9) and each share of common stock of Legacy Freenome, whether vested or unvested, was converted into 0.282895 shares of the Company's common stock and (ii) each outstanding option to purchase common stock and each restricted stock unit of Legacy Freenome was converted into an option to purchase, or a restricted stock unit settleable in, shares of the Company's common stock based on the Exchange Ratio, with corresponding adjustments to the exercise price of options. Immediately prior to the closing, outstanding warrants to purchase 428,560 shares of Legacy Freenome common stock at $0.01 per share were exercised, resulting in 121,237 shares of the Company's common stock after giving effect to the Exchange Ratio.

Note 11—Stock-Based Compensation

2026 Equity Incentive Plan

Prior to the Business Combination, the Company maintained the Freenome Holdings, Inc. 2016 Stock Incentive Plan, as amended (the "2016 Plan"). In connection with the closing of the Business Combination on July 20, 2026 (the "Closing"), each outstanding option under the 2016 Plan, whether vested or unvested, was canceled and exchanged for an option under the Freenome, Inc. 2026 Equity Incentive Plan (the "2026 Plan"). The number of shares subject to each replacement option and its exercise price were adjusted based on the Exchange Ratio of 0.282895. Outstanding restricted stock unit ("RSU") awards under the 2016 Plan were canceled and exchanged for RSU awards under the 2026 Plan. The replacement awards generally remain subject to the terms and conditions, including vesting, expiration and forfeiture provisions, applicable to the corresponding awards under the 2016 Plan. No further awards will be granted under the 2016 Plan.

In July 2026, the Company's stockholders approved the 2026 Plan, which became effective immediately prior to the Closing. The 2026 Plan provides for the grant of equity and equity-based awards to the Company's officers, employees, non-employee directors and consultants. A total of 14,773,227 shares of common stock were initially reserved for issuance under the 2026 Plan. Beginning January 1, 2027, the share reserve will automatically increase each January 1 by 5% of the number of shares of common stock outstanding, including shares issuable upon exercise of outstanding pre-funded warrants, as of the immediately preceding December 31,

or a lesser amount determined by the plan administrator. 2.6 million shares of common stock were available for future issuance under the 2026 Plan as of September 30, 2026.

2026 Employee Stock Purchase Plan

In July 2026, the Company's stockholders also approved the Freenome, Inc. 2026 Employee Stock Purchase Plan (the "ESPP"), which became effective immediately prior to the Closing. Under the ESPP, eligible employees may purchase shares of common stock through payroll deductions at 85% of the lower of the fair market value of a share on the first day of the offering period or on the exercise date. A total of 2,462,204 shares were initially reserved for issuance under the ESPP. Beginning January 1, 2027, and continuing through January 1, 2036, the share reserve will automatically increase annually by the lesser of 1% of the outstanding shares as of the immediately preceding December 31, 1,500,000 shares, or a lesser amount determined by the plan administrator. As of September 30, 2026, no shares had been issued under the ESPP, and 2,462,204 shares remain available for future issuance.

Stock Options

The following table summarizes the Company's stock option activity for the nine months ended September 30, 2026:

	Number of Options	Weighted-Average Exercise Price [2]
Outstanding – December 31, 2025[1]	8,349,052	$ 11.28
Forfeited or canceled	(92,816)	11.48
Outstanding – September 30, 2026	8,256,236	$ 11.27
Exercisable – September 30, 2026	7,411,997	$ 11.13

[1] Share counts and per-share values at December 31, 2025 have been retroactively adjusted for the Exchange Ratio established in the Business Combination Agreement. As previously reported, 29,512,900 Options were outstanding at December 31, 2025 with a weighted-average exercise price of $3.19 per share.

[2] The Weighted-Average Exercise Price does not reflect the Repricing discussed below.

As of September 30, 2026, and December 31, 2025, there were 7,411,997, and 6,564,102 vested stock options outstanding, respectively.

Restricted Stock Units

The vesting of RSUs outstanding at the Closing, which were exchanged for RSUs under the 2026 Plan, is conditioned on a time- and service-based requirement and a Liquidity Event Requirement. The Liquidity Event Requirement is satisfied on the earliest of (i) the earlier of six months after the effective date of an initial public offering and March 15 of the following calendar year, and (ii) a change of control. For the Business Combination, the Liquidity Event Requirement will be satisfied on January 20, 2027. Because the Liquidity Event Requirement was not deemed probable until the Business Combination was consummated, no stock-based compensation expense for RSUs was recognized before the Closing. Upon the Closing, the Company recognized cumulative expense of approximately $39.7 million for RSUs for which the service requirement had been satisfied or partially satisfied. As of September 30, 2026, 2,840,776 RSUs had satisfied the service requirement and remained subject to the Liquidity Event Requirement. During the three months ended September 30, 2026, 130,592 RSUs were released, of which 58,672 shares were issued and 71,920 shares were withheld to satisfy employee tax withholding obligations.

The following table summarizes the Company's RSU activity for the nine months ended September 30, 2026:

	Number of RSUs	Weighted-Average Grant Date Fair Value Per Share
Outstanding – December 31, 2025[3]	4,093,826	$ 12.65
Vested / released	(130,592)	14.00
Forfeited or canceled	(83,579)	14.57
Outstanding – September 30, 2026	3,879,655	$ 12.57

(3) Share counts and per-share values at December 31, 2025 have been retroactively adjusted for the exchange ratio of 0.282895 established in the Business Combination Agreement. As previously reported, 14,472,242 RSUs were outstanding at December 31, 2025 with a weighted-average grant date fair value of $3.58 per share.

Stock-Based Compensation Expense

Stock-based compensation expense was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
Stock-based compensation recognized as:	2026	2025	2026	2025
R&D expenses	$ 11,023	$ 1,326	$ 13,599	$ 4,027
G&A expenses	30,921	1,505	33,982	3,818
Total	$ 41,944	$ 2,831	$ 47,581	$ 7,845

As of September 30, 2026, total unrecognized stock-based compensation expense was approximately $21.0 million and consisted of $10.1 million related to stock options that are expected to be recognized over a weighted-average period of approximately 2.0 years, and $10.9 million related to RSUs that are expected to vest over 1.4 years.

Option repricing

On October 24, 2025 (the "Effective Date"), the Board of Directors approved an option repricing (the “Repricing”) of outstanding stock options held by certain current employees, including the Company’s named executive officers (the “Eligible Participants”), which were granted under the 2016 Amended Plan.

On the Effective Date, the exercise price of outstanding stock options (the “Repriced Options”) granted under the 2016 Amended Plan and held by the Eligible Participants, specifically those with an exercise price per share greater than $2.39 ($8.45 post conversion) was repriced to $2.39 per share ($8.45 post conversion) (the “New Exercise Price”). The closing of the Business Combination with PCSC does not qualify as a Corporate Transaction and would not end the required Retention Period (as defined below).

To exercise the Repriced Options at the New Exercise Price, Eligible Participants must remain in service with the Company throughout the Retention Period (as defined therein). The retention period begins on the Effective Date and ends on the one-year anniversary of the Effective Date. If the Retention Period is not satisfied, the Eligible Participant will be required to pay the original exercise price of the corresponding option upon exercise.

The repricing was communicated to employees during January 2026. The estimated incremental stock compensation cost of approximately $1.9 million, calculated using a lattice model, will be recognized over the retention period. The Company recognized approximately $0.5 million and $1.3 million of incremental stock-based compensation expense during the three and nine month periods ended September 30, 2026, respectively.

Note 12—Net Income (Loss) Per Share Attributable to Common Stockholders

The Company calculates basic and diluted net income (loss) per share attributable to common stockholders using the two-class method required for participating securities. Prior to the closing of the Business Combination on July 20, 2026, the Company’s convertible preferred stock was a participating security because holders would receive dividends on a basis consistent with common stockholders. Upon the closing, all preferred stock converted into common stock. Net losses are not allocated to the preferred stock because its holders have no contractual obligation to share in losses. Deemed dividends, if any, are subtracted from net income (loss) to arrive at net income (loss) attributable to common stockholders. All share and per share amounts for periods prior to the Business Combination have been retroactively adjusted for the Exchange Ratio.

Basic net income (loss) per share is calculated by dividing net income (loss) attributable to common stockholders by the weighted-average number of common shares outstanding during the period. Diluted net income (loss) per share also includes potential dilutive common shares, if dilutive. For periods prior to the Business Combination, diluted net income (loss) per share uses the more dilutive of the two-class method or the if-converted method for the preferred stock, and potential common shares are included for all other dilutive instruments.

For the three months ended September 30, 2026, diluted net income per share includes 1,713,545 shares from stock options, warrants and restricted stock units (treasury stock method) and 1,334,258 shares from the Roche Convertible Note (if-converted method, for the period before conversion on July 20, 2026), with net income increased by $0.8 million of interest expense. Restricted stock units for which the service condition has been met but the liquidity event requirement has not been satisfied are contingently issuable and are excluded from basic and diluted net income (loss) per share until the requirement is met. Vested penny warrants, which were exercisable for nominal consideration, are included in basic weighted-average shares. Immediately prior to the closing, warrants to purchase 428,560 shares of Legacy Freenome common stock at $0.01 per share were exercised, resulting in 121,237 shares of the Company's common stock (see Note 10). As of September 30, 2026, a warrant to purchase 14,003 shares of the Company's common stock at an exercise price of $4.85 per share remained outstanding.

The Exact Convertible Note, which converted on September 8, 2026, was excluded from diluted net income per share for the period before conversion because its effect was anti-dilutive. The Company incurred net losses for the three months ended September 30, 2025 and the nine months ended September 30, 2026 and 2025, so potentially dilutive securities were anti-dilutive in those periods and are excluded from diluted net loss per share.

Basic and diluted net income (loss) per share attributable to common stockholders is calculated as follows (in thousands, except share and per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Numerator:				
Net income (loss)	$ 60,110	$ (64,469)	$ (72,478)	$ (181,074)
Add: interest expense on convertible note	752	—	—	—
Net income (loss) – diluted	$ 60,862	$ (64,469)	$ (72,478)	$ (181,074)
Denominator:				
Weighted-average shares of common stock outstanding – basic and diluted	100,174,038	68,016,817	78,885,912	67,998,124
Dilutive effect of stock options, warrants and RSUs	1,713,545	—	—	—
Dilutive effect of Roche convertible note (if-converted)	1,334,258	—	—	—
Weighted-average shares of common stock outstanding – diluted	103,221,841	68,016,817	78,885,912	67,998,124
Net income (loss) per share attributable to common stockholders – basic	$ 0.60	$ (0.95)	$ (0.92)	$ (2.66)
Net income (loss) per share attributable to common stockholders – diluted	$ 0.58	$ (0.95)	$ (0.92)	$ (2.66)

The following outstanding potentially dilutive securities have been excluded from the calculation of diluted net income (loss) per share, as their effect is anti-dilutive:

	Three Months Ended September 30, 2026	Three Months Ended September 30, 2025	Nine Months Ended September 30, 2026	Nine Months Ended September 30, 2025
Options to purchase common stock	3,997,960	6,337,275	8,256,236	6,337,275
Restricted stock units issued and outstanding	3,853,553	4,263,933	3,879,655	4,263,933
Warrants to purchase common stock	—	14,003	14,003	14,003
Convertible notes	2,523,611	—	7,814,384	—
Total	10,375,124	10,615,211	19,964,278	10,615,211

Note 13—Commitments and Contingencies

Legal Contingencies

The Company may be, from time to time, a party to various disputes and claims arising from normal business activities. The Company accrues for loss contingencies when available information indicates that it is probable that a liability has been incurred and the amount of such liability can be reasonably estimated. For cases in which the Company believes that a reasonably possible loss exists, the Company discloses the facts and circumstances of the loss contingency, including an estimable range, if possible. Management believes

that there are currently no claims or actions pending against the Company where the ultimate disposition could have a material adverse effect on the Company's results of operations, financial condition, or cash flows.

Indemnification Agreements

The Company has agreed to indemnify its officers and directors for certain events or occurrences, subject to certain limits, while the officer or director was serving at the Company's request in such capacity. The maximum amount of potential future indemnification liability is unlimited; however, the Company holds directors' and officers' liability insurance which limits the Company's exposure and may enable it to recover a portion of any future amounts paid.

In the normal course of business, the Company also enters into contracts and agreements with service providers and other parties with which it conducts business that contain indemnification provisions pursuant to which the Company has agreed to indemnify the party against certain types of third-party claims. From time to time, the Company may receive indemnification claims under these contracts in the normal course of business. The Company has not experienced any material losses related to these indemnification provisions and has no material claims with respect thereto. The Company does not expect significant claims related to these indemnification provisions and, consequently, concluded that the fair value of any obligations is negligible, and no related accruals have been established. In the event that one or more of these matters were to result in a claim against the Company, an adverse outcome, including a judgment or settlement, may cause a material adverse effect on the Company's future business, operating results, or financial condition.

Purchase Commitments

In the normal course of business, the Company enters into agreements containing noncancellable purchase commitments for goods and services with various parties. As of September 30, 2026, the Company has a noncancellable cloud services agreement and has committed to purchase cloud computing services totaling $119.1 million over the remaining period of the agreement through January 31, 2029. Other noncancellable unconditional purchase commitments having a remaining term over one year were as follows (in thousands):

Year Ending December 31,		
2026 (remainder of year)	$	783
2027		8,250
Total	$	9,033

Note 14— Leases

The Company's lease portfolio consists primarily of operating leases for its current corporate headquarters, laboratory facilities, and warehouse facilities, with lease terms ranging from 1 to 11 years. Certain of the Company's operating leases contain optional renewal periods to extend the lease terms, which are not reasonably assured. The Company's operating leases include various covenants, indemnities, defaults, termination rights, security deposits and other provisions customary for lease transactions of this nature.

The Company's most significant operating lease pertains to an 11-year lease agreement for approximately 335,419 square feet used as its corporate headquarters, office, and laboratory space in two buildings (building I and building III) located in Brisbane, California. The lease will continue for an initial term of 11 years, with options to extend the term for two successive five-year periods after the initial expiration date.

The components of lease costs were as follows (in thousands):

	Nine Months Ended September 30,	
	2026	**2025**
Operating lease cost	$ 18,395	$ 20,784
Variable lease cost	8,165	8,145
Finance lease cost:		
Finance lease amortization	—	137
Interest on finance lease liabilities	—	3
Total lease cost	$ 26,560	$ 29,069

Certain information related to the Company's leases was as follows (in thousands):

	Nine Months Ended September 30,	
	2026	2025
Cash paid for amounts included in the measurement of lease liabilities:		
Operating leases	$ 21,236	$ 23,468
Finance leases	$ —	$ 159

	September 30, 2026	September 30, 2025
Weighted-average remaining lease term (in years):		
Operating leases	8.2	9.2
Finance leases	—	—
Weighted-average discount rate:		
Operating leases	11.3%	11.3%
Finance leases	—%	—%

The following table summarizes the Company's future principal contractual obligations for lease commitments as of September 30, 2026 (in thousands):

Year Ending December 31,	Operating Leases
2026 (remainder of year)	$ 8,016
2027	32,872
2028	33,944
2029	35,053
2030	36,201
Thereafter	165,841
Total undiscounted lease payments	311,927
Less: Imputed interest	(110,268)
Total lease liabilities	201,659
Less: Current portion of lease liabilities	11,765
Non-current lease liabilities	$ 189,894

There is no remaining finance lease obligation as of September 30, 2026.

Note 15—Related Party Transactions

Transactions with Affiliates

The Company considers Roche Holdings, Inc. and its affiliates (the "Roche Group") to be related parties due to the Roche Group's beneficial ownership in the Company, which exceeded 10% of the voting interests in the Company as of September 30, 2026, and December 31, 2025. The Company has entered into certain agreements with the Roche Group for the purchase or use of equipment, consumable products such as reagents and supplies, and services. In addition, the Company has entered into certain material transfer agreements in which the Company transfers certain samples to the Roche Group for research, testing and evaluation. The Company incurred approximately $1.9 million and $0.6 million during the three months ended September 30, 2026 and 2025, respectively, and $3.7 million and $1.3 million during the nine months ended September 30, 2026 and 2025, respectively under these agreements, which are recognized as R&D expenses in the consolidated statements of operations. The Company has entered into a Research Service Agreement with a member of the Roche Group, pursuant to which the Company uses its multiomics platform to perform tests and data analysis on samples provided by the Roche Group. The Company recognized no revenue for the three and nine months ended September 30, 2026, compared with $0.3 million for the corresponding periods in 2025.

In November 2025, the Company entered into the Roche License and Option Agreement with Roche Sequencing and the Roche Promissory Note Agreement with Roche Holdings for which the Company received total proceeds of $75.0 million. On July 20, 2026, in connection with the closing of the Business Combination, the Roche Convertible Note (principal of $75.0 million and accrued paid-in-kind interest of $2.5 million, net of an unamortized discount of $8.9 million) automatically converted into 6,460,616 shares of the Company's common stock, and its carrying amount of $68.6 million was reclassified to stockholders' equity. The $15.0 million of proceeds allocated to the Roche License and Option Agreement was recorded in other long-term liabilities as of December 31, 2025 and was reclassified to deferred revenue upon delivery of the SBX Platform on September 29, 2026. Upon delivery of the SBX Platform, the Company recorded an $8.0 million receivable from Roche Sequencing, a $3.4 million charge to research and development expense for the sample cohort received at no charge, and a $0.6 million contract asset for reagents to be received.

As of September 30, 2026, the Company had deferred revenue related to Roche of $24.6 million, all of which was non-current. In addition, $1.2 million related to the SBX platform evaluation was included in accrued expenses and other current liabilities, and $1.1 million allocated to the SBX evaluation in other long-term liabilities. The Company recorded interest expense related to the Roche Convertible Note of $0.8 million and $7.3 million for the three and nine months ended September 30, 2026, respectively, including coupon interest of $0.2 million and $2.1 million, respectively. See Note 7 for further description of the Roche License and Option Agreement with Roche Sequencing and Note 8 for further description of the Roche Convertible Note.

PIPE Financing

Certain related parties participated in the PIPE Financing, including affiliates of Perceptive Advisors, LLC (an affiliate of the Company's sponsor), which purchased 5,500,000 shares of common stock for aggregate proceeds of $55.0 million, and RA Capital, a holder of more than 10% of the Company's common stock, which purchased 5,255,376 shares of common stock for aggregate proceeds of $52.6 million.

Note 16—Segment and Geographic Information

The Company operates as one operating and reportable segment focused on the development of an early cancer detection platform and the commercialization of related products through collaboration and licensing arrangements. The Company's chief operating decision maker (the "CODM") is its Chief Executive Officer, who uses consolidated net income (loss), as reported in the condensed consolidated statements of operations, as the key measure of segment profit and loss to allocate resources and assess performance. The CODM does not evaluate operating segment performance using asset information.

The CODM uses consolidated net income (loss) to evaluate the Company's expenditures from the segment and monitor budget-to-actual results. The CODM also considers budget-to-actual variances and available cash when making decisions about the allocation of resources across the organization. Significant segment expenses within consolidated net income (loss) are cost of services, research and development, general and administrative, and other segment items are interest and investment income, net, interest expense, convertible note remeasurement loss, and other income (expense), net, which are separately presented on the Company's condensed consolidated statements of operations.

The following table presents information about reported segment revenue by geographic location (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
United States	$ 182,547	$ 319	$ 187,702	$ 319
International	942	716	2,283	2,211
Total revenue	$ 183,489	$ 1,035	$ 189,985	$ 2,530

During the three and nine months ended September 30, 2026, $182.5 million and $187.7 million of the Company's consolidated revenue is attributable to one customer. As of September 30, 2026 and December 31, 2025, all of the Company's long-lived assets and right-of-use assets are located in the United States.

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

This discussion and analysis of Freenome, Inc.'s ("Freenome," "we," "us" and "our") financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements as of September 30, 2026 and for the three and nine months ended September 30, 2026 and 2025, and the related notes included elsewhere in this Quarterly Report on Form 10-Q. It should also be read in conjunction with our audited consolidated financial statements as of and for the year ended December 31, 2025, and the related notes, included in the proxy statement/prospectus filed with the SEC on June 17, 2026, and the other information contained in this Quarterly Report on Form 10-Q.

Forward-Looking Statements

The following discussion of our financial condition and results of operations contains forward-looking statements within the meaning of Section 27A of the Securities Act, and Section 21E of the Exchange Act, and is intended to be covered by the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. These statements include, among others, statements regarding our strategy, plans, expectations, financial condition, operations, product development and commercialization, clinical and regulatory progress, reimbursement, collaborations and licensing arrangements, and future performance. Forward-looking statements are based on current assumptions and expectations, are not guarantees of future results, and are subject to risks and uncertainties that could cause actual results to differ materially. For a discussion of factors that could cause actual results to differ materially, see "Risk Factors" in Part II, Item 1A of this Quarterly Report on Form 10-Q and in our other SEC filings. Forward-looking statements speak only as of the date made. Except as required by law, we undertake no obligation to update them.

Overview

We are an early cancer detection company developing blood-based screening tests that leverage artificial intelligence and machine learning ("AI/ML") to advance multi-cancer and, ultimately, multi-disease detection. We founded Freenome to develop an automated, scalable multiomics discovery platform that integrates biological insights with AI/ML to identify early signs of disease. Our platform is designed to evaluate and integrate multiple analytes, including DNA, RNA and proteins, using differentiated laboratory automation capabilities and clinical studies to develop tests intended to address the biological heterogeneity of cancer.

In July 2026, the U.S. Food and Drug Administration ("FDA") approved SimpleScreen™ CRC, our blood-based colorectal cancer ("CRC") screening test for adults 45 years of age and older at average risk. In August 2026, the FDA granted Breakthrough Device Designation to SimpleScreen Lung, our blood-based lung cancer screening test intended for adults ages 50 to 80 with a smoking history of at least 20 pack-years who are not participating in guideline-recommended lung cancer screening. Breakthrough Device Designation provides opportunities for interaction with the FDA and prioritized review of future regulatory submissions but does not constitute FDA marketing authorization.

On September 9, 2026, our clinical laboratory received accreditation from the College of American Pathologists ("CAP"). On September 30, 2026, Abbott Cancer Diagnostics commercially launched SimpleScreen CRC in the United States. On October 20, 2026, we launched SimpleScreen Lung as a laboratory-developed test ("LDT"). SimpleScreen Lung was clinically validated in a case-control study among adults meeting American Cancer Society ("ACS") lung cancer screening eligibility criteria. In an independent cohort of 172 lung cancer cases and 436 controls, the test achieved 85% sensitivity at 50% specificity and a 99.8% negative predictive value ("NPV"), meaning approximately two of every 1,000 people with a negative result would be expected to have lung cancer. Stage-specific sensitivity was 82% for stage I, 75% for stage II, 91% for stage III, and 94% for stage IV. SimpleScreen Lung has not been reviewed, cleared or approved by the FDA. The commercial availability of SimpleScreen Lung as an LDT does not constitute FDA clearance or approval. We plan to seek FDA approval for SimpleScreen Lung.

With the launch of SimpleScreen Lung, eligible patients may have access to screening for both lung cancer and CRC through a single blood draw, using two independently validated tests with indication-specific intended uses, as part of our Personalized Cancer Detection approach.

Prior to the approval of SimpleScreen CRC, we had no products approved for commercial sale in the United States and had not generated material revenue. We continue to incur significant research and development and other expenses. Our ability to generate product revenue sufficient to achieve profitability, if ever, will depend on the successful commercialization of SimpleScreen CRC and SimpleScreen Lung and the development of future tests.

The Business Combination

On December 5, 2025, Freenome Holdings, Inc. ("Legacy Freenome") entered into a Business Combination Agreement with Perceptive Capital Solutions Corp. ("PCSC"), a publicly traded special purpose acquisition company, and certain of its subsidiaries. On July 20, 2026, we completed the transactions contemplated by the Business Combination Agreement, as amended on July 20, 2026 (the "Business Combination" or the "Closing").

In connection with the Business Combination, PCSC domesticated from the Cayman Islands to the State of Delaware, changed its name to Freenome, Inc. ("New Freenome"), and adopted a new certificate of incorporation and bylaws. Through a series of merger transactions, Legacy Freenome became a wholly owned subsidiary of New Freenome.

Upon the Closing, the outstanding shares of our common stock and preferred stock were converted into an aggregate of 68,065,429 shares of New Freenome common stock based on the Exchange Ratio. In addition, outstanding options to purchase shares of our common stock were converted into options to purchase an aggregate of 8,272,601 shares of New Freenome common stock, with the number of underlying shares and exercise prices adjusted proportionally based on the Exchange Ratio. Our outstanding restricted stock units were converted into restricted stock units covering an aggregate of 4,034,512 shares of New Freenome common stock.

We also received aggregate gross proceeds of approximately $310.7 million, including $240.0 million of gross proceeds from a private investment in public equity ("PIPE") financing that closed concurrently with the Business Combination. After giving effect to transaction costs, we received net proceeds of approximately $295.5 million. Deferred offering costs previously recorded on the balance sheet were reclassified as a reduction of the proceeds from the de-SPAC transaction upon the Closing.

In connection with the Closing on July 20, 2026, the outstanding principal and accrued interest under the convertible promissory note issued to Roche Holdings, Inc. automatically converted into approximately 6,460,616 shares of New Freenome common stock at a conversion price of $12.00 per share.

On September 8, 2026, approximately $50.5 million of principal and accrued and unpaid interest under the convertible promissory note originally issued to Exact Sciences Corporation ("Exact"), which became a wholly owned subsidiary of Abbott Laboratories on March 23, 2026, automatically converted into approximately 3,364,814 shares of New Freenome common stock at a conversion price of $15.00 per share.

The Business Combination was accounted for as a reverse recapitalization, with the Company determined to be the accounting acquirer and PCSC treated as the acquired company for financial reporting purposes. Accordingly, the historical financial statements of the Company became the historical financial statements of New Freenome upon the Closing.

As a result of the Business Combination, we became the successor to an SEC-registered and Nasdaq-listed company. We have incurred and expect to continue to incur recurring expenses associated with operating as a public company, including directors' and officers' liability insurance, director compensation, and increased accounting, legal, compliance, administrative, personnel, audit, and other professional service costs.

Key Trends, Opportunities and Uncertainties

Since our inception, we have incurred significant operating losses and negative cash flows from our operations. Our primary uses of cash to date have been conducting R&D, acquiring Oncimmune in 2023, raising capital, building infrastructure, developing intellectual property, hiring personnel and providing general and administrative support for these operations. To date, we have funded our operations primarily through private placements of our convertible preferred stock, convertible notes and funds received pursuant to our license agreements. As of September 30, 2026, we had raised aggregate gross proceeds of approximately $1.6 billion from these financings, and had cash, cash equivalents and short-term marketable securities of $430.0 million.

We have incurred operating losses in each year since our inception. Our net losses were $72.5 million for the nine months ended September 30, 2026. As of September 30, 2026, we had an accumulated deficit of $1.4 billion. We expect our expenses and operating losses will increase as we:

- accelerate the development of our AI/ML-driven multiomics platform that seeks to identify the early biological signals of disease;
- expand our commercial and data infrastructure to support future launch of multiple blood-based cancer detection tests;
- further advance our R&D programs;
- seek to identify additional indications;
- expand commercial and operational personnel;
- maintain, expand, enforce, defend and protect our intellectual property portfolio and provide reimbursement of third-party expenses related to our patent portfolio; and
- seek regulatory approvals for any future product candidates for which we successfully complete clinical trials.

Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of regulatory approvals and R&D activities.

As of the date of this Quarterly Report, we do not believe that inflation has had a material effect on our business, financial condition, or results of operations. Given our early stage of operations, if our costs become subject to significant inflationary pressures, we may not fully offset such higher costs. Our inability or failure to do so could harm our business, financial condition, and results of operations.

Based on our current operating plan, we believe the cash, cash equivalents and short-term marketable securities available as of September 30, 2026, including the net proceeds from the July 20, 2026 Business Combination and the $100.0 million regulatory milestone payment received from Exact, now a wholly owned subsidiary of Abbott Laboratories, on September 22, 2026, will be sufficient to fund our operations into 2028. This estimate is based on assumptions that may prove to be incorrect, and we could use our capital resources sooner than expected. Accordingly, we may need to raise additional capital in the future through equity offerings, debt financings, collaborations, licensing arrangements or other strategic transactions. If additional funding is not available on acceptable terms, or at all, it could adversely affect our business, financial condition and ability to execute our long-term operating plans.

Abbott Laboratories, which acquired Exact, exclusively commercializes SimpleScreen CRC in the United States, and Freenome manufactures the test. We may incur manufacturing and other costs to fulfill our obligations under the commercial arrangement, and we continue to incur significant research and development and other operating expenses to advance our other products and product candidates. We receive milestone payments and expect to receive royalties under the arrangement. We expect to fund our cash needs through cash on hand, cash generated from operations, if any, and, as needed, equity offerings, debt financings or other capital sources, including collaborations, licenses, royalty financings and similar arrangements. We may be unable to raise additional funds or enter into such arrangements when needed on favorable terms or at all. If we are unable to do so, we may need to delay, limit, reduce or terminate product development or future commercialization efforts, or grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves. See “Liquidity and Capital Resources”.

Exact Sciences License Agreement

In August 2025, we entered into an exclusive license agreement with Exact for U.S. rights to our blood-based colorectal cancer screening test. Exact became a wholly owned subsidiary of Abbott Laboratories on March 23, 2026. The agreement provided for an upfront payment of $75.0 million, received in November 2025, as partial consideration for the rights and licenses granted. It also provides for up to $700.0 million in development milestone payments tied to specified regulatory and screening-guideline milestones, as well as royalties on product sales based on profitability. We earned a $100.0 million milestone upon FDA approval of SimpleScreen CRC in July 2026 and received payment on September 22, 2026. Exact committed to contribute $20.0 million annually for three years toward development costs under the agreed development plan. During the nine months ended September 30, 2026, we received a payment of $20.0 million from Exact, for research and development services performed during that period.

In August 2025, we entered into a Convertible Promissory Note Purchase Agreement with Exact. Under the agreement, we issued Exact a senior unsecured convertible promissory note with an aggregate principal amount of $50.0 million. The note accrues interest at 5% per annum and matures in August 2030. On September 8, 2026, approximately $50.5 million of principal and accrued interest automatically converted into 3,364,814 shares of Freenome, Inc. common stock at a conversion price of $15.00 per share.

Roche License Agreement

In November 2025, we entered into an exclusive license and option agreement with Roche Sequencing Solutions, Inc. (“Roche Sequencing”). The agreement grants Roche Sequencing (i) an exclusive option to obtain an exclusive, royalty-bearing, sublicensable (subject to certain restrictions) license under certain of our intellectual property rights to exploit kitted assays for cancer screening, including colorectal and lung cancer, outside the United States, and (ii) a preferred partner right to negotiate a definitive agreement to offer centralized testing services for cancer screening outside the United States. The agreement also provides for our evaluation of Roche’s SBX sequencing platform (the “SBX Evaluation”) and related research and development milestones.

We may receive up to $100.0 million in milestone payments, as well as royalties on non-U.S. test sales of Licensed Products ranging from the low single digits to the mid-teens, depending on sales. The agreement also provides for up to $24.0 million in aggregate SBX research and development milestone payments. On September 29, 2026, Roche Sequencing delivered the SBX instrument platform to us, triggering an $8.0 million milestone payment. We recorded an $8.0 million receivable as of September 30, 2026.

In November 2025, we also issued to Roche Holdings, Inc. (“Roche Holdings”) a convertible promissory note with an aggregate principal amount of $75.0 million. The convertible promissory note bore interest at 5% per annum and had a maturity date in May 2027. In connection with the Closing on July 20, 2026, the outstanding principal and accrued interest under the note automatically converted into approximately 6,460,616 shares of New Freenome common stock at a conversion price of $12.00 per share.

Components of Results of Operations

Revenue

We recognize license and collaboration revenue in the United States under our exclusive license agreement with Exact, pursuant to which we granted exclusive commercialization rights, as well as development, data, and manufacturing and other licenses.

We also generate revenue from the sale and distribution of EarlyCDT Lung test kits in the United Kingdom and other international markets, royalties on EarlyCDT Lung tests performed, and the sale of EarlyCDT Lung test plates through our U.K.-based subsidiary, Freenome Ltd.

In addition, we generate revenue from diagnostic and research services performed using our proprietary multiomics platform under a Research Services Agreement with a related party.

Following FDA approval of SimpleScreen CRC in July 2026, the $100.0 million milestone under our agreement with Exact was earned and included in the transaction price. Exact paid the milestone on September 22, 2026. Based on the updated transaction price, we recognized approximately $182.5 million in revenue under the agreement during the three months ended September 30, 2026. This included $22.5 million cumulative catch-up adjustment to revenue recognized in the fourth quarter of 2025 and the six months ended June 30, 2026, and $2.5 million related to development services. For the nine months ended September 30, 2026, we collected $120.0 million in cash under the agreement and recognized $187.7 million in revenue. As of September 30, 2026, we had $11.4 million of contract assets under the agreement, which we expect to bill in future periods.

Operating Expenses

Cost of services

Cost of services reflects the aggregate costs incurred in delivering our products and services and is composed of material and service costs including personnel costs, cost of consumables, kits, contract maintenance, labor, and freight associated with the service and other revenue. Our cost of services will increase with commercialization of our products.

Research and Development Expenses

Research and Development (“R&D”) has been, and will continue to be, central to our business model. Our R&D expenses to date have been primarily attributable to the development of our next-generation blood tests for early cancer detection, development of our multiomics platform, and clinical validation of our early colorectal cancer detection test. Our R&D expenses primarily include salaries and benefits, stock-based compensation expenses, direct research and development expenses (testing cost, pre-clinical and clinical trial costs including external R&D expenses incurred under arrangements with third parties), materials, laboratory supplies and equipment, information technology (including cloud computing and data storage, equipment and computer hardware costs, and software related expenses), facility costs (including rent, depreciation and amortization, repairs and maintenance and other facility related expenses), consulting, contractor costs, along with other expenses.

Payments, including non-refundable advance payments, made prior to the receipt of goods or services to be used in R&D activities are deferred and recognized as an expense in the period in which the related goods are received or services are rendered. Costs to develop our technology capabilities are recorded as R&D expenses unless they meet the criteria to be capitalized as internal-use software costs.

Prior to obtaining premarket regulatory approval for our diagnostic tests, we expensed pre-launch inventory costs as R&D expenses unless future economic benefits were considered probable. Accordingly, materials, equipment, and validation costs associated with our diagnostic workflow process that did not have an alternative future use were recognized as R&D expense.

In June 2026, in anticipation of FDA approval of our colorectal cancer screening test, we began capitalizing qualifying inventory costs associated with commercial production as we determined that future economic benefits associated with such costs were expected to be realized. As a result, we capitalized approximately $1.9 million of qualifying raw material costs as inventory. Costs incurred that do not qualify for capitalization, including costs for which no future economic benefit is expected, continue to be recognized as research and development expense.

We accrue and expense nonclinical study and clinical trial activities performed by third parties based on the actual work completed in accordance with agreements established with our service providers.

We have not historically tracked or recorded R&D expenses on a program-by-program basis and, therefore, have not reported program costs. We do not allocate indirect costs to specific product development programs because these costs support multiple programs and our technology platform and, as such, are not separately classified.

We expect our R&D expenses to continue to increase as we advance our technology platform, support additional product development activities, and conduct future clinical studies.

The timing and costs of our R&D activities remain uncertain and may vary significantly due to the inherently unpredictable nature of product development and clinical research. We expect to continue evaluating our development priorities and allocating resources among our programs based on nonclinical and clinical results, regulatory developments, and our ongoing assessment of each program's commercial potential.

Our future development costs may vary significantly based on various factors such as timely and successful completion of nonclinical studies and ongoing and future clinical trials, positive results from our current and future clinical trials, receipt of marketing approvals from applicable regulatory authorities, establishment and maintenance of arrangements with third parties, intellectual property updates and continued acceptable safety, tolerability and efficacy profile of any current and future product candidates that we may develop following approval.

Stock-based compensation expense included in R&D was $11.0 million and $13.6 million for the three and nine months ended September 30, 2026, respectively. Of the $11.0 million recognized for the three months ended September 30, 2026, $9.9 million related to converted RSUs for which the service conditions had been satisfied as of September 30, 2026. Incremental stock-based compensation expense in research and development related to the October 2025 option repricing was $0.2 million and $0.6 million for the three and nine months ended September 30, 2026, respectively.

General and Administrative Expenses

Our general and administrative (“G&A”) expenses primarily consist of costs for our executive, accounting and finance, legal, human resources, marketing, and other administrative support functions. These expenses consist principally of personnel costs, including salaries, bonuses, fringe benefits, stock-based compensation expenses, and travel expenses, as well as professional services fees such as consulting, audit, tax, and legal fees, and general corporate costs and allocated overhead expenses.

We expect our general and administrative expenses to increase in future periods as we support the growth of our business, commercialize SimpleScreen CRC, expand our infrastructure and pursue commercialization of additional diagnostic test candidates, if approved. As a public company, we also expect to continue incurring expenses for accounting, audit, legal, regulatory and tax services; Nasdaq and SEC compliance; directors’ and officers’ insurance; investor relations; and other public-company requirements.

Stock-based compensation expense included in G&A expenses was $30.9 million and $34.0 million for the three and nine months ended September 30, 2026, respectively. Of the $30.9 million recognized for the three-month period, $29.8 million related to converted RSUs for which the service conditions had been satisfied as of September 30, 2026. The October 2025 option repricing resulted in incremental stock-based compensation expense included in general and administrative expenses of $0.3 million and $0.7 million for the three and nine months ended September 30, 2026, respectively.

Other Income (Expense), Net

Other income (expense), net, consists of interest and investment income, interest expense on our convertible notes, and losses from the fair value remeasurement of the Exact Convertible Note. For the three and nine months ended September 30, 2026, the remeasurement losses were $11.6 million and $11.7 million, respectively, and were recognized before the note converted on September 8, 2026.

Comparison of the Three and Nine Months Ended September 30, 2026 and 2025

The following table summarizes the results of our operations for the periods indicated (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Revenue:				
License and collaboration revenue	$ 182,547	$ —	$ 187,702	$ —
Service and other revenue	942	1,035	2,283	2,530
Total revenue	183,489	1,035	189,985	2,530
Operating costs and expenses:				
Cost of services	$ 478	611	1,415	1,494
Research and development	68,417	50,627	174,804	145,486
General and administrative	44,628	15,055	71,252	41,070
Total operating costs and expenses	113,523	66,293	247,471	188,050
Income (loss) from operations	69,966	(65,258)	(57,486)	(185,520)
Other income (expense), net:				
Interest and investment income	$ 2,969	1,420	5,698	5,137
Interest expense	(1,188)	(644)	(8,951)	(646)
Convertible note remeasurement loss	(11,631)	—	(11,731)	—
Other income (expense), net	(6)	13	(8)	(45)
Net income (loss)	$ 60,110	$ (64,469)	$ (72,478)	$ (181,074)

Revenue

The following table summarizes our revenues for the following periods (in thousands):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2026	2025	Change	2026	2025	Change
Revenue:						
License and collaboration revenue	$ 182,547	$ —	$ 182,547	$ 187,702	$ —	$ 187,702
Service and other revenue	942	1,035	(93)	2,283	2,530	(247)
Total revenue	$ 183,489	$ 1,035	$ 182,454	$ 189,985	$ 2,530	$ 187,455

License and collaboration revenue was $182.5 million for the three months ended September 30, 2026, compared with no revenue for the same period in 2025. The increase was primarily driven by $180.0 million of revenue recognized under our collaboration agreement with Exact following FDA approval of SimpleScreen CRC in July 2026. The approval triggered the effectiveness of the exclusive commercialization license and transfer of control of the license to Exact, resolving the constraint on the $100.0 million FDA approval milestone. The milestone was included in the transaction price and allocated to the performance obligations under the Exact License Agreement using the relative stand-alone selling price methodology applied at contract inception. This resulted in $157.5 million of revenue related to the exclusive commercialization license and a $22.5 million cumulative catch-up adjustment related to intellectual property licenses and development cost reimbursements. The remaining $2.5 million of revenue related to research and development services performed during the quarter. Revenue recognized upon FDA approval relates to a discrete event; future revenue under the agreement will depend on the achievement of additional development and regulatory milestones and reimbursement of development costs. See Note 6 to our condensed consolidated financial statements for additional details.

Service and other revenue decreased by $0.1 million to $0.9 million for the three months ended September 30, 2026, from $1.0 million for the same period in 2025. The decrease was primarily due to diagnostic and research services performed under a research and service agreement with Roche, which generated $0.3 million of revenue in the three months ended September 30, 2025 and none in 2026. Revenue for the three months ended September 30, 2026 included $0.5 million of royalties on EarlyCDT Lung tests performed,

$0.3 million from the sale and distribution of EarlyCDT Lung test kits in the United Kingdom and other international markets, and $0.1 million from the sale of EarlyCDT Lung test plates.

License and collaboration revenue was $187.7 million for the nine months ended September 30, 2026, compared with no revenue for the same period in 2025. The increase was primarily driven by $180.0 million of revenue recognized under our collaboration agreement with Exact following FDA approval of SimpleScreen CRC in July 2026. The approval triggered the effectiveness of the exclusive commercialization license and transfer of control of the license to Exact, resolving the constraint on the $100.0 million FDA approval milestone. The milestone was included in the transaction price and allocated to the performance obligations under the Exact Sciences License Agreement using the relative stand-alone selling price methodology applied at contract inception. This resulted in $157.5 million of revenue related to the exclusive commercialization license and a $22.5 million cumulative catch-up adjustment related to intellectual property licenses and development cost reimbursements. The remaining $7.7 million of revenue related to research and development services performed under the agreement, of which $2.5 million was recognized in the third quarter and $5.2 million in the first half of 2026. See Note 6 to our condensed consolidated financial statements for additional details.

Service and other revenue decreased by $0.2 million to $2.3 million for the nine months ended September 30, 2026, from $2.5 million for the same period in 2025. The decrease was primarily due to diagnostic and research services performed under a research and service agreement with Roche Sequencing, which generated $0.3 million of revenue in the nine months ended September 30, 2025 and none in 2026. Revenue for the nine months ended September 30, 2026 included $1.3 million of royalties on EarlyCDT Lung tests performed, $0.8 million from the sale and distribution of EarlyCDT Lung test kits in the United Kingdom and other international markets, and $0.2 million from the sale of EarlyCDT Lung test plates.

Cost of services

The following table summarizes our cost of services for the following periods (in thousands):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2026	2025	Change	2026	2025	Change
Cost of services	$ 478	$ 611	$ (133)	$ 1,415	$ 1,494	$ (79)

The decrease in cost of services for the three and nine months ended September 30, 2026, compared with the corresponding periods in 2025, was not material. As we expand commercial activities, we expect cost of services to increase as we incur and recognize costs associated with commercial products and testing.

Research and Development Expenses

The following table summarizes our research and development expenses for the following periods (in thousands):

	Three Months Ended September 30,		Change	Change
	2026	2025	$	%
Salaries and benefits	$ 18,147	$ 18,073	$ 74	— %
Facility, depreciation and amortization	18,293	15,591	2,702	17 %
Materials, laboratory supplies and equipment	9,715	9,232	483	5 %
Information technology	4,216	2,687	1,529	57 %
Direct research and development costs	5,595	2,587	3,008	116 %
Stock-based compensation	11,023	1,326	9,697	731 %
Consulting and contractor	1,151	878	273	31 %
Other	277	253	24	9 %
Total	$ 68,417	$ 50,627	$ 17,790	35 %

Research and development expenses increased by $17.8 million, from $50.6 million for the three months ended September 30, 2025, to $68.4 million for the three months ended September 30, 2026.

The increase was primarily attributable to:

- $9.8 million increase in personnel-related expenses, including salaries, benefits, and stock-based compensation, primarily due to $9.9 million of stock-based compensation expense related to converted RSUs for which the service conditions had been satisfied as of September 30, 2026. This increase was partially offset by decreases in other personnel-related expenses;

- $3.0 million increase in direct research and development costs, primarily due to $3.4 million of expense for free sample cohorts received from Roche, partially offset by decreases in other individually immaterial costs.

- $2.7 million increase in facilities, depreciation, and amortization expenses, primarily due to higher amortization of leasehold improvements associated with our headquarters and laboratory facilities. This increase was partially offset by a reduction in other facilities-related costs;

- $1.5 million increase in information technology-related expenses, including software, cloud-computing, and data-storage costs;

- $0.5 million increase in materials, laboratory supplies, and equipment expenses, primarily due to increased raw material purchases following the commencement of Early Access Program ("EAP") testing in early 2026 to operationalize the end-to-end commercial workflow for the CRC test, as well as increased spending on development projects; and

- $0.3 million increase in consulting and contractor expenses and other expenses.

The following table summarizes our research and development expenses for the following periods (in thousands):

	Nine Months Ended September 30,		Change	Change
	2026	2025	$	%
Salaries and benefits	$ 54,763	$ 53,497	$ 1,266	2 %
Facility, depreciation and amortization	57,117	47,036	10,081	21 %
Materials, laboratory supplies and equipment	25,433	18,909	6,524	35 %
Information technology	10,125	8,655	1,470	17 %
Direct research and development costs	9,708	9,298	410	4 %
Stock-based compensation	13,599	4,027	9,572	238 %
Consulting and contractor	3,206	3,130	76	2 %
Other	853	934	(81)	(9)%
Total	$ 174,804	$ 145,486	$ 29,318	20 %

Research and development expenses increased by $29.3 million, from $145.5 million for the nine months ended September 30, 2025, to $174.8 million for the nine months ended September 30, 2026.

The increase was primarily attributable to:

- $10.8 million increase in personnel-related expenses, including salaries, benefits, and stock-based compensation, primarily due to $9.9 million of stock-based compensation expense related to converted restricted stock units ("RSUs") for which the service conditions had been satisfied as of September 30, 2026. This increase was partially offset by decreases in other personnel-related expenses;

- $10.1 million increase in facilities, depreciation, and amortization expenses, primarily due to higher amortization of leasehold improvements associated with our headquarters and laboratory facilities. This increase was partially offset by a reduction in other facilities-related costs;

- $6.5 million increase in materials, laboratory supplies, and equipment expenses, primarily due to increased raw material purchases following the commencement of EAP testing in early 2026 to operationalize the end-to-end commercial workflow for the CRC test, as well as increased spending on development projects;

- $1.5 million increase in information technology-related expenses, including software, cloud-computing, and data-storage costs; and

- $0.4 million increase in direct research and development costs, primarily due to $3.4 million of expense for free sample cohorts received from Roche, partially offset by lower clinical trial costs.

The increase was partially offset by:

- $0.1 million decrease in other expenses.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the following periods (in thousands):

	Three Months Ended September 30,		Change	Change
	2026	2025	$	%
Salaries and benefits	$ 7,038	$ 6,400	$ 638	10 %
Consulting and contractor	4,025	5,169	(1,144)	(22)%
Stock-based compensation	30,921	1,505	29,416	1,955 %
Information technology	1,538	1,144	394	34 %
Facility, depreciation and amortization	431	401	30	7 %
Other	675	436	239	55 %
Total	$ 44,628	$ 15,055	$ 29,573	196 %

G&A expenses increased by $29.6 million, from $15.1 million for the three months ended September 30, 2025, to $44.6 million for the three months ended September 30, 2026.

The increase in G&A expenses was primarily attributable to:

- $30.1 million increase in personnel-related expenses, including salaries, benefits, and stock-based compensation, primarily due to $29.8 million of stock-based compensation expense related to converted RSUs for which the service conditions had been satisfied as of September 30, 2026;
- $0.4 million increase in information technology-related expenses; and
- $0.2 million increase in other expenses.

The increase was partially offset by:

- $1.1 million decrease in consulting and contractor expenses.

The following table summarizes our general and administrative expenses for the following periods (in thousands):

	Nine Months Ended September 30,		Change	Change
	2026	2025	$	%
Salaries and benefits	$ 19,649	$ 19,103	$ 546	3 %
Consulting and contractor	9,950	12,112	(2,162)	(18)%
Stock-based compensation	33,982	3,818	30,164	790 %
Information technology	4,406	3,280	1,126	34 %
Facility, depreciation and amortization	1,743	1,607	136	8 %
Other	1,522	1,150	372	32 %
Total	$ 71,252	$ 41,070	$ 30,182	73 %

G&A expenses increased by $30.2 million, from $41.1 million for the nine months ended September 30, 2025, to $71.3 million for the nine months ended September 30, 2026.

The increase in G&A expenses was primarily attributable to:

- $30.7 million increase in personnel-related expenses, including salaries, benefits, and stock-based compensation, primarily due to $29.8 million of stock-based compensation expense related to converted RSUs for which the service conditions had been satisfied as of September 30, 2026;
- $1.1 million increase in information technology-related expenses;
- $0.4 million increase in other expenses; and

- $0.1 million increase in facilities, depreciation, and amortization expenses, primarily due to higher amortization of leasehold improvements associated with our headquarters and laboratory facilities, partially offset by a reduction in other facilities-related costs.

The increase was partially offset by:

- $2.2 million decrease in consulting and contractor expenses.

Other income (expense), net

The following table summarizes our other income (expense), net, for the following periods (in thousands):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2026	2025	Change	2026	2025	Change
Other income (expense), net:						
Interest and investment income	$ 2,969	$ 1,420	$ 1,549	$ 5,698	$ 5,137	$ 561
Interest expense	(1,188)	(644)	(544)	(8,951)	(646)	(8,305)
Convertible note remeasurement loss	(11,631)	—	(11,631)	(11,731)	—	(11,731)
Other income (expense), net	(6)	13	(19)	(8)	(45)	37
Total other income (expense), net	$ (9,856)	$ 789	$ (10,645)	$ (14,992)	$ 4,446	$ (19,438)

Interest and Investment Income, Net

Interest and investment income, net, increased by $1.5 million, from $1.4 million for the three months ended September 30, 2025, to $3.0 million for the three months ended September 30, 2026. Interest and investment income, net, increased by $0.6 million, from $5.1 million for the nine months ended September 30, 2025, to $5.7 million for the nine months ended September 30, 2026. The increases were primarily attributable to higher interest income resulting from increased balances of cash, cash equivalents, and marketable securities related to proceeds from the Business Combination and PIPE Financing.

Interest expense

Interest expense increased by $0.5 million to $1.2 million for the three months ended September 30, 2026, and by $8.3 million to $9.0 million for the nine months ended September 30, 2026, compared with $0.6 million in each prior-year period. The nine-month increase was primarily due to $7.7 million of non-cash interest expense and amortization of debt issuance costs. Interest expense on the Roche Convertible Note, which converted at the July 20, 2026 closing, was $0.8 million for the three months and $7.3 million for the nine months, including $2.1 million of coupon interest. Interest expense also included interest accrued on the Exact convertible note before its September 8, 2026 conversion. Neither note was outstanding at September 30, 2026.

Loss on remeasurement of convertible note

We recorded a non-cash loss on remeasurement of the convertible note of $11.6 million and $11.7 million for the three and nine months ended September 30, 2026 related to change in fair value of the Exact convertible note before its conversion on September 8, 2026.

Cash Flows

Comparison of the Nine Months Ended September 30, 2026 and 2025

The following table summarizes our cash flows during the periods indicated (in thousands):

	Nine Months Ended September 30,		Change
	2026	2025	$
Net cash flows used in operating activities	$ (58,696)	$ (141,682)	$ 82,98
Net cash flows (used in) provided by investing activities	(124,521)	107,041	(231,56
Net cash flows provided by financing activities	285,499	41,537	243,96

Operating Activities

For the nine months ended September 30, 2026, net cash used in operating activities was $58.7 million, primarily attributable to our net loss of $72.5 million and $70.7 million of net cash used by changes in operating assets and liabilities, partially offset by net non-cash adjustments of $84.5 million. Non-cash adjustments primarily included stock-based compensation expense of $47.6 million, depreciation and amortization of $18.3 million, a loss on remeasurement of the convertible note of $11.7 million, non-cash interest expense and amortization of debt issuance costs of $7.7 million, and non-cash lease expense of $1.9 million, partially offset by net accretion and amortization of investments in marketable securities of $2.7 million. The $70.7 million of net cash used by changes in operating assets and liabilities primarily reflected a decrease of $31.7 million in deferred revenue, a decrease of $13.4 million in other long-term liabilities, an increase of $11.8 million in prepaid expenses and other current assets, an increase of $7.5 million in accounts receivable (including an $8.0 million receivable for the SBX platform delivery milestone from Roche), a decrease of $7.5 million in operating lease liabilities, and an increase of $1.9 million in inventory, partially offset by an increase of $4.0 million in accounts payable.

For the nine months ended September 30, 2025, net cash used in operating activities was $141.7 million, primarily attributable to our net loss of $181.1 million, partially offset by non-cash charges of $26.3 million and $13.1 million of net cash provided by changes in operating assets and liabilities. Non-cash charges primarily included depreciation and amortization of $18.1 million, stock-based compensation expense of $7.8 million, and non-cash lease expense of $3.4 million, partially offset by net accretion and amortization of investments in marketable securities of $3.1 million. The $13.1 million of net cash provided by changes in operating assets and liabilities primarily reflected increases of $8.4 million in deferred revenue, $4.9 million in operating lease liabilities, $1.3 million in accounts payable, and $1.0 million in accrued expenses and other current liabilities, partially offset by a decrease of $2.1 million in accrued compensation and other related benefits and an increase of $0.8 million in prepaid expenses and other current assets.

Investing Activities

Net cash used in investing activities was $124.5 million during the nine months ended September 30, 2026, and consisted of net purchases of marketable securities of $109.3 million ($271.6 million of purchases, partially offset by $162.3 million of proceeds from maturities) and $15.2 million used for the purchase of property and equipment.

Net cash provided by investing activities was $107.0 million during the nine months ended September 30, 2025, and consisted primarily of net proceeds from the maturity and purchase of marketable securities of $127.4 million, offset by $20.3 million used for the purchase of property and equipment.

Financing Activities

Net cash provided by financing activities was $285.5 million during the nine months ended September 30, 2026 and consisted primarily of $295.5 million of proceeds from the issuance of common stock upon the Business Combination and PIPE Financing, partially offset by $8.9 million of payments of transaction costs related to the Business Combination and $1.1 million of payments for taxes on the net settlement of equity awards.

Net cash provided by financing activities was $41.5 million during the nine months ended September 30, 2025 and consisted primarily of proceeds from the issuance of a convertible note to Exact.

Liquidity and Capital Resources

Sources of Liquidity

We have historically financed our operations primarily through the sale of equity securities and the issuance of convertible notes and, to a lesser extent, upfront payments received under licensing arrangements. As of September 30, 2026, we had cash, cash equivalents, and marketable securities of $430.0 million, including cash and cash equivalents of $180.4 million. In connection with the July 20, 2026 closing, approximately $77.5 million of principal and accrued interest outstanding under the Roche Convertible Note automatically converted into shares of Freenome, Inc. common stock. On September 8, 2026, approximately $50.5 million of principal and accrued and unpaid interest under the convertible promissory note originally issued to Exact automatically converted into 3,364,814 shares of Freenome, Inc. common stock at a conversion price of $15.00 per share. Following these conversions, neither of those convertible notes remained outstanding.

Since our inception, we have incurred significant operating losses and negative cash flows from operations. During the nine months ended September 30, 2026, we incurred a net loss of $72.5 million, used $58.7 million of cash in operating activities, and had an accumulated deficit of $1.4 billion.

Since inception, we have received aggregate gross proceeds of approximately $1.6 billion from the sale of convertible preferred stock in private placements, the issuance of convertible notes, and upfront payments and cost-sharing arrangements under our strategic collaborations. As described above, upon closing of the Business Combination, we received aggregate gross proceeds of $310.7 million, including $240.0 million in gross proceeds from a PIPE financing. After giving effect to transaction costs, New Freenome received net proceeds of approximately $295.5 million.

In August 2025, we entered into an exclusive license agreement with Exact, which became a wholly owned subsidiary of Abbott Laboratories in March 2026, to advance commercialization of our blood-based colorectal cancer screening test. Under the agreement, we received a $75.0 million upfront payment as partial consideration for the rights and licenses granted. We may also receive up to $700.0 million in specified development and regulatory milestone payments. In July 2026, following FDA approval of SimpleScreen CRC, we earned a $100.0 million milestone payment, which we received on September 22, 2026. In addition, Exact is obligated to reimburse us for up to $20.0 million per year of mutually agreed development costs over a three-year period.

Under the Roche License and Option Agreement, we are eligible to receive up to $100.0 million in milestone payments and tiered royalties on non-U.S. test sales, ranging from the low single digits to the mid-teens, depending on sales levels. The agreement also provides for up to $24.0 million in aggregate milestone payments in connection with the SBX Evaluation, consisting of three milestones of $8.0 million each. Roche delivered the SBX platform on September 29, 2026, which triggered the first $8.0 million milestone, payable within 30 days of delivery. As of September 30, 2026, we recorded an $8.0 million receivable from Roche, a related party, and a corresponding contract liability. We have not recognized revenue on this milestone.

Future Funding Requirements

As of September 30, 2026, we had cash, cash equivalents, and short-term marketable securities of $430.0 million. Based on our current operating plan, we believe these balances, together with expected cash receipts not already included in them, will be sufficient to fund our operations into 2028. This estimate is a forward-looking statement that involves risks and uncertainties, and actual results could differ materially. In addition, the process of commercializing our approved products, conducting nonclinical studies and clinical trials, and developing future product candidates is costly, and the timing and extent of related expenditures are uncertain. Accordingly, we may need to raise additional capital in the future.

Our future capital requirements will depend on many factors, including:

- the type, number, scope, progress, timing, results, and costs of our discovery activities, nonclinical studies, and clinical trials for our current and future products and product candidates;
- the costs, timing, and outcome of regulatory review of our current and future product pipeline;
- the timing and terms of establishing and maintaining license, collaboration, and other strategic arrangements;
- the costs of obtaining, maintaining, defending, and enforcing our patents and other intellectual property rights;
- our efforts to enhance our operational infrastructure and hire additional personnel to support our obligations as a public company;
- the costs associated with expanding our workforce and engaging consultants as our development and commercialization activities increase;
- the costs and timing of establishing or expanding sales and marketing capabilities for approved products;

- our ability to achieve market acceptance, obtain coverage and adequate reimbursement from third-party payers, and generate sufficient market share and revenue from approved products; and

- the costs associated with acquiring or licensing additional products, technologies, or intellectual property.

Although we have completed the Business Combination and received the related proceeds, and our SimpleScreen CRC test has received FDA approval, we expect to continue to require substantial capital to support the commercialization of our approved product, advance our research and development programs, pursue additional regulatory approvals, expand our commercial infrastructure, and fund our operations. We may seek to finance our future cash needs through equity offerings, debt financings, or other capital sources, including license agreements, royalty financings, collaborations, and other strategic arrangements.

However, we may be unable to raise additional funds or enter into such arrangements when needed on favorable terms, or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our stockholders may be diluted, and the terms of these securities could include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt and equity financings, if available, may also involve agreements that include covenants restricting our ability to incur additional indebtedness, make capital expenditures, or take other actions.

If we raise additional capital through license agreements, collaborations, or other strategic arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams, research programs, approved products, or future product candidates, or grant licenses on terms that may not be favorable to us. Our inability to obtain additional funding or enter into such arrangements when needed could adversely affect our financial condition and our ability to execute our business strategy. If additional capital is unavailable when required, we may be forced to delay, limit, or reduce investments in commercialization activities, research and development programs, or future product development initiatives.

Contractual Obligations and Commitments

Convertible Notes

The $50.0 million convertible promissory note originally issued to Exact, now a wholly owned subsidiary of Abbott Laboratories, automatically converted on September 8, 2026. Approximately $50.5 million of principal and accrued and unpaid interest converted into 3,364,814 shares of Freenome, Inc. common stock at a conversion price of $15.00 per share.

The $75.0 million convertible promissory note issued to Roche Holdings automatically converted in connection with the July 20, 2026 closing into 6,460,616 shares of Freenome, Inc. common stock at a conversion price of $12.00 per share.

Leases

Our lease portfolio consists primarily of operating leases for our current corporate headquarters, laboratory facilities, and warehouse facilities, with lease terms ranging from 1 to 11 years. Under the terms of the leases, as of September 30, 2026, our lease obligations consist of $311.9 million in payments through March 31, 2035.

Purchase Commitments

As of September 30, 2026, we have entered into a non-cancellable cloud services agreement and committed to purchase cloud computing services totaling $119.1 million through January 31, 2029.

Our other non-cancellable unconditional purchase commitments with a remaining term over one year were $9.0 million as of September 30, 2026.

License and Collaboration Agreements

See Notes 6 and 7 to the accompanying unaudited condensed consolidated financial statements for a detailed description of our license and collaboration agreements.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our condensed consolidated financial statements, which are prepared in accordance with GAAP. The preparation of our condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, costs and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements and accompanying notes. We base our estimates and assumptions on historical experience and other factors that we believe to be reasonable under the circumstances. We evaluate our estimates and judgments on an ongoing basis. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making

judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Our actual results may differ from these estimates under different assumptions or conditions.

Our significant accounting policies are described in Note 2, "Summary of Significant Accounting Policies," to our audited consolidated financial statements and related notes included in the proxy statement/prospectus filed with the SEC on June 17, 2026, and in Note 1, "Organization and Business," to our unaudited condensed consolidated financial statements included in our Current Report on Form 8-K/A filed on August 13, 2026. Except as described below, during the three and nine months ended September 30, 2026, there were no material changes to our critical accounting policies and estimates from those disclosed in our most recent filing.

Prior to regulatory approval, we expensed pre-launch inventory costs as research and development expense. Beginning in June 2026, in anticipation of FDA approval of SimpleScreen CRC, we began capitalizing the purchase price of reagents used in commercial testing, as we determined that regulatory approval and future economic benefits were probable. The FDA approved SimpleScreen CRC in July 2026. Reagent costs incurred before June 2026 were expensed as research and development and have not been capitalized. Capitalized inventory is expensed to cost of goods sold when the related test is performed. See Note 2 to our condensed consolidated financial statements.

Recent Accounting Pronouncements

See Note 1, Organization and Summary of Significant Accounting Policies, to our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Pursuant to Item 305(e) of Regulation S-K, the Company is a smaller reporting company and is not required to provide the information required by this Item.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

As of September 30, 2026, the end of the period covered by this Quarterly Report on Form 10-Q, management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of September 30, 2026, our disclosure controls and procedures were effective at the reasonable assurance level.

Disclosure controls and procedures are designed to provide reasonable assurance that information required to be disclosed in reports filed or submitted under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

During the quarter ended September 30, 2026, there were no changes in the Company's internal control over financial reporting that materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Part II — Other Information

Item 1. Legal Proceedings

From time to time, we may be involved in legal proceedings and claims arising in the ordinary course of business. We are not currently a party to any litigation or legal proceedings that, in the opinion of our management, are probable to have a material adverse effect on our business.

Item 1A. Risk Factors

Our business involves significant risks, some of which are described below. You should carefully consider the risks and uncertainties described below, together with all of the other information contained in this Quarterly Report on Form 10-Q, including "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the condensed consolidated financial statements and the related notes, before deciding whether to invest in our securities. The occurrence of one or more of the events or circumstances described in these risk factors, alone or in combination with other events or circumstances, may have a material adverse effect on our business, reputation, revenue, financial condition, results of operations and future prospects, in which event the market price of our common stock could decline, and you could lose part or all of your investment. Unless otherwise indicated, reference in this section and elsewhere in this Quarterly Report on Form 10-Q to our business being adversely affected, negatively impacted or harmed will include an adverse effect on, or a negative impact or harm to, the business, reputation, financial condition, results of operations, revenue and our future prospects. The material and other risks and uncertainties summarized above and described below are not intended to be exhaustive and are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. This Quarterly Report on Form 10-Q also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of a number of factors, including the risks described below and elsewhere in this Quarterly Report.

Risks Related to Our Business and Financial Condition

We operate in a rapidly evolving field and have a limited operating history, which makes it difficult to evaluate our current business and predict our future performance.

We operate in a rapidly evolving field and have a limited operating history. Although we have received FDA approval for SimpleScreen CRC initial version ("v1") as a blood-based screening option for CRC in adults 45 and older who are at average risk for the disease, and Abbott has commenced commercialization of SimpleScreen CRC in the U.S. pursuant to the commercial agreement entered into between Freenome and Exact in August 2025, we have limited commercial history and our other products are still in development. Prior to the closing of the Business Combination, as Legacy Freenome, we funded our operations primarily through private placements of our convertible preferred stock, the issuance of convertible notes, and payments received under our license and collaboration agreements. On July 20, 2026, we completed the Business Combination and received gross proceeds of approximately $310.7 million. We have not yet demonstrated an ability to generate material product revenue, obtain regulatory approval for additional products, manufacture any product on a commercial scale or arrange for a third party to do so on our behalf or conduct sales and

marketing activities necessary for successful product commercialization beyond our existing commercial arrangements. We will encounter risks and difficulties frequently experienced by early-stage companies in rapidly evolving fields, and we have not yet demonstrated an ability to successfully overcome such risks and difficulties. If we do not address these risks and difficulties successfully, our business will suffer.

We have incurred significant net losses in each period since our inception and anticipate that we will continue to incur net losses for the coming years.

Since our inception, we have incurred significant and negative cash flows from our operations. We have incurred operating losses in each year since our inception. Our net losses were $72.5 million for the nine months ended September 30, 2026 and $219.3 million for the year ended December 31, 2025, respectively. As of September 30, 2026, we had an accumulated deficit of $1.4 billion. Substantially all of our net losses since inception have resulted from our research and development programs, commercialization efforts, investments in our facilities, payments to licensors, and general and administrative costs associated with our operations.

We have invested significant financial resources in research and development activities, including to develop our multiomics technology platform, SimpleScreen™ CRC, SimpleScreen™ Lung, and our other product candidates. The amount of our future net losses will depend, in part, on the level of our future expenditures and our ability to generate additional revenue. Moreover, our net losses may fluctuate significantly from quarter to quarter and year to year depending on the timing of regulatory approvals and R&D activities, such that a period-to-period comparison of our results of operations may not be a good or reliable indication of our future performance.

We expect to continue to incur significant expenses and operating losses as we:

- accelerate the development of our multiomics platform driven by artificial intelligence (“AI”) and machine learning (“ML”), which seeks to identify the early biological signals of disease;
- expand our commercial and data infrastructure to support future launch of multiple blood-based cancer detection tests;
- further advance our R&D programs;
- seek to identify additional indications;
- expand commercial and operational personnel;
- maintain, expand, enforce, defend and protect our intellectual property portfolio and provide reimbursement of third-party expenses related to our patent portfolio;
- seek regulatory approvals for any future product candidates for which we successfully complete clinical trials; and
- meet the requirements and demands of being a public company.

We may need to raise additional capital to fund our existing operations, develop our platform, commercialize our product or new product candidates or expand our operations.

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

- fund development and marketing efforts of our product or any other future products we may develop;
- acquire, license or invest in technologies;
- increase our efforts to drive market adoption of our current products and tests, and address competitive developments; and
- finance capital expenditures and general and administrative expenses.

Our present and future funding requirements will depend on many factors, including:

- the type, number, scope, progress, expansions, results, costs and timing of, discovery, nonclinical studies and clinical trials of our product and any product candidates;
- the costs, timing and outcome of regulatory review of our current and future product pipeline;
- the terms and timing of establishing and maintaining license, collaboration and other similar arrangements;
- the legal costs of obtaining, maintaining and enforcing our patents and other intellectual property rights;
- our efforts to enhance operational systems and hire additional personnel to satisfy our obligations as a public company;
- the costs associated with hiring additional personnel and consultants as our development and commercial activities increase;
- the costs and timing of establishing or securing sales and marketing capabilities if any current and future product pipeline is approved;
- our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payers and adequate market share and revenue for any approved products; and
- costs associated with any products or technologies that we may in-license or acquire.

Based on our current operating plans, we believe that our existing cash, cash equivalents and short-term marketable securities as of September 30, 2026, including approximately $295.5 million of net proceeds from the Business Combination and PIPE Financing
and the $100.0 million regulatory milestone payment we received in September 2026 following FDA approval of SimpleScreen CRC, will be sufficient to fund our operations into 2028. We have based this estimate on assumptions that may prove to be wrong, and we

could use our capital resources sooner than we expect. If we are unable to raise sufficient funding, we may be unable to continue to operate in the long term.

Because SimpleScreen CRC v1 received FDA approval in July 2026, we have begun to incur, and expect to continue to incur, significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Accordingly, until such time as we can generate significant revenue from sales of our product and any product candidates, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, including potential collaborations, licenses, royalty financings and other similar arrangements.

However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements when needed would have a negative impact on our financial condition and could force us to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market current or future product candidates that we would otherwise prefer to develop and market ourselves.

Raising additional capital may cause dilution to our stockholders, restrict our operations and could cause the price of our common stock to decline.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations with our existing cash and cash equivalents, the net proceeds from the Business Combination and the PIPE investments, short-term investments, or any future equity or debt financings and upfront and milestone and royalties payments, if any, received under any of our existing or future licenses or collaborations. In the future, if we raise additional capital through the sale of equity or convertible debt securities or issue any equity or convertible debt securities in connection with a collaboration agreement or other contractual arrangement, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a holder of our common stock. For example, we issued convertible notes to Exact and Roche Holdings with aggregate principal amounts of $50 million and $75 million, respectively. Upon the Closing of the Business Combination, the $75 million Roche Convertible Note, including $2.5 million of accrued interest, converted into 6,460,616 shares of New Freenome common stock, On September 8, 2026, the outstanding $50.0 million principal balance of the convertible note originally issued to Exact, together with $472,222 of accrued and unpaid interest, converted into 3,364,814 shares of the Company's common stock at a conversion price of $15.00 per share. Going forward, the possibility of additional issuances of equity or convertible debt securities may cause the market price of our common stock to decline. Debt financing, if available, may result in increased fixed payment obligations and involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends or acquiring, selling or licensing intellectual property rights or assets, which could adversely impact our ability to conduct our business.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties in the future, we may have to relinquish valuable rights to our intellectual property, technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. We could also be required to seek funds through arrangements with collaborators or others at an earlier stage than otherwise would be desirable. Any of these occurrences may have a material adverse effect on our business, operating results and prospects.

We maintain the majority of our cash and cash equivalents in accounts with major U.S. and multinational financial institutions, and our deposits at certain of these institutions exceed insured limits. Market conditions and changes in financial regulations and policies can impact the viability of these institutions. In the event of failure of any of the financial institutions where we maintain our cash and cash equivalents, there can be no assurance that we would be able to access uninsured funds in a timely manner or at all. Any inability to access or delay in accessing these funds could adversely affect our business and financial position. In addition, changes in regulations governing financial institutions are beyond our control and difficult to predict; consequently, the impact of such changes on our business and results of operations is difficult to predict and may have an adverse effect on us.

If we cannot maintain our current collaborations or partnerships, including our arrangements with Exact and Roche, and enter into new collaborations or partnerships in a timely manner and on acceptable terms, our efforts to develop and commercialize our products could be delayed or adversely affected.

We rely, and expect to continue to rely, on collaborative partners to help us commercialize our product and enhance our research and development efforts. For example, we currently have an agreement with Exact which was acquired by Abbott in March 2026, to commercialize SimpleScreen CRC in the U.S. and with Roche to commercialize "kitted" tests outside of the U.S. These partnerships help us to reach additional markets in the U.S. and globally. Our reliance on these or other third parties reduces our control over sales of SimpleScreen products and product development activities. Although we received a $100.0 million regulatory milestone payment from Exact in September 2026 following FDA approval of SimpleScreen CRC, this was a one-time payment, and future payments under the agreement, if any, may depend on the achievement of additional contractual milestones and other conditions. Separately, upon delivery of the SBX Platform on September 29, 2026, the Company recorded an $8.0 million receivable from Roche Sequencing, due within 30 days.

If any of our collaborators or partners were to breach or terminate their agreements with us or otherwise fail to conduct the contracted activities successfully and in a timely manner, the sale of our product or research and development activities of certain of our product candidates could be delayed or terminated. For example, Abbott completed its acquisition of Exact on March 23, 2026, and

Exact became a subsidiary of Abbott. Under the terms of our collaboration agreement with Exact, the agreement will continue to be binding on Abbott, however, if Abbott fails to prioritize its obligations under the agreement, our expected timelines could be delayed and our business could be harmed. Further, our collaborators or partners may fail to properly protect our intellectual property rights, may infringe the intellectual property rights of third parties, may misappropriate our trade secrets, or may use our proprietary information or others' in such a way as to expose us to litigation and potential liability. Disagreements or disputes with our collaborators or partners, including disagreements over proprietary rights, funding, or contract interpretation, might cause delays or termination of the research, development or commercialization of our products, might lead to additional responsibilities for us with respect to these products or activities or might result in litigation or arbitration, any of which would divert management attention and resources and be time-consuming and expensive. We may not be able to renew our current agreements with collaborators or partners or negotiate additional collaboration or partnership agreements on acceptable terms, if at all, and these collaborations and partnerships may not be successful. We also compete with some of our collaborative partners in other areas, for example, Exact with respect to MCED products, and this could negatively impact our relationships with partners and therefore the success of our collaborations.

From time to time, we expect to engage in discussions with potential development and/or commercial collaborators that may or may not lead to collaborations. However, we cannot guarantee that any discussions will result in development or commercial collaborations. Further, once news of discussions regarding possible collaborations are known in the general public, regardless of whether the news is accurate, failure to announce a collaboration agreement, or the entity's announcement of a collaboration with an entity other than us, could result in adverse speculation about us, our products, or our technology, resulting in harm to our reputation and our business. In addition, establishing collaborations is difficult, time-consuming and may require our significant financial investment. Potential collaborators may elect not to work with us based on their assessment of our financial, regulatory, or intellectual property position. Even if we establish new collaborations, they may not result in the successful development or commercialization of our products or technology.

Our approach to the development of multiple blood-based screening tests through the use of our technology platform is unproven, which makes it difficult to predict the time, cost of development and likelihood of successfully developing and launching additional tests.

Other than SimpleScreen CRC v1, our blood-based screening tests are still in development and therefore our strategy of using the same technology underlying our proprietary platform for new screening tests remains unproven. Although we launched SimpleScreen Lung as a laboratory-developed test ("LDT") in October 2026, it has not been reviewed, cleared or approved by the FDA and remains subject to continued clinical and regulatory development. We have incurred significant expenses to develop and prepare for launching SimpleScreen CRC v1 and SimpleScreen Lung, and expect to incur significant expenses to develop a pipeline for future product candidates, but such efforts may not be successful. Product development is expensive, may take years to complete, and can have uncertain outcomes. Failure can occur at any stage of development.

Candidate products that may initially show promise may fail to achieve the desired results in larger clinical studies or may not achieve acceptable levels of clinical accuracy. Results from early studies or trials are not necessarily predictive of future clinical study or trial results, and preliminary data from an early study, such as that from our second version of SimpleScreen CRC ("v2") that was presented at ASCO 2026, are not necessarily indicative of final results. Although the FDA has approved SimpleScreen CRC v1, for v1 and any new product that we may develop, we would need to commit substantial resources to commercialize, sell, and market it before it could be profitable, and the product or service may never be commercially viable.

Our business strategy is focused on multi-cancer early detection, which is a nascent market. We also have programs for which we are actively developing tests for a single cancer indication, such as colorectal and lung. If we determine that any of our current or future product candidates are unlikely to succeed, we may abandon them without any return on our investment.

Further, the development of our technology is an ongoing process. Any development problems we encounter either with our technology, including our proprietary AI/ML multiomics platform, for additional screening tests may prevent us from commercializing any current or future product candidates on a timely or profitable basis, if at all. Even if we are able to successfully launch our first test, we will have limited commercial experience, and the launch of any additional tests may be delayed, be less successful than we anticipate, or fail for any of the reasons that large commercial launches are ultimately unsuccessful. For example, our screening tests, produced at large scale, might not perform to standards that we have experienced to date. We may not obtain or maintain regulatory approval, authorization, certification or clearance for some of our diagnostic tests in research and development, which may have a significant impact on our commercialization goals.

Product launches of the type and scope that we are targeting are subject to many uncertainties, and many that are undertaken are unsuccessful. We cannot be certain that we will be able to achieve our business objectives, and if our assumptions regarding these risks and uncertainties are incorrect or change, or if we do not address these risks successfully, our results of operations could differ materially from our expectations and our business, financial condition and results of operations could be adversely affected.

If we are unable to support demand for SimpleScreen CRC, SimpleScreen Lung or future products, if approved, including ensuring that we have adequate capacity to meet increased demand, or we are unable to successfully manage our anticipated growth, our business could suffer.

We have limited experience operating a commercial scale laboratory, and our lack of prior experience may result in unforeseen expenses, difficulties, complications, delays, and other known and unknown factors in connection with meeting potentially increased demand for SimpleScreen CRC, SimpleScreen Lung, or future products, if approved. We will need to transition to a company capable of supporting commercial activities, including scaling our operations such as increased capacity for sample intakes, customer service, and billing, and we may not be successful in such a transition.

In August 2025, we entered into an agreement with Exact, to commercialize SimpleScreen CRC in the U.S. and we expect that successful commercialization will greatly increase demand for our product. As we commercialize and scale manufacturing of our product, we may need to incorporate new equipment, implement new technology systems and laboratory processes, and hire new personnel with different qualifications. We will also need to purchase additional equipment, some of which can take several months or more to procure, set up and validate, and increase our software and computing capacity to meet increased demand. Our process is complex and requires multiple work-stations, processing steps and automation, each of which can break down and cause delays in providing timely results. In addition, as we plan to launch multiple tests, these will add additional complexity and may cause delays or prevent us from meeting our timing goals. 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, if at all, or that we will have adequate space in our laboratory facility or be able to secure additional facility space to accommodate such required expansion. Failure to manage this growth or transition could result in turnaround time delays, higher product costs, declining product quality, deteriorating customer service and slower responses to competitive challenges. A failure in any one of these areas could make it difficult for us to meet market expectations for our products and could damage our reputation and the prospects for our business.

The value of our products, and any future products will depend, in part, on our ability to perform tests and return results to providers on a timely basis and at an appropriate quality standard, and on our reputation for such timeliness and quality. Failure to implement necessary procedures, to transition to new equipment or processes, or to hire the appropriate, qualified personnel could result in inaccurate or incorrect tests and results, higher costs of processing, longer turnaround times or an inability to meet market demand. Our tests also require the use of special blood tubes, and physicians may not submit samples properly, which may also result in delays and re-processing. 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.

We may experience challenges attracting and retaining qualified personnel due to competitive labor markets and we may be unable to manage our future growth effectively, all of which could make it difficult to execute our business strategy.

Since our inception, we have experienced rapid growth and anticipate further growth in our business operations. Our future growth could create strain on our organizational, administrative and operational infrastructure, including laboratory operations, quality control, customer service and sales organization management. We expect to continue to increase headcount and to hire more specialized personnel as we grow our business. We will need to continue to hire, train and manage additional qualified scientists, laboratory personnel, client and account services personnel, as well as sales and marketing staff, and improve and maintain our technology to properly manage our growth.

The competition for qualified personnel in the biotechnology industry is intense, and our future success depends upon our ability to attract, retain, and motivate highly skilled scientific, technical and managerial employees. We face competition for personnel from other companies, universities, public and private research institutions, and other organizations. In this competitive environment, our business could be adversely impacted by increases in labor costs triggered by regulatory actions regarding wages, scheduling and benefits, and the need to attract and retain high quality employees with the requisite skill sets.

In addition, we expect to need additional managerial, operational, marketing, sales, financial and other personnel as we grow our operations in connection with the launch of SimpleScreen CRC and SimpleScreen Lung. Our ability to manage our growth properly will also require us to continue to improve our operational, financial and management controls, as well as our reporting systems and procedures. The time and resources required to implement these new systems and procedures is uncertain and could be demanding, and failure to complete this in a timely and efficient manner could adversely affect our operations.

If we lose the services of our founder, our Chief Executive Officer, or other members of our senior management team, we may not be able to execute our business strategy.

We are highly dependent on the research and development, clinical, financial, operational and other business expertise of our executive officers, in particular, our founder and Chief Product Officer, Riley Ennis, and our Chief Executive Officer, Aaron Elliott, as well as the other principal members of our management, scientific and clinical teams. Although we have entered into or intend to enter into employment offer letters with our executive officers, each of them may terminate their employment with us at any time. We do not maintain “key person” insurance for any of our executives or other employees. The loss of our founder and our Chief Executive Officer, or one or more other members of our senior management team could have an adverse effect on our business.

If our existing facility becomes damaged or inoperable or we are required to vacate our existing facility, our ability to pursue our research and development efforts may be jeopardized.

We currently have one facility located in Brisbane, California. Our facility and equipment could be harmed or rendered inoperable by natural or man-made disasters, including war, fire, earthquake, power loss, communications failure or terrorism, which may render it difficult or impossible for our laboratory operations. The inability to perform our tests or to reduce the backlog that could develop if our facility is inoperable, for even a short period of time, may result in the loss of customers or harm to our reputation, and we may be unable to regain those customers or repair our reputation.

Furthermore, our facility and the equipment we use to perform our research and development work could be unavailable or costly and time-consuming to repair or replace. It would be difficult, time-consuming and expensive to rebuild our facility, to locate and qualify a new facility or enable a third party to practice our proprietary technology, particularly in light of licensure and accreditation requirements. Even if we are able to find a third party with such qualifications to perform our tests, the parties may be unable to agree on commercially reasonable terms.

We carry insurance for damage to our property and disruption of our business, but this insurance may not cover all of the risks associated with damage or disruption to our facility and business, may not provide coverage in amounts sufficient to cover our potential losses and may not continue to be available to us on acceptable terms, if at all.

We rely on commercial courier delivery services to transport samples to our laboratory facility in a timely and cost-efficient manner and if these delivery services are disrupted, our business will be harmed.

Our business depends on our ability to deliver test results quickly and reliably to our customers. Blood samples need to be received within seven days for analysis at our facility. Disruptions in delivery services to transport samples to that facility, whether due to labor disruptions, bad weather, natural disaster, terrorist acts or threats or for other reasons could adversely affect specimen integrity and our ability to process samples in a timely manner, delay our provision of test results to our customers, and ultimately our reputation and our business. In addition, if we are unable to continue to obtain expedited delivery services to transport samples to us on commercially reasonable terms, our operating results may be adversely affected.

We face intense competition from other companies and may not be able to compete successfully.

We operate in a rapidly evolving and highly competitive industry. There are a number of private and public companies that offer products, or have announced that they are developing products that compete with ours.
Some of our current and potential competitors may have significant competitive advantages over us, which may make them more attractive to hospitals, clinics, group purchasing organizations, and physicians. See “Business— Competition” for additional information regarding our competitors and the effects of competition on our business.

We may also be unable to compete effectively against our competitors because their products and services are superior or because they are more effective or can more quickly develop or commercialize competing products and services. For example, large and long-tenured healthcare, life sciences, or technology companies may initiate research and development of multi-cancer early detection and bring significant resources and disruption to the cancer detection space. Furthermore, even if we do develop new marketable products or services, our current and future competitors may develop products and services that are more clinically or commercially attractive than ours, and they may bring those products and services to market earlier or more effectively than us. If we are unable to compete successfully against current or future competitors, we may be unable to increase market acceptance for, and sales of, our tests, which could prevent us from increasing or sustaining our revenues or achieving sustained profitability and could cause the market price of our common stock to decline.

Cybersecurity incidents such as security breaches, loss of data and other disruptions in relation to our information technology systems, as well as those of our third-party service providers, could compromise sensitive information related to our business, prevent us from accessing it and expose us to substantial liability, which could adversely affect our business and reputation.

We depend on information technology systems for significant elements of our operations. Our information technology systems support a variety of functions, including laboratory operations, test validation, sample tracking, quality control, research and development activities, scientific and medical curation and general administrative activities. Our information technology systems store a wide variety of information critical to our business, including research and development information, patient data, commercial information and business and financial information. We face a number of risks related to protecting this critical information, including loss of access, inappropriate use or disclosure, unauthorized access, inappropriate modification and our being unable to adequately monitor, audit or modify our controls over such critical information. This risk extends to the third-party vendors and subcontractors we use to manage this sensitive data or otherwise process it on our behalf.

Cybersecurity incidents such as security breaches, computer viruses, malware and other incidents could cause misappropriation, loss or other unauthorized disclosure of confidential data, materials or information, including those concerning our customers and employees. Increasingly complex methods have been used in cyberattacks, including ransomware, phishing, structured query language injections, social engineering schemes, insider threats, AI-tool-supported attacks, and distributed denial-of-service attacks conducted by actors including computer attackers, foreign governments and cyber terrorists. A cyberattack can also be in the form of unauthorized access or a blocking of authorized access. The risk of a cybersecurity incident has generally increased as the number, intensity and sophistication of attempted attacks has increased. As a result of the continued hybrid working environment, we and our third party service providers and partners may face increased cybersecurity risks due to our reliance on internet technology and

the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. 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 may be unable to anticipate these techniques or implement adequate preventative measures. We may experience cybersecurity incidents that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate cybersecurity incidents due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. We can provide no assurance that we or our vendors will be able to detect, prevent or contain the effects of such attacks or other information security risks or threats in the future.

The costs of attempting to protect against the foregoing risks and the costs of responding to a cybersecurity incident are significant. Large-scale cybersecurity incidents at other entities increase the challenge we and our vendors face in maintaining the security of our information technology systems and of our customers' sensitive information. Following a cybersecurity incident, our and/or our vendors' remediation efforts may not be successful, and a cybersecurity incident could result in interruptions, delays or cessation of service, and loss of existing or potential customers. In addition, cybersecurity incidents or failures of our and/or our vendors' security measures and the unauthorized dissemination of sensitive personal information or proprietary information or confidential information about us, our customers or other third parties, could expose our customers' private information and our customers to the risk of financial or medical identity theft, or expose us or other third parties to a risk of loss or misuse of this information, and result in investigations, regulatory enforcement actions, material fines and penalties, loss of customers, litigation or other actions which could have a material adverse effect on our business, prospects, reputation, results of operations and financial condition. In addition, if we fail to adhere to our privacy policy and other published statements or applicable laws concerning our processing, use, transmission and disclosure of protected information such as protected health information ("PHI"), or if our statements or practices are found to be deceptive or misrepresentative, we could face regulatory actions, fines and other liability.

It could be difficult to predict the ultimate resolution of any such cybersecurity incidents or to estimate the amounts or ranges of potential loss, if any, that could result therefrom. If we cannot successfully resolve a cybersecurity incident, it could materially impact our ability to operate our business as well as our results of operations and financial position.

We maintain cyber liability insurance; however, this insurance may not be sufficient to cover the financial, legal, business or reputational losses that may result from an interruption or breach of our systems.

We, our collaborators and our service providers are subject to a variety of privacy and data security laws, regulations and contractual obligations, which may require us to incur substantial compliance costs, and any failure or perceived failure by us to comply with them could expose us to significant fines and other penalties and otherwise harm our business and operations.

The legislative and regulatory framework for the collection, use, safeguarding, sharing, transfer and other processing of personal information worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. Globally, several jurisdictions, including those in which we operate or collect personal information, have established their own data security and privacy frameworks with which we must comply. In the U.S., numerous federal and state laws and regulations, including federal health information privacy laws, state information security and data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure and protection of health-related and other personal information, could apply to our operations or the operations of our collaborators and service providers. In particular, regulations promulgated pursuant to the Health Insurance Portability and Accountability Act ("HIPAA") establish privacy and security standards that limit the use and disclosure of individually identifiable health information, or PHI, and impose requirements regarding the privacy and security of individually identifiable health information, including mandatory contractual terms, for covered entities, or certain healthcare providers, health plans and healthcare clearinghouses, and their business associates that provide services to the covered entity that involve individually identifiable health information and their subcontractors that use, disclose or otherwise process individually identifiable health information. Our business may be indirectly impacted by HIPAA in our interactions with providers, payers, and others that have HIPAA compliance obligations. If we become a covered entity under HIPAA, and are unable to properly protect the privacy and security of PHI, we could be found to have violated these privacy and security laws and/or breached certain contracts. Further, if we fail to comply with applicable privacy laws, including applicable HIPAA privacy and security standards, we could face significant civil and criminal penalties. U.S. Department of Health & Human Services, or HHS, enforcement activity can result in financial liability and reputational harm, and responses to such enforcement activity can consume significant internal resources.

At the state level, numerous states have enacted comprehensive data privacy and security laws, rules and regulations. For example, California enacted the California Consumer Privacy Act ("CCPA"), which creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal data. While subject to several exceptions, the CCPA generally requires covered companies to provide certain disclosures to consumers about its data collection, use and sharing practices, and to provide affected California residents with ways to opt-out of certain sales or transfers of personal information. Following California's lead, more than a dozen additional states, including Virginia, Colorado, Connecticut, New Jersey, New Hampshire and others, have adopted comprehensive privacy laws. Many of these laws incorporate similar concepts to those in the CCPA, however there are also several key differences in the scope, application, and enforcement that will change the operational practices of regulated businesses. These laws will, among other things, impact how regulated businesses collect and process sensitive personal data, conduct data protection assessments, transfer personal data to affiliates, and respond to consumer rights requests. Other states have focused on more narrow aspects of privacy. In the state of Washington, for example, the My Health My Data Act, which has a private right of action that

further increases the relevant compliance risk, requires regulated entities to obtain consent to collect health-related information and grants consumers certain rights, including to request deletion of their information. Connecticut and Nevada have also passed similar laws regulating consumer health data. Other states have proposed and/or passed legislation that regulates the privacy and/or security of certain specific types of information. For example, a small number of states have passed laws that regulate biometric data specifically. Although many of the existing state privacy laws exempt clinical trial information and health information governed by HIPAA, future privacy and data protection laws may be broader in scope. The existence of comprehensive privacy laws in different states increases the complexity of our compliance requirements and potential legal risk. Our compliance efforts may require additional investment of resources, impact strategies and the availability of previously useful data and could result in increased compliance costs. Such laws may also impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products.

In the European Economic Area (the "EEA") and/or the United Kingdom (the "U.K.") we will be subject to additional, more stringent privacy laws in other jurisdictions, such as the General Data Protection Regulation (the "EU GDPR") as well as other national data protection legislation in force in relevant European Union (the "EU") member states. The EU GDPR imposes strict regulations and establishes a series of requirements regarding the collection, transfer, storage and processing of personal data. Following the U.K.'s withdrawal from the EU on January 31, 2020 and the end of the transitional arrangements agreed between the U.K. and EU as of January 1, 2021, the EU GDPR has been incorporated into U.K. domestic law by virtue of Section 3 of the European Union (Withdrawal) Act 2018 and amended by the Data Protection, Privacy and Electronic Communications (Amendments etc.) (EU Exit) Regulations 2019, (the "U.K. GDPR") and, together with the EU GDPR (the "GDPR"). The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including strict requirements relating to processing of sensitive data (such as health data), ensuring there is a legal basis or condition to justify the processing of personal data, where required strict requirements relating to obtaining consent of individuals, disclosures about how personal information is to be used, limitations on retention of information, implementing safeguards to protect the security and confidentiality of personal data, where required providing notification of data breaches, maintaining records of processing activities, documenting data protection impact assessments where there is high risk processing and taking certain measures when engaging third-party processors.

The GDPR also imposes strict rules on the transfer of personal data to countries outside the EEA or the U.K., including the U.S. (see below), and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million (£17.5 million) or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. Non-compliance could also result in the imposition of orders to stop data processing activities, which could have a material adverse effect on our business, financial position and results of operations.

We may not have all the mechanisms in place to ensure compliance, including as implemented by national laws of EU Member States which may partially deviate from the EU GDPR and impose different and more restrictive obligations from country to country. Compliance with the GDPR is a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European and U.K. activities.

The U.K. GDPR and the U.K. Data Protection Act 2018 set out the U.K.'s data protection regime, which is independent from but currently aligned to the EU's data protection regime. The legal mechanisms supporting transfers of personal data between the U.K., the EEA and the U.S. may change, which could increase our compliance burden and disrupt data flows. The U.K. Government has enacted the Data Use and Access Act 2025, which may further alter the similarities between the U.K. and EU data protection regimes.

In addition, we may not have all the adequate safeguards to enable the transfer of personal data outside of the EEA or the U.K., in particular to the U.S., in compliance with the GDPR. In some cases, we rely upon the EC's approved standard contractual clauses to legitimize transfers of personal data out of the EEA from controllers or processors established outside the EEA (and not subject to the GDPR). The U.K. is not subject to the EC's standard contractual clauses but has published its own transfer mechanism, the International Data Transfer Addendum/Agreement, which enables transfers from the U.K. Changes with respect to any of these matters may lead to additional costs and increase our overall risk exposure. The EU and U.S. adopted the EU Commission's adequacy decision for the EU U.S. Data Privacy Framework (the "Framework"), which entered into force on July 11, 2023. This Framework provides that the protection of personal data transferred between the EU and certified companies in the U.S. is comparable to that offered in the EU. Moreover, the U.K. Government adopted the Data Protection (Adequacy) Regulations 2023, also referred to as the "U.K.-U.S. Data Bridge," which, since October 12, 2023 allows companies to transfer personal data from the U.K. to the U.S. on the basis of the Framework. This provides a further avenue to ensuring transfers to the U.S. are carried out in line with GDPR. However, the long-term validity of the Framework remains uncertain and it has already been challenged before European courts.

All of these evolving compliance and operational requirements impose significant costs, such as costs related to organizational changes, implementing additional protection technologies, training employees and engaging consultants and legal advisors, which are likely to increase over time. In addition, such requirements may require us to modify our data processing practices and policies, utilize management's time and/or divert resources from other initiatives and projects. Any failure or perceived failure by us to comply with any applicable federal, state or foreign laws and regulations relating to data privacy and security could result in damage to our reputation, as well as proceedings or litigation by governmental agencies or other third parties, including class action privacy litigation in certain

jurisdictions, which would subject us to significant fines, sanctions, awards, injunctions, penalties or judgments. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Additionally, the NIS 2 Directive ("NIS 2") is replacing the cybersecurity legal framework under the current NIS framework in the EU, aiming to ensure a high level of cybersecurity in the region. NIS 2 brings new medium and large organizations providing services in the EU within scope of the legal framework. It extends to additional sectors and expands the list of in-scope healthcare organizations, including to certain providers engaged in research and development of medicinal products. The new regime imposes direct obligations on management in respect of an in-scope organization's compliance with NIS 2, requires covered organizations to put in place certain cyber risk management measures, strengthens incident reporting requirements, and provides supervisory authorities with greater oversight. Implementation and enforcement may vary by EU Member State, and the cybersecurity regulatory landscape in the EU may remain fragmented and uncertain. To the extent we are subject to NIS 2, we will require additional investment of our resources in compliance programs. Under NIS 2, companies may be subject to administrative fines of up to the greater of €10 million or 2% of worldwide turnover.

Risks Related to Product Development and Commercialization

Failure of, or defects in, our machine learning algorithms, artificial intelligence, and cloud-based computing infrastructure, including interruptions of service through third-party service providers, or increased regulation in the machine learning or artificial intelligence space, could impair our ability to process our data, develop products, or provide test results, and harm our business and results of operations.

AI is increasingly being used across the global business landscape, including in the life sciences and healthcare industries. AI and machine learning tools drive our proprietary technology and we expect our use of AI to increase as the technology rapidly evolves and improves. However, AI innovation presents risks and challenges that could impact our business. AI algorithms may be flawed. Datasets may be insufficient or contain biased information. Ineffective AI development and deployment practices by us or our commercial partners could result in violations of our confidentiality and privacy obligations or applicable laws and regulations, jeopardize our intellectual property rights, cause or contribute to unlawful discrimination, result in the misuse of personally identifiable information, including PHI, or give rise to significant cybersecurity risks, any of which could have a material adverse effect on our business, results of operations, and financial condition.

We may also face increased competition from other companies that are employing AI and related technologies, some of whom may develop more effective methods than we and any of our commercial partners have, which could have a material adverse effect on our business, results of operations, or financial condition. In addition, uncertainties regarding developing legal and regulatory requirements and standards may require significant resources to modify and maintain business practices to comply with U.S. and foreign laws concerning the use of AI and related technologies, the nature of which cannot be determined at this time.

We depend on technology systems for significant elements of our business operations. These technology systems support a variety of functions, including manufacturing operations, laboratory operations, data analysis, quality control, partner service and support, billing, research and development activities, and scientific and general administrative activities. The design, development, maintenance, and operation of our technology over time is expensive and complex, and may involve unforeseen difficulties including 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 results of operations.

Additionally, regulation in the machine learning and AI space is constantly evolving and limitations placed on the use of data, including personal information, health data, or genetic/genomic data in such systems may make it difficult for us to continue using our machine learning algorithms. For example, the EU's Artificial Intelligence Act (the "AI Act")—the world's first comprehensive AI law—entered into force on August 1, 2024 and, with some exceptions, is now partly applicable, with full applicability anticipated in August 2028. This legislation imposes significant obligations on providers and deployers of high risk artificial intelligence systems, and encourages providers and deployers of artificial intelligence systems to account for EU ethical principles in their development and use of these systems. If we deploy AI systems that are governed by the AI Act, we may be required to adopt higher standards of data quality, transparency, and human oversight, and adhere to specific and potentially burdensome and costly ethical, accountability, and administrative requirements. 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 or comparable regulatory authorities of AI or medical device software, we may be unable to provide, or our customers may stop using, our products. We expect that increased investment will be required in the future to continuously improve our use of AI technologies. As with many technological innovations, there are significant risks involved in developing, maintaining and deploying these technologies and there can be no assurance that the usage of or our investments in such technologies will always enhance our products or services or be beneficial to our business, including our efficiency or profitability.

Our vendors may in turn incorporate AI tools into their own offerings, and the providers of these AI tools may not meet existing or rapidly evolving regulatory or industry standards, including with respect to privacy and data security. Further, bad actors around the world use increasingly sophisticated methods, including the use of AI, to engage in illegal activities involving the theft and misuse of personal information, confidential information and intellectual property. Any of these effects could damage our reputation, result in the loss of valuable property and information, cause us to breach applicable laws and regulations, and adversely impact our business.

Our current products and future products, if cleared or approved, may be subject to product recalls. A recall of our products, either voluntarily or at the direction of the FDA or another governmental authority, or the discovery of serious safety issues with our products, could have a significant adverse impact on us. In addition, recalls—whether required or voluntary—can trigger increased regulatory scrutiny of our quality systems, manufacturing processes, and post-market surveillance activities.

The FDA has the authority to require the recall of commercialized devices that are subject to FDA regulation in the event of material deficiencies or defects in design or manufacture. The authority to require a recall must be based on an FDA finding that there is reasonable probability that the device would cause serious, adverse health consequences or death. We may also, on our own initiative, recall a product. The FDA requires that certain classifications of recalls be reported to the FDA within ten working days after the recall is initiated. In the case of our FDA-approved tests, a government-mandated or voluntary recall by us or one of our distributors could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products could impair our ability to produce our products in a cost-effective and timely manner, which would have an adverse effect on our reputation, results of operations and financial condition. Recall-related corrective actions may also require us to suspend manufacturing operations, quarantine inventory, retrain personnel, or implement significant modifications to our quality system, any of which could disrupt supply and increase costs. We may be subject to liability claims, may be required to bear costs or may take other actions that may have a negative impact on our future sales and our ability to generate profits. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving our products in the future that we determine do not require notification to the FDA. If the FDA disagrees with our determinations, the FDA could require us to report those actions and take enforcement actions for failing to report the recalls when they were conducted. Similar requirements apply in foreign jurisdictions. A future recall announcement could harm our reputation with customers and negatively affect our sales and financial condition.

If we initiate a correction or removal for one of our tests, issue a safety alert or undertake a field action or recall to reduce a risk to health imposed by the test, this could lead to increased scrutiny by the FDA, other foreign regulatory authorities, and our customers regarding the quality and safety of our tests and to negative publicity, including FDA alerts, press releases or administrative or judicial actions. Furthermore, circulation of any such negative publicity could harm our reputation, be used by competitors against us in competitive situations and cause customers to delay purchase decisions or cancel orders.

The sizes of the markets for our current product and future products, if approved, have not been established with precision, and may be smaller than we estimate.

Our estimates of the annual total addressable markets for our product and product candidates are based on a number of internal and third-party estimates, including, without limitation, the size of screening and patient populations, screening intervals, and the assumed prices at which we can sell tests for markets that have not been established. While we believe our assumptions and the data underlying our estimates are reasonable, these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors. As a result, our estimates of the annual total addressable market for our current or future products may prove to be incorrect. If the actual number of patients who would benefit from our products, the price at which we can sell our products, or the annual total addressable market for our products is smaller than we have estimated, it may impair our sales growth and have an adverse impact on our business.

We rely on a limited number of suppliers or, in some cases, sole suppliers, for some of our products and materials and may not be able to find replacements or promptly transition to alternative suppliers.

We rely on a limited number of suppliers or, in some cases, sole suppliers, for certain sequencers, reagents, blood tubes and other equipment, instruments and materials that we use in our laboratory operations. For example, Illumina, Inc. is our sole supplier of certain sequencers and related reagents and New England Biolabs, Inc. is our sole supplier of reagents for DNA analysis. In addition, certain of the laboratory equipment used in our research and development processes is customized or otherwise not readily replaceable with off-the-shelf alternatives. As a result, we may experience longer lead times to procure, repair or replace such equipment, including due to supply chain constraints, vendor capacity limitations, or the need for specialized components or technical expertise. An interruption in our laboratory operations could occur if we encounter delays or difficulties in securing this equipment, these instruments or these materials, and if we cannot then obtain an acceptable substitute. Any such interruption could significantly and adversely affect our business, financial condition, results of operations and reputation. These limited or sole suppliers could engage in diverse types of businesses, including selling products or providing services in competition with us, and there can be no assurance that we can continue to receive required equipment, instruments or materials from them.

We believe that there are only a limited number of other manufacturers that are capable of supplying and servicing the equipment and materials necessary for our laboratory operations, including sequencers and various associated reagents, and potentially replacing our current suppliers. The use of equipment or materials furnished by these replacement suppliers would require us to alter our laboratory operations. Transitioning to a new supplier would be time-consuming and expensive, may result in interruptions in our laboratory operations, could affect the performance specifications of our laboratory operations or could require that we revalidate our tests. There can be no assurance that we will be able to secure alternative equipment, reagents and other materials, bring such equipment, reagents and materials online, and revalidate our tests without experiencing interruptions in our workflow. If we should encounter delays or difficulties in securing, reconfiguring or integrating the equipment and reagents we require for our products or in revalidating our products, our business, financial condition, results of operations and reputation could be materially and adversely affected.

Risks Related to Government Regulation

The regulatory clearance, approval, or certification processes of the FDA and comparable foreign regulatory authorities or notified bodies are lengthy, time-consuming, and unpredictable. If we are ultimately unable to obtain any necessary or desirable regulatory approvals, clearances, or certifications, or if such approvals, clearances, or certifications are significantly delayed, our business will be substantially harmed.

We have obtained FDA approval for SimpleScreen CRC v1 in adults 45 and older who are at average risk for the disease, but have not yet obtained FDA clearance or approval for our other products in development. We also received breakthrough device designation from the FDA for our investigational blood-based lung cancer screening assay, SimpleScreen Lung, with proposed use in adults ages 50 to 80 who have at least a 20 pack-year smoking history and are not currently participating in guideline-recommended lung cancer screening and will continue clinical evaluation of the test, including through our prospective PROACT LUNG study (NCT06122077). We may also seek FDA approval or clearance for other products in the future. The time required to obtain, and our ability to obtain, clearance or approval by the FDA and comparable foreign regulatory authorities are unpredictable and typically depend on numerous factors, including the type, complexity, and novelty of our products and product candidates. In addition, policies, laws, regulations, or the type and amount of clinical data necessary to gain clearance or approval may change during the course of a test's clinical development and may vary among jurisdictions, which may cause delays in the clearance or approval 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 all or part of our data are unusable or insufficient for clearance or approval, require additional clinical or other data, including analytical validation data, determine that our manufacturing and quality systems are insufficient or in violation of applicable requirements, or determine that our clinical research program is insufficient or in violation of applicable good clinical practices ("GCPs") or other requirements related to research compliance, human subject protections, or data integrity. 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 U.S., a company must first submit an application for and receive 510(k) clearance pursuant to a premarket notification submitted under Section 510(k) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), approval of a premarket approval application ("PMA") submission with the FDA, or grant of a de novo classification request from the FDA, unless an exemption applies. In the process of obtaining PMA approval, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, analytical validation, nonclinical, 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.

The PMA approval process can be expensive, lengthy and uncertain. The process of obtaining a PMA is costly and uncertain and generally takes from one to three years, or even longer, from the time the application is submitted to the FDA, including if an Advisory Committee is needed to evaluate a novel technology. 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 regulatory 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 test, which may limit the potential commercial market for the test.

In the U.S., any modification to a product for which we receive marketing authorization may require us to submit a PMA and obtain FDA approval prior to implementing the change. For example, certain modifications to a PMA-approved device may require approval of a new PMA or a PMA supplement, or alternatively a notification or other submission to the FDA. If we obtain PMA approvals from the FDA, we may make modifications or add additional features in the future that we believe do not require approval of a PMA application or supplement or other regulatory submission. 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 products or modifications to existing products than we had expected, product introductions or modifications could be delayed or canceled, which could adversely affect our business.

In addition, we are or may become subject to new laws, regulations, and industry standards concerning medical devices proposed and enacted in various foreign jurisdictions. The EU regulatory landscape concerning in vitro diagnostic devices ("IVDs") has evolved and continues to undergo legislative change. On May 26, 2022, the EU Regulation 2017/746 on in vitro diagnostic medical devices (the "EU IVDR") became applicable, which repealed and replaced the EU Directive 98/79/EC on in vitro diagnostic medical devices (the "EU IVDD"). Subject to the transitional provisions (i.e., a tiered system extending the grace period for many devices, depending on their risk classification, before they have to be fully compliant with the EU IVDR) and in order to sell our products in the EU Member States, our products must comply with the general safety and performance requirements of the EU IVDR. Compliance with these requirements is a prerequisite to be able to affix the CE mark to our products under the EU IVDR, without which they cannot be sold or marketed in the EU. All in vitro diagnostic medical devices placed on the market in the EU must meet the general safety and performance requirements laid down in Annex I to the EU IVDR, including the requirement that a medical device must be designed and manufactured in such a way that, during normal conditions of use, it is suitable for its intended purpose. Medical devices must be safe and effective and must not compromise the clinical condition or safety of patients, or the safety and health of users and—where applicable—other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed

against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art. To demonstrate compliance with the general safety and performance requirements, manufacturers must undergo a conformity assessment procedure, which varies according to the type of in vitro diagnostic medical device and its (risk) classification. For most in vitro diagnostic medical devices (other than certain lowest-risk class A devices), a conformity assessment procedure requires the intervention of a notified body. The notified body would typically audit and examine the technical file and the quality system for the manufacture, design and final inspection of our devices. If satisfied that the relevant product conforms to the relevant general safety and performance requirements, the notified body issues a certificate of conformity, which the manufacturer uses as a basis for its own EU declaration of conformity. The manufacturer may then apply the CE mark to the device, which allows the device to be placed on the market throughout the EU.

If we fail to comply with applicable laws and regulations, we would be unable to affix the CE mark to our products, which would prevent us from selling them within the EU. The aforementioned EU rules are generally applicable in the EEA (which consists of the 27 EU Member States plus Iceland, Norway and Liechtenstein). Türkiye has aligned its national regulations with the EU framework for medical devices, and similar CE-marking requirements apply in Türkiye. Non-compliance with the above requirements would also prevent us from selling our products in these countries.

Following Brexit, EU laws such as the EU IVDR do not apply directly in Great Britain, however under the terms of the Windsor Framework (which amends and replaces aspects of the Protocol on Ireland/Northern Ireland), the EU IVDR does apply in Northern Ireland. Consequently, there are currently different regulations in place in Great Britain as compared to both Northern Ireland and the EU, respectively. Ongoing compliance with both sets of regulatory requirements may result in increased costs for our business.

Furthermore, on December 16, 2024, the U.K. government signed into law an amendment to the U.K. MDR, the Medical Devices (Post-market Surveillance Requirements) (Amendment) (Great Britain) Regulations 2024, to clarify and strengthen the post-market surveillance requirements for medical devices (including IVDs) in Great Britain. This amendment came into force on June 16, 2025. In addition, the Medicines and Healthcare products Regulatory Agency ("MHRA") (the U.K. medicines and medical devices regulator) launched a consultation from November 14, 2024 to January 5, 2025 on proposed changes to the pre-market requirements for medical devices in Great Britain. The MHRA has stated that it will incorporate feedback from this consultation into new U.K. legislation on pre-market requirements for medical devices in Great Britain. This new legislation is expected to come into force in 2026. Under the U.K. MDR, in order to be lawfully placed on the Great Britain market, Class A (non-sterile) IVDs need to be United Kingdom Conformity Assessment ("UKCA") certified by a UK approved body. However, certain IVDs in compliance with either the EU IVDD or EU IVDR (and that hold valid CE certificates) can continue to be placed on the Great Britain market until the sooner of certificate expiration or June 30, 2030. One of the key areas in the pre-market consultation was to obtain feedback on whether to remove the requirement for a medical device and its labeling (i.e. packaging and instructions for use) in Great Britain to bear a physical UKCA mark. Instead of requiring a medical device and its labeling to bear a UKCA mark, manufacturers would be required to assign a unique design identification ("UDI") to medical devices before they are placed on the Great Britain market. If this change is implemented, we may no longer be required to affix the physical UKCA mark to our devices, but we may need to assign and affix a UDI. Understanding and ensuring compliance with any new requirements is likely to lead to further complexity and increased costs to our business.

It is currently unclear to what extent the U.K. government will seek to align new U.K. legislation on pre-market requirements for medical devices in Great Britain with the EU. The EU laws that have been transposed into U.K. law through secondary legislation remain applicable in Great Britain, however the full extent of the new U.K. legislation on pre-market requirements for medical devices in Great Britain remains uncertain and may cause additional cost to our business.

The FDA, other regulators or notified bodies can delay, limit, or deny clearance, approval, or certification of a product for many reasons, including but not limited to the following:

- disagreement with the design, implementation, or results of, or interpretation of the data from, our clinical studies;
- determination that our product 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 certification, 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 product to assure effectiveness and safety in the population for which we seek approval, clearance, or certification;
- disagreement with our interpretation of data from clinical studies or may fail to accept data from clinical studies (or clinical sites), including if we fail to establish the integrity of our data;
- determination that our clinical studies otherwise fail to comply with applicable regulations, including GCP requirements;
- serious or unexpected adverse effects or other performance issues are identified with our existing or future products;
- determination that our manufacturing or quality system fails to comply with applicable regulations or otherwise fails to meet the standards necessary to support approval or certification; and
- the approval (or certification) policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval or certification.

There can be no assurance that our existing or future products for which we may seek clearance, approval, or certification will be approved, cleared, or certified by the FDA, a comparable foreign regulatory authority or a notified body on a timely basis, if at all. If our products or future products receive clearance, approval, or certification but there is uncertainty about such products among providers or payers, reimbursement may be adversely affected and we may not be able to sell our products. Compliance with FDA or comparable

foreign 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 products, if and when cleared, approved, or certified. The lengthy and unpredictable clearance, approval, and certification processes, as well as the unpredictability of the results of our clinical studies, may result in our failing to obtain regulatory clearance, approval, or certification to market our products, which would significantly harm our business, results of operations, reputation, and prospects.

Delays in receipt of, or failure to obtain, required FDA clearances or approvals, or approvals required in other jurisdictions for our products in development, or improvements to or expanded indications for our current offerings, could materially delay or prevent us from commercializing or otherwise adversely impact future product commercialization.

Unless otherwise exempted or subject to enforcement discretion, medical devices, which include in vitro diagnostic tests, must receive either FDA regulatory approval or clearance before being marketed in the U.S. Our product and our products in development will be regulated by the FDA as medical devices and we may develop new tests that are deemed medical devices and require FDA clearance or approval.

The FDA determines whether a medical device will require either regulatory approval or clearance based on statutory criteria that include the risk associated with the device and whether the device is similar to an existing, legally marketed product. The process to obtain either regulatory approval or clearance is costly, time-consuming, and uncertain. The regulatory approval process is generally more challenging than the clearance process. Even if we design a product that we expect to be eligible for the regulatory clearance process, the FDA may require that the product undergo the regulatory approval process. There can be no assurance that the FDA will ever permit us to market any new product that we develop. Even if regulatory approval or clearance is granted, such clearance or approval may include significant limitations on indicated uses, which could materially and adversely affect the prospects of any new medical device. Further, any post-market obligations such as post-approval studies, labeling changes, or enhanced reporting requirements could increase our costs and limit commercial uptake.

FDA regulatory approval or clearance is also required for certain enhancements we may make to any of our future FDA-approved or -cleared tests. FDA approval or clearance may also be required to make changes to the processes, equipment, reagents, and other consumables used in connection with any such future FDA-approved or -cleared test. FDA may further disagree with our assessment that certain modifications made to any of our future FDA-approved or -cleared tests do not require a new clearance or approval, and could require us to cease marketing the affected product until appropriate submissions are cleared or approved. Further, we may in the future develop and launch laboratory developed tests ("LDTs") and subsequently seek FDA clearance or approval of IVD versions of such LDTs. In 2024, the FDA finalized a regulation pursuant to which LDTs would be subject to the FDA's medical device requirements through a phase-out of its historical policy of enforcement discretion over LDTs over a period of four years (the "LDT Final Rule").

On March 31, 2025, the U.S. District Court for the Eastern District of Texas vacated the LDT Final Rule, reasoning that LDTs are not medical devices subject to the FDCA, and remanded the matter to the FDA for further consideration. This district court ruling was not appealed, and the FDA's final rule will no longer be implemented or enforced by the agency.

It remains uncertain what impact this ruling may have on the FDA's authority to review marketing applications for LDTs or to take enforcement action against tests marketed as LDTs. If the FDA imposes new or different requirements for marketing applications of LDTs to be reviewable in light of the District Court's decision, LDT manufacturers seeking FDA review may be required to establish that the test is a medical device subject to the FDCA, which could involve significant modification to test configurations, processes, or operations. If we could not ultimately obtain marketing authorization for our SimpleScreen Lung test or other tests where required or appropriate, our business would be substantially harmed. It is possible that the District Court's decision may limit the FDA's authority to review or approve tests that are in the process of pursuing marketing authorization, or that we may need to perform additional activities to support FDA review of our products as a result of this ruling.

For an in-vitro diagnostic device to be placed on the EU market, a CE mark (Conformité Européenne) demonstrating compliance with the EU IVDR is required. While Class A, non-sterile devices can be self-certified, all other devices require conformity assessment by an independent notified body. There is no certainty regarding the final EU IVDR approval. The transition from the previous EU IVDD to the EU IVDR continues to present regulatory, operational, and financial challenges, including potential delays in obtaining notified body certification and increased compliance costs.

Delays in receipt of, or failure to obtain, clearances or approvals could materially delay or prevent us from commercializing our products or result in substantial additional costs that could decrease our profitability. In addition, even if we receive FDA clearance or approval for a new or enhanced product, the FDA may condition, withdraw, or materially modify its clearance or approval.

Changes in funding for, or disruptions caused by global health concerns impacting, the FDA and other government agencies or notified bodies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new medical device products from being developed, authorized or commercialized in a timely manner, which could negatively impact our business.

The ability of the FDA, foreign regulatory authorities and notified bodies to review and authorize the sale or certify new products can be affected by a variety of factors, including government budget and funding levels; the ability of the FDA, foreign regulatory authorities, and notified bodies to hire and retain key personnel and accept the payment of user fees; statutory, regulatory, and

policy changes; personnel, policy and leadership shifts at the FDA; and other events that may otherwise affect their ability to perform routine functions. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA, other agencies and notified bodies may also slow the time necessary for new devices, including in vitro diagnostics to be reviewed and/or authorized or certified for marketing by necessary government agencies or notified bodies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

In the EU, notified bodies must be officially designated to certify in-vitro diagnostic devices in accordance with the EU IVDR. Only a small number of notified bodies have been designated to date and, therefore, they are facing a heavy workload and their review times have lengthened. This situation could impact the timelines for gaining the required certification under the EU IVDR to sell our future products in the EU and the way we are conducting, or intend to conduct, our business in the EU and the EEA (which consists of the 27 EU member states plus Iceland, Norway and Liechtenstein).

Clinical development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies may not be predictive of future study results. In addition, regulatory authorities may require more extensive clinical evidence than we anticipate, and the standards for clinical data adequacy can evolve over time.

Our ongoing research and development and clinical study activities are subject to extensive regulation and review by numerous governmental authorities both in the U.S. and abroad; as well as by notified bodies in some foreign jurisdictions. Obtaining the requisite regulatory approvals to commercialize any of our product candidates will require the completion of certain clinical development activities that demonstrate the performance and safety of our product candidates. For example, we received FDA approval for our SimpleScreen CRC v1 test in July 2026 for adults 45 and older who are at average risk for the disease, following the submission of our PMA and our response to a major deficiency letter from the FDA. While we have obtained FDA approval for SimpleScreen CRC v1, there can be no assurance that we will be able to obtain regulatory approval for future versions of SimpleScreen CRC or for any of our other product candidates in a timely fashion, if at all.

Clinical testing is difficult to design and implement, can take many years, can be expensive and carries uncertain outcomes. The results of nonclinical and clinical studies of our products conducted to date, and ongoing or future studies of our current, planned or future products may not be predictive of the results of later clinical studies, and interim results of a clinical study do not necessarily predict final results. The data and results from our clinical studies do not ensure that we will achieve similar results in future clinical studies. Failure can occur at any stage of clinical testing. Clinical studies may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and nonclinical testing in addition to those we have planned before we are able to seek marketing authorizations or certifications for our products or product candidates.

We may experience delays in our clinical studies for a number of reasons, which could adversely affect the costs, timing or successful completion of such clinical studies. Patient enrollment in clinical studies and completion of patient follow up depend on many factors, including the size of the patient population, the nature of the study protocol, the proximity of patients to clinical sites, the eligibility criteria for the clinical study, patient compliance, competing clinical studies and clinicians' and patients' perceptions as to the potential advantages of the product being studied in relation to other available products. In addition, patients participating in our clinical studies may drop out before completion of the study or experience adverse medical events unrelated to our products. Delays in patient enrollment or failure of patients to continue to participate in a clinical study may delay commencement or completion of the clinical study, cause an increase in the costs of the clinical study, or result in the failure of the clinical study.

Each of these outcomes would harm our ability to market our tests, generate revenue or achieve sustained profitability.

If the third parties on which we rely for the conduct of our clinical trials and results do not perform our clinical trial activities in accordance with good clinical practices and related regulatory requirements, we may be unable to obtain regulatory clearance or approval for our product candidates or commercialize our products.

In addition, we may find it necessary to engage CROs to perform data collection and analysis and other aspects of our clinical studies, which might increase the cost and complexity of our studies. We may also depend on clinical investigators, medical institutions and contract research organizations to perform the studies, and would control only certain aspects of their activities. We would be responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on third parties would not relieve us of our regulatory responsibilities. We and our third-party contractors are required to comply with GCPs which are regulations and guidelines enforced by the FDA, European Medicines Agency ("EMA") and comparable regulations enforced by foreign regulatory authorities for products in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of study sponsors, principal investigators and study sites. Sponsors, institutional review boards ("IRBs"), clinical trial sites, and investigators are subject to GCP bioresearch monitoring inspections by the FDA. The FDA has signaled that foreign GCP inspections will be increasing alongside greater transparency of GCP inspection outcomes. Recent policy proposals in the U.S., if enacted in the future, may make acceptance by the FDA of foreign clinical data more difficult or costly, including through potential higher fees on marketing applications that rely on foreign clinical data. If we or any third-party contractor fails to comply with applicable GCPs, the clinical data generated in clinical studies may be deemed unreliable and the FDA or comparable foreign regulatory authorities or notified bodies may require us to perform additional clinical studies before clearing or approving our marketing applications or certifying our products. In some cases, the FDA may refuse to accept data from a non-compliant clinical site entirely,

which could invalidate previously completed work or significantly reduce the statistical power of a study. A failure to comply with these regulations may require us to repeat clinical studies, which would delay the regulatory clearance, approval or certification process.

If there are delays in testing or clearances, approvals or certifications as a result of the failure to perform by third parties, our research and development costs would increase, and we may not be able to obtain regulatory clearance, approval, or certification for our tests. In addition, we may not be able to establish or maintain relationships with these parties on favorable terms, if at all. Each of these outcomes would harm our ability to market our tests, generate revenue or achieve sustained profitability.

Interim, "topline" and preliminary data from our clinical studies that we announce or publish from time to time 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 nonclinical studies or clinical studies, which is 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 related to the particular study. 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 at the time of disclosure. 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 data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. In some instances, additional statistical analyses or regulatory feedback may require re-analysis of data sets or exclusion of data previously considered valid. As a result, topline data should be viewed with caution until the final data are available.

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

Further, others, including regulatory agencies, such as the FDA, 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, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular clinical study is based on what is typically extensive information, and you or others may not agree with what we determine is 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 a particular product, product candidate or our business.

If the interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain clearance or approval for and commercialize our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Our current products and, if cleared or approved, future products may fail to achieve the degree of market acceptance necessary for commercial success.

The commercial success of our current products and any of our future products will depend on the degree of market acceptance by consumers, including self-insured employers, health systems, healthcare providers, life insurance companies, patients, and third-party payers. The degree of market acceptance of our products will depend on a number of factors, including:

- the performance, validation, and clinical utility of such products as demonstrated in clinical studies, from real-world use, and published in peer-reviewed journals;
- our ability to demonstrate the clinical validation and utility of our products and their potential advantages to the medical community;
- the ability of our products to demonstrate comparable or non-inferior performance in real-world intended use populations as in clinical studies;
- the willingness of consumers, including self-insured employers, health systems, healthcare providers, life insurance companies, patients, and others in the medical community to utilize our products;
- the willingness of commercial third-party payers and government payers to cover and reimburse our products, the scope and amount of which will affect an individual's or entity's willingness or ability to pay for our products and likely heavily influence healthcare providers' decisions to recommend our products;
- willingness of providers, patients, and others to learn about our products, and establish a sense of understanding and confidence in the use of our products;
- the concern that products could lead to unnecessary medical screening procedures or a high false positive rate and the associated costs of unnecessary workups resulting from false positives;

- the belief of providers, patients, and others that the use of our products in its intended use population is clinically appropriate, and not restricting its use to a narrower intended population;
- the introduction or market acceptance of future third-party products, including the expansion of the capabilities of existing products and tests that are reimbursed;
- the ability of our partners and our employees and contractors to ensure the safety and privacy of our patient data;
- publicity (adverse or positive) concerning our products or operations (including third-party partners, patient-facing service providers, vendors, or suppliers) or future third-party products, including adverse publicity resulting from the use of our products or offerings by third parties, including partners;
- our ability to fulfill test orders in a timely manner; and
- the strength of our marketing and distribution support and patient-facing service providers.

The failure of our products to be listed in physician guidelines or to be recommended as a first-line screening option or of our studies to produce favorable and consistent results or to be published in peer-reviewed journals could limit the adoption of our products. In addition, healthcare providers and third-party payers, including the Centers for Medicare and Medicaid Services ("CMS"), may rely on physician guidelines issued by industry groups, medical societies, and other key organizations, such as the U.S. Preventive Services Task Force ("USPSTF"), an independent, volunteer panel of experts in the field of prevention, evidence-based medicine and primary care, before utilizing or reimbursing the cost of any diagnostic or screening test.

Further, if our products or the technology underlying them do not receive sufficient favorable exposure in peer-reviewed publications, the rate of physician and market acceptance of our products and positive reimbursement coverage decisions for our products could be negatively affected. The publication of clinical data in peer-reviewed journals is a crucial step in commercializing and helping obtain reimbursement for products, and our inability to control when, if ever, results are published, if positive, may delay or limit our ability to derive sufficient revenues from any product that is developed using data from a clinical study.

Failure to achieve broad market acceptance of our products would materially harm our business, financial condition, and results of operations.

We market SimpleScreen Lung, and may market other future products as LDTs and we may seek to commercialize certain of our products in development as LDTs.

Our current and future products may be marketed as LDTs and we may seek to commercialize certain of our products in development as LDTs. For example, in October 2026, we announced the launch of SimpleScreen Lung, a laboratory-developed test. LDTs are clinical laboratory tests that are developed and validated by a laboratory for its own use. The FDA historically has taken the position that it has the authority to regulate such tests as medical devices under the FDCA but until recently has for the most part exercised enforcement discretion and has not required clearance, de novo classification, or approval of LDTs prior to marketing.

In May 2024, the FDA issued a final rule which amended the FDA's regulations to make explicit that LDTs are devices under the FDCA (the "LDT Rule"). Along with the LDT Rule, the FDA finalized a policy to phase out its enforcement discretion policy over a period of four years from issuance of the final rule. However, on March 31, 2025, the U.S. District Court for the Eastern District of Texas vacated the LDT Rule, reasoning that LDTs are not medical devices, and remanded the matter to the FDA for further consideration. The decision was not appealed, and in September 2025, the FDA rescinded the LDT Rule.

The FDA may assert that we are improperly marketing our current and future tests as LDTs and may assert we do not comply with applicable medical device requirements, and in such cases may take enforcement action against us and/or require us to seek premarket review and obtain marketing authorizations, which may require that we cease marketing any future LDT products until such marketing authorizations are obtained or the relevant applications are submitted. There can be no assurance that we will be able to obtain any required marketing authorization for our tests or that any labeling claims will be consistent with the claims we have made or intend to make for such products when launched as LDTs, or that such claims would be adequate to support continued adoption of and reimbursement for our products. In the event we are required to seek FDA marketing authorization for any current or planned products, 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 clinical studies, 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 studies beyond those we currently contemplate to support the intended uses of our products or future products, our planned commercial launches may be delayed and we may be required to cease commercialization of any products marketed as LDTs. A delay in the launch of our products or new versions of existing products, or significantly narrowing their intended uses, could negatively impact our 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. For example, in recent years, Congress has worked on legislation to create a novel regulatory framework governing a new category of FDA-regulated products, referred to as in vitro clinical tests ("IVCTs"), which would govern LDTs and would be separate and distinct from the existing medical device regulatory framework. For example, most recently, in March 2023, the Verifying Accurate Leading-edge IVCT Development Act of 2023 (the "VALID Act") was introduced. The bill would have established a risk-based approach to imposing requirements related to premarket review, quality systems, and labeling requirements on all IVCTs, including LDTs, but would grandfather certain LDTs marketed before the effective date of the bill and exempt them from

certain requirements. It is unclear whether legislative proposals such as the VALID Act (including any proposals that would, in contrast, reduce FDA oversight of LDTs) will be introduced or passed by Congress or signed into law by the President. Depending on the approach adopted under any potential legislation or regulation, certain LDTs (likely those of higher risk) may be required to undergo some form of premarket review, potentially with a transition period for compliance and a grandfathering provision. Any such legislation could substantially alter our commercial offering and marketing of LDTs and negatively impact our financial condition and results of operations. Additionally, as a result of the District Court decision the regulatory environment around LDTs could be significantly relaxed, which could increase competition and reduce the effectiveness of our regulatory and reimbursement strategy.

If the FDA does not have authority to regulate LDTs as medical devices, there could be significant impacts to us and our industry, and our ability to compete could be impaired.

We invested significantly in pursuing a PMA for our SimpleScreen CRC test, including conducting our "Prevention of Colorectal Cancer Through Multiomics Blood Testing" ("PREEMPT CRC") trial to support our PMA. We received PMA approval for our SimpleScreen CRC test in July 2026 for adults 45 and older who are at average risk for the disease, which we believe bolsters our position in the CRC screening market, and may increase or accelerate provider and patient adoption, commercial and government reimbursement and coverage, and international opportunities. In the event the FDA is not able to exercise its medical device authority with respect to LDTs, our competitors or potential competitors in the CRC screening market may face less stringent regulatory requirements to enter the market or to continue to market their tests and we may face increased competition in our industry, and adapting to the new regulatory and competitive environment could be difficult, costly and time-consuming. If we are not able to adapt to the changed regulatory environment and increased competition, our business and prospects could be materially impacted.

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

Obtaining and maintaining regulatory authorization or certification of products in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory authorization or certification in any other jurisdiction, but a failure or delay in obtaining regulatory authorization or certification in one jurisdiction may have a negative effect on the regulatory authorization or certification process in others. For example, even if the FDA or a comparable foreign regulatory authority grants clearance or approval for our products, comparable regulatory authorities or notified bodies in foreign jurisdictions may also need to authorize or certify the products in those countries. Premarket authorization and certification processes vary among jurisdictions and can involve requirements and administrative review periods different from those in the U.S., including additional clinical studies, because clinical studies conducted in one jurisdiction may not be accepted by regulatory authorities or notified bodies in other jurisdictions or the data may not be considered applicable to the jurisdiction's intended patient population based on demographic, medical practice, genetic, or other differences. In some cases, the price that we intend to charge for our products may also be subject to approval.

Obtaining foreign regulatory authorization or certification 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 products 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 or certification in other jurisdictions, our target market will be reduced and our ability to realize the full market potential of our products will be harmed.

Even if we receive regulatory authorization or certification of our products, we will continue to be subject to extensive regulatory oversight.

Medical devices are subject to extensive regulation by the FDA in the U.S. and comparable regulatory agencies in other territories where we do business. Now that SimpleScreen CRC v1 has received FDA approval, and if any of our other products are cleared or approved by the FDA or other comparable foreign regulatory agencies or certified by notified bodies in foreign jurisdictions, we will be required to timely file various reports. If these reports are not filed timely, regulators may impose sanctions and sales of our products may suffer, and we may be subject to product liability or regulatory enforcement actions, all of which could harm our business. In addition, as a condition of approving a PMA, the FDA may also require some form of post-approval study or post-market surveillance, whereby the applicant conducts a follow-up study or follows certain patient groups for a number of years and makes periodic reports to the FDA on the clinical status of those patients when necessary to protect the public health or to provide additional safety and effectiveness data for the device. The product labeling must be updated and submitted in a PMA supplement as results, including any adverse event data from the post-approval study, become available. Failure to conduct or timely complete post-approval studies in compliance with applicable regulations, update the product labeling, or comply with other post-approval requirements could result in withdrawal of approval of the PMA, which would harm our business and revenue.

The FDA and the FTC also regulate the advertising and promotion of medical devices to ensure that their promotional claims made are consistent with the applicable marketing authorizations, that there are adequate and reasonable data to substantiate the claims, and that the promotional labeling and advertising is neither false nor misleading in any respect. If the FDA or FTC determines that any of our promotional claims are false, misleading, not substantiated or not permissible, we may be subject to enforcement actions and we may be required to revise our promotional claims and make other corrections or restitutions. Similar requirements apply in foreign jurisdictions.

The FDA, state and foreign authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA, state or foreign regulatory agencies, which may include any of the following sanctions:

- adverse publicity, warning letters, untitled letters, fines, injunctions, consent decrees and civil penalties;
- repair, replacement, refunds, recalls, termination of distribution, administrative detention or seizures of our products;
- operating restrictions, partial suspension or total shutdown of production;
- customer notifications or repair, replacement or refunds;
- refusing our requests for clearances or approvals of new products, new intended uses or modifications to existing products;
- withdrawals of current clearances, approvals or certifications, resulting in prohibitions on sales of our products;
- refusal to issue certificates needed to export products for sale in other countries; and
- criminal prosecution.

Any of these sanctions could also result in higher than anticipated costs or lower than anticipated sales of our products and have a material adverse effect on our reputation, business, results of operations and financial condition.

In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay approval or clearance of our current or future products under development. For example, on February 23, 2022, the FDA issued a proposed rule to amend the Quality Management System Regulation ("QMSR") which establishes current good manufacturing practice requirements for medical device manufacturers, to align more closely with the International Organization for Standardization ("ISO") standards. This proposal was finalized by a final rule issued on January 31, 2024, and the requirements of this new Quality Management System Regulation became effective February 2, 2026.

In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new statutes, regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of any product candidates or make it more difficult to obtain marketing authorizations for, manufacture, market or distribute any product candidate we are developing. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require: additional testing prior to seeking marketing authorization, changes to manufacturing methods recalls, replacement or discontinuance of our products or additional record keeping.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be promulgated that could prevent, limit or delay marketing authorization of any product candidates we develop. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability.

The EU regulatory landscape concerning medical devices (including in vitro diagnostic medical devices) has evolved in recent years. On April 5, 2017 the EU IVDR was adopted to establish a modernized and more robust EU legislative framework, with the aim of ensuring better protection of public health and patient safety. Unlike directives, the EU IVDR does not need to be transposed into national law and therefore reduces the risk of discrepancies in interpretation across the different EU markets.

The misuse or off-label use of our products may harm our reputation in the marketplace, result in injuries that 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 or certification we may receive or obtain for our products by the FDA, comparable foreign regulatory authorities, or notified bodies will include specified indications for use and approved (or certified) labeling. Upon receipt of FDA authorization, or certification, we will continue to train our marketing personnel and direct our sales force to not promote our authorized (or certified) tests for uses outside of FDA-authorized (or certified) indications for use, known as "off-label uses." However, we are reliant on physicians and other providers to accurately provide information about our products to patients, including purposes, limitations, risks benefits, and interpretation of results, and we cannot, prevent a provider from using our products off-label, when in the provider's independent professional medical judgment he or she deems it appropriate. There may be increased risk of injury to patients if physicians attempt to use our products off-label, which could harm our reputation in the marketplace among physicians and patients.

If, after FDA authorization or certification, 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 products if they are not adequately trained, potentially leading to injury and an increased risk of product liability. If our devices are misused or used with improper technique, 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.

If our product, or any future products, if approved, result in direct or indirect participant or patient harm or injury, or otherwise involve errors that give rise to legal or regulatory exposure, we could be subject to significant reputational and liability risks.

Our success will depend on the market's confidence that our tests and test candidates can provide reliable, high-quality results. We believe that patients, customers, physicians, and regulators are likely to be sensitive to errors in the use of our tests or failure of our tests to perform as described, and there can be no guarantee that our tests will meet these expectations. A negative blood-based screening test does not rule out the presence of a particular disease.

Additionally, an individual undergoing unnecessary diagnostic tests on the basis of a false positive result or an erroneous result could expose us to reputational risks and potential liability. Similarly, an individual who receives a diagnosis shortly following a test result that did not detect the presence of a particular disease may create negative publicity about our tests or future tests, which would discourage adoption.

In addition to errors in test performance, our laboratory operations involve the risk of patient sample misidentification or mix-up, including circumstances in which one patient's sample may be inadvertently associated with another patient's identity, resulting in erroneous results. Such errors, whether arising from labeling, collection, handling, chain-of-custody failures, or information systems errors, could cause a patient to receive an incorrect screening result, delay appropriate diagnosis or treatment, or prompt unnecessary clinical intervention. A sample mix-up resulting in a false negative could prevent timely detection of a serious disease, while one resulting in a false positive could subject a patient to unnecessary and potentially harmful diagnostic follow-up. Either scenario could expose us to significant reputational harm, patient safety claims, and regulatory scrutiny, including potential enforcement action by CMS under the Clinical Laboratory Improvement Amendments of 1988 ("CLIA") or by applicable state laboratory licensing authorities.

Performance failures could establish a negative perception of our products among physicians, patients, customers, and regulators, jeopardize our ability to successfully commercialize our products, 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 for certain applications of our blood-based screening tests or test candidates directly involved with the choice to use certain treatments in a particular case. 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 false positive or false negative results, or from patient sample misidentification or other laboratory handling errors that result in the delivery of incorrect results to patients or ordering physicians. If our products result in direct or indirect participant or patient harm or injury, we could be subject to significant reputational and liability risks, and our reputation, business, financial condition, results of operations, and growth prospects could be materially adversely affected.

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

In the U.S., some of our products are currently 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 clinical sites enrolling participants in our registrational clinical studies. 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, while the FDA regulations require that RUO products be labeled "For Research Use Only. Not for use in diagnostic procedures," and that IUO products be labeled "For Investigational Use Only. The performance characteristics of this product have not been established," such products are not subject to the FDA's pre- and post-market controls for medical devices.

A significant change in the laws or policies governing RUO or IUO products or how they are enforced may require us to change our business model in order to maintain compliance. 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," or the RUO/IUO Guidance, which highlights the FDA's interpretation that distribution of RUO or IUO products with any labeling, advertising or promotion that suggests that clinical laboratories can validate the test through their own procedures and subsequently offer it for clinical diagnostic use as an LDT is in conflict with the RUO or IUO status. The RUO/IUO Guidance further articulates the FDA's position that any assistance offered in performing clinical validation or verification, or similar specialized technical support, to clinical laboratories, is in conflict with RUO or IUO status. 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 Guidance, 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, and results of operations.

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

Our operations are subject to various U.S. federal and state fraud and abuse laws. In addition, the commercialization of our products outside the U.S. would also subject us to foreign equivalents of the healthcare laws described below, among other foreign laws. The laws that may, currently or in the future, impact our operations include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering, or paying any remuneration (including any kickback, bribe, or rebate), 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 or recommendation 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 that statute as being violated if merely one purpose of any arrangement is to induce referrals or purchases. In 2018, Congress enacted 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 a clinical laboratory. Violations of EKRA may result in fines, imprisonment, or both, for each occurrence. The law includes a limited number of exceptions, some of which closely align with corresponding Anti-Kickback Statute exceptions and safe harbors, and others that materially differ. Currently, there is no regulation interpreting or implementing EKRA, nor any guidance released by a federal agency regarding the scope of EKRA. Based on the plain language of EKRA and recent case law, certain sales-based incentive sales representatives, or customers will not be subject to scrutiny or will withstand regulatory challenge under EKRA. In a notice published September 25, 2026, the U.S. Department of Justice denied a petition from the American Clinical Laboratory Association asking the Department to issue rules permitting laboratories to pay variable compensation to employed sales representatives, stating that doing so could reintroduce the kickback structures EKRA was designed to eliminate and that the existing EKRA framework permits employee compensation structures unrelated to referral volume. Because EKRA's exceptions differ from the Anti-Kickback Statute safe harbors and interpretive authority remains limited, we cannot assure you that our compensation arrangements, or those of commercial partners that promote tests performed by our laboratory, including incentive compensation for sales representatives, will withstand scrutiny or challenge under 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, including clinical laboratory services, if the physician or an immediate family member of the physician has a financial relationship 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;
- federal civil and criminal false claims laws, including the False Claims Act, which impose criminal and civil penalties, including through civil "qui tam" or "whistleblower" actions, against individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other third-party payers that are false or fraudulent. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute or Stark Law constitutes a false or fraudulent claim for purposes of the False Claims Act;
- federal criminal healthcare fraud and false statements laws, which prohibit, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program or falsifying or concealing material facts in connection with the delivery of or payment for healthcare benefits, items, or services; and the reverse false claims provisions of the False Claims Act, which prohibit knowingly making a false statement to improperly avoid, decrease, or conceal an obligation to pay money to the federal government. Similar to the federal Anti-Kickback Statute, 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;
- healthcare fraud and false statements laws, which prohibit, among other things, knowingly making a false statement to improperly avoid, decrease, or conceal an obligation to pay money to the federal government. Similar to the federal Anti-Kickback Statute, 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, subject to certain exceptions, prohibits, among other things, the offer or transfer of remuneration, including 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 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 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, as well as ownership and investment interests held by physicians and their immediate family members;
- federal 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, 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 arrangement, 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.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available and lack of clear guidance, it is possible that some of our business activities could, despite our efforts to comply, be subject to challenge under one or more of such laws. These risks extend to our arrangements with commercial partners, including Abbott, which commercializes SimpleScreen CRC in the United States, and government authorities could seek to hold us responsible for the conduct of partners that promote tests performed by our laboratory. Efforts to ensure that our business arrangements will comply with applicable healthcare and other applicable laws may involve substantial costs. In the future, it is possible that governmental and enforcement authorities will conclude that our business practices may 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. 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 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, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

If third-party payers, including commercial payers and government healthcare programs, do not provide coverage of, or adequate reimbursement for, our tests, our business and results of operations will be negatively affected.

Our revenue and commercial success depend on achieving coverage and reimbursement for our tests from payers, including both commercial and government payers. If payers do not provide coverage of, or do not provide adequate reimbursement for our tests, we may need to seek payment from the patient, which may adversely affect demand for our tests. Coverage determinations by a payer may depend on a number of factors, including but not limited to a payer's determination that a test is appropriate, medically necessary or cost-effective. If we are unable to provide payers with sufficient evidence of the clinical utility and validity of our test, they may not provide coverage, may provide limited coverage or may terminate coverage, which will adversely affect our revenues and our financial condition. To the extent that more competitors enter our markets, the availability of coverage and the reimbursement rate for our tests may decrease as we encounter pricing pressure from our competitors.

Each payer makes its own decision as to whether to provide coverage for our tests, whether to enter into a contract with us and the reimbursement rate for a test. Negotiating with payers is time-consuming, and payers often insist on their standard form contracts. There is no guarantee that a payer will provide adequate coverage or reimbursement for our tests or that we can reach an agreement with the payer on reasonable terms without being subject to additional regulatory and compliance risks. In cases where there is no coverage, or we do not have a contracted rate for reimbursement with the payer, the patient is typically responsible for a greater share of the cost of the test, which may result in delay of revenue, increase collection costs or decrease the likelihood of collection.

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. Payers may perform audits of historically paid claims and 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 tests 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, any subsequent recoupment could result in a material 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 do not have a mechanism to dispute these retroactive adjustments, and we cannot predict when, or how often, a payer might engage in these reviews.

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 specifically covered indications or where prior approval has been obtained. Becoming a participating provider can result in higher reimbursement amounts for covered uses of our test and, potentially, no reimbursement for non-covered uses identified under the payer's policies or the contract.

On June 8, 2026, CMS finalized a revision to NCD 210.3 covering qualifying non-invasive biomarker tests for colorectal cancer screening. Under the revised NCD, qualifying tests are covered once every three years for asymptomatic, average-risk Medicare beneficiaries ages 45 through 85, subject to specified ordering and patient-information requirements. Tests must be FDA market authorized and indicated for colorectal cancer screening, processed in a CLIA-certified laboratory, and demonstrate, based on FDA labeling, either sensitivity of at least 90% and specificity of at least 87%, or sensitivity of at least 79% and specificity of at least 90%, for detection of colorectal cancer compared with colonoscopy. Continued coverage also requires that the test meet the requirements of the FDA-required post-approval study, which for SimpleScreen CRC is a prospective, longitudinal study with defined enrollment milestones and periodic reporting to the FDA. Coverage and reimbursement for SimpleScreen CRC depends on satisfying the applicable requirements of this NCD, and FDA approval alone does not establish that all Medicare coverage requirements have been met. If SimpleScreen CRC does not satisfy these requirements, or if the NCD is further revised, Medicare coverage could be delayed, limited, or lost, which would adversely affect adoption of SimpleScreen CRC and the royalties and milestone payments we expect to receive from

Abbott. Medicare's NCD for Next Generation Sequencing, first established in 2018 and subsequently updated in 2020, similarly conditions national coverage on FDA authorization and defined patient criteria.

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 us, 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 tests in favor of less expensive tests, require pre-authorization for our tests, or impose additional pricing pressure on and substantial administrative burden for reimbursement for our tests. We expect to continue to focus substantial resources on increasing adoption of, and coverage and reimbursement for, our current tests and any future tests 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 tests. However, we cannot predict whether, under what circumstances, or at what price levels payers will cover and reimburse our tests. If we fail to establish and maintain broad adoption of, and coverage and reimbursement for, our tests, our ability to generate revenue could be harmed and our business and prospects could suffer.

The commercialization of our product and future products will depend heavily on payer coverage and reimbursement, and we may be unable to obtain or maintain adequate coverage or payment levels.

Reimbursement amounts and coverage decisions will heavily influence adoption and utilization of our product and future products. Payers may deny coverage, limit coverage to certain patient populations, require prior authorization, or reduce reimbursement levels. To secure favorable coverage decisions, we will need to generate sufficient clinical and economic evidence, which may be costly, time-consuming, or unsuccessful. Even where coverage is obtained, payment rates may be low, uncertain, or subject to frequent change.

One of the key elements of our strategy is to expand access to our tests by pursuing coverage and reimbursement from third-party payers, both private and government payers. If our products do not receive adequate coverage and reimbursement, if at all, from third-party payers, our ability to expand access to our products beyond our existing sales channels will be limited and our overall commercial success will be limited.

Coverage and reimbursement by third-party payers for early detection tests can be limited and uncertain. Healthcare providers may not order our products unless third-party payers cover and provide adequate reimbursement rates for a substantial portion of the price of our products. If we are not able to obtain adequate coverage and an acceptable level of reimbursement for our products from third-party payers, patients or other payers may be required to pay all or a substantial portion of the cost out-of-pocket, which could dissuade providers from ordering our tests and could reduce utilization and delay or reduce our collection of payment.

Even if our tests are covered by third-party payers, including commercial payers and government healthcare programs, those payers may modify coverage policies, billing rules, documentation requirements, prior authorization processes, utilization controls, or claims-processing practices at any time, often without advance notice. Such changes may delay or prevent payment for covered tests, increase administrative burdens, or require additional submissions or approvals. In addition, payers may withhold, delay, or deny payment for covered tests for administrative, technical, or compliance-related reasons, or may rely on third-party utilization management vendors or external review organizations whose determinations could further delay or reduce reimbursement. Resolving such payment delays or denials may require costly and time-consuming appeals or resubmissions, with uncertain outcomes.

Coverage determinations and reimbursement levels may be made on an indication-by-indication basis and may include restrictions based on population, ordering provider, frequency, or other criteria. In addition, even if we establish relationships with payers to provide our products at negotiated rates, such agreements would not obligate any healthcare providers to order our tests or guarantee that we would receive reimbursement at adequate levels.

Tests used in screening contexts may face incremental scrutiny from third-party payers given the potential downstream costs of follow-on diagnostic workups and the potential for false positives on an absolute basis when deployed at scale.

If we are unable to obtain or maintain adequate coverage and reimbursement, or if we experience material payment delays, denials, or increased administrative burdens, our ability to commercialize our future products, generate revenue, and achieve profitability may be materially impaired.

Traditional fee-for-service Medicare generally does not cover screening tests absent a statutory benefit, and if our tests are treated as screening tests, our ability to obtain Medicare coverage and reimbursement may be limited, delayed, or require legislative or guideline changes.

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. Traditional fee-for-service Medicare generally does not cover screening tests, which are considered preventive services, that are performed in the absence of signs or symptoms of illness or injury, unless there is a statutory provision that explicitly authorizes coverage of the test. Medicare coverage of SimpleScreen CRC rests on NCD 210.3, as described above. SimpleScreen Lung is marketed as an LDT, and there is currently no formal Medicare coverage for SimpleScreen Lung, and obtaining it would require a new national coverage determination or legislative change, and CMS could condition coverage on FDA authorization, which could take years or not occur.

CMS has authority to cover certain additional preventive services through an NCD process where the service is recommended with a grade of A or B by the USPSTF, among other criteria, and the USPSTF generally waits for regulatory authorization (e.g., FDA authorization) before it considers undertaking reviews of novel technology. Historically, evidence packages supporting USPSTF A/B recommendations have included long-term outcomes (including mortality) data, which may require extended follow-up and significant resources. We do not expect SimpleScreen CRC's post-approval study to generate longitudinal data for several years, which could delay or limit USPSTF consideration. The USPSTF did not meet for an extended period beginning in 2025, and HHS appointed new members in 2026. We cannot predict whether or when the USPSTF will review blood-based colorectal cancer or other screening tests, what it will recommend, or how it will treat blood-based tests relative to other screening options. Without a USPSTF A or B recommendation, commercial plans are generally not required under the Affordable Care Act to cover our tests without patient cost-sharing, which could reduce utilization.

If our future tests are treated as screening tests under Medicare, fee-for-service Medicare coverage and reimbursement may be unavailable unless we pursue substantial additional measures (which may include obtaining a favorable USPSTF grade and seeking an NCD) or unless Congress enacts a statutory provision authorizing coverage of multi-cancer early detection or similar screening tests. Medicare coverage can also be changed by statute, but any legislative effort may be delayed, may not be enacted, or may be enacted in narrower or less favorable terms. Any such pathway could take several years, require significant investments and resources, and may ultimately be unsuccessful.

If we are unable to obtain Medicare coverage and reimbursement for screening uses, adoption and utilization of our future tests may be materially limited, our commercial strategy may be delayed or require modification, and our business, financial condition, and results of operations could be adversely affected.

See the section of our proxy statement/prospectus filed with the SEC on June 17, 2026 titled "Business—Payer Coverage and Reimbursement" for additional information.

Our product and future products may not receive favorable payment determinations under Medicare, and changes in Medicare payment methodologies, including under the federal law PAMA, could reduce the reimbursement amounts for our tests.

Medicare coverage, coding, and payment will be essential to our commercial strategy. Payment amounts for diagnostic tests under the Clinical Laboratory Fee Schedule ("CLFS") may be negatively affected by changes in methodology, including future rulemaking or legislative reform affecting the Protecting Access to Medicare Act of 2014 ("PAMA"). As described in the section of our proxy statement/prospectus filed with the SEC on June 17, 2026 titled "Business—Payer Coverage and Reimbursement—Government Payers—Medicare Coverage and CLFS Payment," PAMA requires certain laboratories to report private-payer rates that CMS uses to establish CLFS payment rates; Congress has repeatedly delayed reporting cycles, most recently in the Consolidated Appropriations Act, 2026, which delayed scheduled payment reductions through 2026 and reopened private-payer data reporting from May 1 through July 31, 2026, but did not change PAMA's underlying structure, so reductions of up to 15% per year may resume beginning in 2027 and continue through 2029. Future changes to PAMA or CMS implementation of updated median rates following the 2026 reporting period could materially affect reimbursement for our tests. If Medicare payment rates for our future tests are insufficient, our revenue, margins, and commercial viability could be materially harmed.

We may be unable to obtain the coding necessary to secure appropriate payment for our future tests, and coding changes may adversely affect reimbursement.

As described in the section of our proxy statement/prospectus filed with the SEC on June 17, 2026 titled "Business—Payer Coverage and Reimbursement—Government Payers— Coding and the MolDx Program," coding, including Current Procedural Terminology ("CPT") codes and Z-Codes issued through the MolDx program, plays a significant role in how payers adjudicate claims. We may be unable to obtain unique CPT codes or Z-Codes, or payers may determine that our tests should be billed under less favorable miscellaneous or existing codes. Coding assignments may also change over time, which could reduce payment levels or delay claims adjudication. Any of these outcomes could materially adversely affect our commercialization strategy and financial results.

Commercial payer contracting is complex and uncertain, and failure to secure contracted status with key payers could limit adoption of our tests.

Commercial payers may determine not to contract with us, may impose restrictive terms, or may reimburse us only as a non-participating provider at significantly lower rates. As described in the section of our proxy statement/prospectus filed with the SEC on June 17, 2026 titled "Business—Payer Coverage and Reimbursement—Commercial Payers," contracted status often improves payment levels but may exclude non-covered or investigational uses of our tests. If we fail to obtain and maintain favorable commercial payer contracts, adoption of our future tests may be limited, reimbursement for out-of-network services may be insufficient, and our business and prospects could be adversely affected. Even if commercial payers contract with us, they may still deny payment or change requirements for payment at any time without notice which may require us to appeal claims which could be costly and time consuming and unsuccessful. Furthermore commercial payers may break contracts and withhold payment at any time and for any reason and threaten the company with legal action should we demand fulfillment of the contract. We may not have sufficient time or resources for protracted legal disputes with payers.

Evolving federal and state laboratory regulations, including the CLIA and state licensure requirements, may impose significant costs or delay commercialization of our future tests.

We are required to hold certain federal, state and local licenses, certifications and permits to conduct our business. CMS regulates all non-research laboratory testing performed on humans in the U.S. through the CLIA. The Division of Clinical Laboratory Improvement & Quality, within the Quality, Safety & Oversight Group, under the Center for Clinical Standards and Quality ("CCSQ"), has the responsibility for implementing the CLIA program. Under CLIA, we are required to hold a certificate applicable to the type of laboratory tests we perform and to comply with standards applicable to our operations, including test processes, personnel, facilities administration, equipment maintenance, recordkeeping, quality systems and proficiency testing, which are intended to ensure, among other things, that clinical laboratory testing services are accurate, reliable and timely.

We maintain CLIA certification for our Brisbane, California laboratory that allows us to perform high complexity testing. A laboratory that is certified as "high complexity" under CLIA may develop, manufacture, validate and use proprietary tests referred to as LDTs. CLIA requires analytical validation including accuracy, precision, specificity, sensitivity and establishment of a reference range for any LDT used in clinical testing. The regulatory and compliance standards applicable to the testing we perform may change over time, and any such changes could have a material effect on our business. In addition, CLIA allows states to impose additional laboratory licensure requirements, some of which apply to out-of-state laboratories performing testing for residents of those states. Penalties for non-compliance with CLIA requirements include a range of enforcement actions, including suspension, limitation or revocation of the laboratory's CLIA certificate, as well as directed plan of correction, state on-site monitoring, civil monetary penalties, civil injunctive suit or criminal penalties.

If we were to lose our CLIA certification, whether as a result of a revocation, suspension or limitation, we would no longer be able to offer our tests, which would limit our revenues and seriously harm our business. If we were to lose, or fail to obtain, a license in any other state where we are required to hold a license, we would not be able to test specimens from those states, which also could limit our revenues and seriously harm our business.

As described in the section of our proxy statement/prospectus filed with the SEC on June 17, 2026 titled "Business—Clinical Laboratory Framework—Federal and State Laboratory Licensing Requirements," our failure to maintain required certifications or licenses could require us to redirect testing, suspend test availability in affected jurisdictions, or delay commercialization. Changes to CLIA or state laboratory laws could also impose additional requirements or create uncertainty around the regulatory treatment of multi-omics tests. These developments could increase our costs, delay commercial launch, or materially limit our ability to offer testing services.

We are subject to extensive federal and state fraud and abuse laws, and failure to comply with these laws could result in significant penalties or impair our ability to commercialize our future products.

As described in the section of our proxy statement/prospectus filed with the SEC on June 17, 2026 titled "Business—Federal and State Fraud and Abuse Laws," we are or may be subject to numerous federal and state laws governing financial relationships with healthcare providers, laboratories, and referral sources, including the Anti-Kickback Statute ("AKS"), Eliminating Kickbacks in Recovery Act ("EKRA"), Stark Law, and the False Claims Act ("FCA"). These laws are complex, broadly interpreted, and subject to evolving enforcement priorities. Any actual or alleged failure to comply could result in substantial civil, criminal, and administrative penalties, corporate integrity agreements, exclusion from government healthcare programs, reputational harm, and significant business disruption. Even arrangements that are common industry practice carry inherent compliance risk. Investigations or enforcement actions, regardless of outcome, could materially harm our business, financial condition, and results of operations.

Failure to comply with HIPAA, state privacy laws, or international data protection requirements could expose us to liability and disrupt our operations.

As described in the section of our proxy statement/prospectus filed with the SEC on June 17, 2026 titled, "Business—Privacy and Security Regulations," we are or will be subject to HIPAA, certain aspects of state privacy laws such as the CCPA, and potentially the GDPR and other international privacy frameworks as we expand globally. These laws impose obligations related to the use, disclosure, security, and breach reporting of personal information. Non-compliance may result in civil monetary penalties, regulatory investigations, litigation, contractual liability, and reputational harm. Evolving legal requirements may increase our compliance burden and require modifications to our processes, systems, and data governance practices.

Changes in healthcare policy, including future healthcare reform measures, could adversely affect our business.

As described in the section of our proxy statement/prospectus filed with the SEC on June 17, 2026 titled, "Business—U.S. Healthcare Reform," federal and state governments continue to propose and adopt healthcare reforms that impact coverage, reimbursement, payment methodologies, and market access. Future reforms could reduce payment rates, restrict coverage of preventive or diagnostic tests, impose new compliance obligations, or otherwise negatively affect demand for our future products. Because we cannot predict the scope or timing of future healthcare policy changes, their impact on our business is inherently uncertain.

We are subject to export and import controls, economic sanctions and anti-corruption laws and regulations of the U.S. and other jurisdictions. We can face criminal liability and other serious consequences for violations of these laws and regulations, which can harm our business.

We are 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. We are also subject to anti-corruption and anti-bribery laws, including the U.S. Foreign Corrupt Practices Act of 1977 ("FCPA") as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, and other state and national anti-bribery laws in the countries in which we conduct activities and/or operate, including the U.K. Bribery Act. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other partners from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. 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. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other partners, even if we do not explicitly authorize or have actual knowledge of such activities. Any violation of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

If we or any third-party we engage now or in the future fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs or liabilities that could have a material adverse effect on our business.

We and any contract manufacturers and suppliers we engage are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. We may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and waste. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties. With respect to the operations of our current and any future third party contract manufacturers, it is possible that if they fail to operate in compliance with applicable environmental, health and safety laws and regulations or properly dispose of wastes associated with our products, we could be held liable for any resulting damages, suffer reputational harm or experience a disruption in our operations. In addition, our supply chain may be adversely impacted if any of our third-party contract manufacturers become subject to injunctions or other sanctions as a result of their non-compliance with environmental, health and safety laws and regulations. Although we maintain general liability insurance as well as workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities.

Further, our headquarters and laboratory facilities are located on a former landfill for which redevelopment or use is complicated by the presence or potential presence of a hazardous substance, pollutant, or contaminant. Although this has not impacted us to date, certain events could occur that may require us to pay significant clean-up or other costs in order to maintain our operations. Such events include, but are not limited to, changes in environmental laws, discovery of new contamination, or unintended exacerbation of existing contamination. The occurrence of any such event could materially affect our ability to continue our business operations on such property.

Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and commercial partners. Misconduct by these parties could include intentional failures to comply with the regulations of the FDA, CMS and non-U.S. regulators, comply with healthcare fraud and abuse laws and regulations in the U.S. and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing, and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct could also involve the improper use of information obtained in the course of clinical studies, which could result in regulatory sanctions and cause serious harm to our reputation. We currently have a code of conduct applicable to all of our employees, but it is not always possible to identify and deter employee misconduct, and our code of conduct and the other 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, lawsuits or other actions stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant civil, criminal and administrative penalties, including, without limitation, damages, monetary fines, individual imprisonment, disgorgement of profits, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs or from coverage of commercial payers, contractual damages, reputational harm, diminished profits and future earnings, additional reporting or oversight obligations if we become subject to

a corporate integrity agreement or other agreement to resolve allegations of non-compliance with the law and curtailment or restructuring of our operations, which could have a significantly adverse impact on our business. Whether or not we are successful in defending against such actions, we could incur substantial costs and expenses, including legal fees, and divert the attention of management from the operation of our business.

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 may develop and commercialize technology and tests similar or identical to ours, and our ability to successfully commercialize our products may be impaired.

Our ability to compete successfully will depend in part on our ability to obtain and/or enforce intellectual property protection for our tests and products, preserve our trade secrets, and operate without infringing, misappropriating or otherwise violating the intellectual property and proprietary rights of third parties. Filing, prosecuting, and defending intellectual property rights for our tests, products and other technologies in all countries throughout the world may be prohibitively expensive and time-consuming. Furthermore, the laws of some foreign countries do not protect intellectual property rights to the same extent or in the same manner as the laws of the U.S. As a result, we may encounter significant problems in protecting and enforcing our intellectual property both in the U.S. and abroad.

We may not be able to file, prosecute, maintain, enforce, and/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. We may choose not to seek patent protection for certain innovations and may choose not to pursue patent protection in certain jurisdictions. It is also possible that we may fail to identify patentable technologies in a timely fashion, which may impair our ability to obtain patent protection on such technology at all. Furthermore, in some cases, we have only filed provisional patent applications on certain aspects of our products and technologies, and these provisional patent applications are 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 did not 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 U.S. or other jurisdictions.

Moreover, while we have applied for patents that protect aspects of our technology in the U.S. and several other jurisdictions, we cannot assure you that our intellectual property position, including our pending patent applications and any patents that may issue from our patent applications, will not be challenged or that all patents for which we have applied 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. The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability, and any of our patents may be challenged in the courts or patent offices in the U.S. or abroad. As a result of such challenges, our pending or future patent applications may not result in issued patents, or the scope of future patents may not be as broad as we anticipate, or our future issued patents may be held invalid or unenforceable. If we were to lose patent coverage for any of our products or product candidates, this may adversely impact our commercial partnerships, which could put us at a competitive disadvantage with respect to commercialization.

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

Our competitors or other third parties may be able to circumvent our future patents by developing similar or alternative technologies or tests in a non-infringing manner. Competitors could also set up laboratories outside the countries in which we have filed patent applications in order to compete without infringing upon our intellectual property, even if they collect patient samples from countries in which we do have patent protection. Competitors could also run machine learning models outside of the countries in which we have filed patent applications in order to compete without infringing upon our intellectual property, even if certain parts of the data from the models are used in countries in which we do have patent protection. If a third party obtains an issued patent on inventions we use in our products, that party could 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. In addition, to the extent we may grant in the future, licenses or sublicenses of our intellectual property rights to third parties, we cannot provide any assurance 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. We also cannot provide assurances that third-party patents or other intellectual property do not exist that our current or future technology, manufacturing methods, products, methods or tests infringe or will infringe, which could result in litigation, the imposition of injunctions preventing our use of such technology, manufacturing methods, products or future methods or tests, 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. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition to the protection that may be afforded by future patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce, and any other elements of our technology and products that involve proprietary know-how, information or technology that will not be covered by future patents. We may also rely on trade secret protection as temporary protection for concepts that may be included in a future patent filing. However, trade secret protection will not protect us from innovations that a competitor develops independently of our proprietary know-how. If a competitor independently develops a technology that we protect as a trade secret and files a patent application on that technology, then we may not be able to patent that technology in the future, and may require a license from the competitor to use our own know-how, and if the license is not available on commercially viable terms or at all, then we may not be able to launch our product or may be prevented from using our product. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us. Although we require all of our employees to assign their inventions to us and require all of our employees, consultants, advisors, and any third parties who have access to our trade secrets, know-how, and proprietary information or technology to enter into confidentiality agreements, we cannot be certain we have entered into such agreements with all applicable parties, and such agreements can be breached. We cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques, or determine our trade secrets through the reverse engineering of our products. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we may not be able to establish or maintain a competitive advantage in our market, and this scenario could materially adversely affect our business, financial condition, and results of operations.

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

In addition to seeking patents for our products and other technologies, we also 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. Some machine learning and algorithmic technologies are commonly protected as trade secrets rather than being patented. We expect our trade secrets and know-how to be disseminated over time within the industry through independent development, the publication of journal articles describing the methodology, and the movement of personnel from academic to industry scientific positions.

Trade secrets and know-how can be difficult to protect. We seek to protect these trade secrets and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, directors, corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, suppliers, service providers, consultants, advisors, and other third parties. It is also our policy to enter into confidentiality and invention or patent assignment agreements with our employees and consultants as well as to train our employees not to bring or use proprietary information or technology from former employers to us or use it in their work and remind departing employees when they leave their employment of their continuing confidentiality obligations. We cannot guarantee that we have entered into such agreements with each party that may have access to our trade secrets or proprietary technology and processes. Despite our efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, and time-consuming, and the outcome is unpredictable. Some courts outside the U.S. are less willing or unwilling to protect trade secrets. For example, in China, claims regarding infringement or misappropriation of trade secrets are difficult to prove, and consequently plaintiffs are rarely successful in bringing these claims. 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. 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 materially and adversely harmed.

Despite our active trade secret registry and training, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. Though our agreements with third parties typically restrict the ability of our advisors, employees, collaborators, licensors, suppliers, third-party contractors, and consultants to publish data potentially relating to our trade secrets, our agreements may contain certain limited publication rights. Because from time to time we expect to rely on third parties in the development, manufacture, and distribution of our products and provision of our services, we must, at times, share trade secrets with them. Despite employing the contractual and other security precautions described above, the need to share trade secrets increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. 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. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be harmed. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We cannot ensure that patent rights relating to inventions described and claimed in our pending patent applications will issue or that future patents based on our patent applications will not be challenged and rendered invalid and/or unenforceable.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting our products or technologies by obtaining and defending patents. We have 144 pending patent applications in our portfolio consisting of 31 pending U.S. patent applications and 113 pending foreign patent applications; however, we cannot predict:

- if and when patents may issue based on our patent applications;
- the scope of protection of any patent issuing based on our patent applications;
- whether the claims of any patent issuing based on our patent applications will provide protection against competitors;
- whether or not third parties will find ways to invalidate or circumvent our patent rights;
- whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications;
- whether we will need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose; and/or
- whether our patent applications will result in issued patents with claims that cover our products or technologies or uses thereof in the U.S. or in other jurisdictions.

We cannot be certain that the claims in our pending patent applications directed to our tests, products or technologies will be considered patentable by the U.S. Patent and Trademark Office ("USPTO") or by patent offices in foreign countries. There can be no assurance that any such patent applications will issue as granted patents. One aspect of the determination of patentability of our inventions depends on the scope and content of the "prior art," information that was or is deemed available to a person of skill in the relevant art prior to the priority date of the claimed invention. There may be prior art of which we are not aware that may affect the patentability of our patent claims or, if issued, affect the validity or enforceability of a patent claim. Publications of discoveries in scientific literature often lag behind the actual discoveries, and patent applications in the U.S. 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 pending patent applications, or that we were the first to file for patent protection of such inventions. In some jurisdictions, including the U.S., certain cancer screening, detection and diagnostic inventions, or software- or machine learning-based inventions may be determined not to be patentable because they fail to meet patent eligibility requirements. 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 new diagnostic tests, patents protecting such tests might expire before or shortly after such products are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing tests similar or identical to ours.

Even if patents do issue based on our patent applications, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, future patents in our portfolio may not adequately exclude third parties from practicing relevant technology or prevent others from designing around our claims. If the breadth or strength of our intellectual property position with respect to our products or technologies is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize our products or technologies. In the event of litigation or administrative proceedings, we cannot be certain that the claims in any of our issued future patents will be considered valid by courts in the U.S. or foreign countries. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

Periodic maintenance fees, renewal fees, annuity fees, and various other government fees on patents and applications will be due to be paid to the USPTO and patent agencies outside of the U.S. over the lifetime of our patent applications and future patents. Such agencies also require compliance with several procedural, documentary, fee payment, and other similar provisions during the patent application process. In certain circumstances, we may in the future rely on our licensing partners to pay these fees and to take the necessary actions to comply with other requirements to maintain licensed patents during their term. We rely on industry-standard service providers to help us comply with these requirements and effect payment of these fees with respect to the patent applications and future patents that we own. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which 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. In such an event, third parties and other competitors might be able to enter the market with similar or identical tests or technology, which could have a material adverse effect on our business, financial condition, results of operations, and prospects. It is also possible that a deadline for the USPTO or a foreign patent office could be inadvertently missed during prosecution of our patents that may result in an unrecoverable loss of patent rights.

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

Patents are of national or regional effect, and although we have pending patent applications in the U.S., filing, prosecuting and defending patents on all of our research programs and technologies in all jurisdictions throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the U.S. can be less extensive than those in the U.S.

In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the U.S. Diagnostic test inventions and machine learning inventions may not be able to be protected in foreign countries in the same manner or with the same scope as they are in the U.S. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S. or from selling or importing products made using our inventions in and into the U.S. or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is

not as strong as that in the U.S. These competitor products may compete with our products or technologies, and our future patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Various companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of many countries do not favor the enforcement of patents and other intellectual property protection, particularly those relating to the biotechnology and pharmaceutical industries, which could make it difficult for us to stop the infringement of our future patents or marketing of competing products in violation of our proprietary rights. Various countries outside the U.S. have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. As a result, a patent owner may have limited remedies in certain circumstances, which could materially diminish the value of such patents. If we are forced to grant a license to third parties with respect to any future patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Further, the standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. As such, we do not know the degree of future protection that we will have on our technologies and products. While we will endeavor to protect our technologies and products with patents, as appropriate, the process of obtaining patents is time-consuming, expensive, and unpredictable.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to ours but that are not covered by the claims of our patent applications or patents that may issue from such patent applications;
- we or our collaborators or future licensors might not have been the first to make the inventions covered by a pending patent application or future patent that we own or license;
- we or our collaborators or future licensors might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating or otherwise violating our intellectual property or proprietary rights;
- it is possible that noncompliance with the USPTO's and foreign governmental patent agencies' requirements for a number of procedural, documentary, fee payment, and other provisions during the patent process can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- it is possible that our pending patent applications will not lead to issued patents;
- future issued patents that we own may be revoked, modified or held invalid or unenforceable, as a result of legal challenges by our competitors or other third parties;
- our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- we cannot predict the scope of protection of any patent issuing based on our patent applications, including whether the patent applications that we own will result in issued patents with claims that are directed to our products or technologies in the U.S. or in other jurisdictions;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the U.S. for disease detection, diagnostic, and/or screening technologies that prove successful, as a matter of public policy regarding worldwide health concerns;
- countries other than the U.S. may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing products or technologies;
- the claims of any patent issuing based on our patent applications may not provide protection against competitors or any competitive advantages or may be challenged by third parties;
- if enforced, a court may not hold that our future patents are valid, enforceable and infringed;
- we may need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose;
- we may choose not to file a patent application in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent application covering such intellectual property;
- we may fail to adequately protect and police our trademarks and trade secrets;
- the government could have the option to gain certain rights in inventions covered by our patents if the inventions relate to government grants received by us, especially if we do not meet certain grant requirements for inventions under the Bayh-Dole Act;
- the patents of others may have an adverse effect on our business, including if others obtain patents claiming subject matter similar to or improving that covered by our patent applications and future patents; and

- the patents of others may have an adverse effect on our business if they are asserted against a third-party supplier for components, accessories, and/or materials that we utilize in our products; such an event could result in a disruption or interruption in supply from these suppliers, or in the operations of such suppliers, which may negatively impact our business, supply chain and laboratory operations and could delay our ability to develop and commercialize our tests, including our CRC genomics assay.

Should any of these or similar events occur, they could significantly harm our business, financial condition, results of operations and prospects.

Our success depends on our ability to develop and commercialize our technology without infringing, misappropriating or otherwise violating the intellectual property rights of third parties. Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our commercial success in part depends upon our ability, and the ability of our partners, to market, sell, and distribute our products and use our proprietary technologies without infringing, misappropriating or otherwise violating the proprietary rights of third parties. Many of our competitors have sizable patent portfolios that cover various aspects of cancer diagnostics and machine learning, including patents that may potentially be alleged to cover our products or technology. As our industry expands and more patents are issued, the risk increases that our products and technologies may be subject to claims of infringement of the patent rights of third parties. We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope, or expiration of a third-party patent, which might adversely affect our ability to develop and market our products. There can be no assurance that our operations do not, or will not in the future, infringe existing or future third-party patents. Identification of third-party patent rights that may be relevant to our operations is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases, and the difficulty in assessing the meaning of patent claims. We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims, or the expiration of relevant patents, are complete or thorough, nor can we be certain that we identify each and every third-party patent and pending application in the U.S. and abroad that is relevant to or necessary for the commercialization of our products or technologies in any jurisdiction.

Numerous U.S. and foreign patents and pending patent applications exist in our technology space that are owned by other parties. Our competitors and other parties in both the U.S. and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained, or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our products. We do not always conduct independent reviews of pending patent applications of and patents issued to other parties. Patent applications in the U.S. and elsewhere are typically published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Certain U.S. applications that will not be filed outside the U.S. can remain confidential until patents issue. In addition, patent applications in the U.S. and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived. Furthermore, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, our products or the use of our products. As such, other parties may have patent applications now pending or recently revived patents of which we are unaware. Such patent applications may later result in issued patents, or the revival of previously abandoned patents, that will prevent, limit or otherwise interfere with our ability to make, use or sell our products. And even if we are aware of other patents or patent applications, we may incorrectly determine that our products are not covered by such patents or may incorrectly predict whether other pending applications will issue with claims of relevant scope. Our determination of the expiration date of any patent in the U.S. or abroad that we consider relevant may be incorrect. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products. As such, we cannot provide any assurances that other patents do not currently, or will not in the future, exist which might be enforced against our current and future products and technology, and could result in either an injunction prohibiting their manufacture or future sales or an obligation on our part to pay royalties and/or other forms of compensation to other parties, which could be significant.

There is considerable intellectual property litigation in the medical technology, biotechnology, diagnostic, and pharmaceutical industries, including in the cancer detection space. Our competitors have been involved in complex patent litigation and in some cases have settled their disputes via complex licensing arrangements. In addition, there is ongoing intellectual property litigation, the outcome of which could also impact future litigation involving our intellectual property or our ability to commercialize our products. For example, a third party has asserted patent infringement claims against one of our suppliers relating to patents and technologies used in our colorectal and lung cancer diagnostic assays. Specifically, biomodal Limited and Children’s Medical Center Corporation ("CMCC") initiated patent infringement litigation against our supplier New England Biolabs, Inc. ("NEB") alleging infringement of eight patents, claims from three of which were found invalid under 35 U.S.C. § 101. Although NEB and biomodal and CMCC settled their litigation on or about August 31, 2026, we may become subject to litigation in connection with these patents and technologies. Accordingly, on September 2, 2026, we filed a petition for declaratory judgment against biomodal and CMCC seeking declarations of non-infringement, patent invalidity, and patent exhaustion as to the CMCC patents. If such petition is denied, we believe that the doctrine of patent exhaustion should substantially limit, if not preclude, any potential liability of Freenome arising from its use of products supplied by NEB.

We could also become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our products, including interference, derivation or other proceedings before the USPTO and similar bodies in other jurisdictions. Infringement claims may be asserted against us based on existing patents or patents that may be issued in the future.

Even if we believe intellectual property claims asserted against us are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, enforceability or priority. In order to successfully challenge the validity of a U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. If we are found to infringe, misappropriate or otherwise violate another's intellectual property rights, we could be required to pay commercially significant monetary damages, obtain a license from such party to continue developing, marketing, selling, and distributing our products, or to cease using the infringing technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other parties access to the same technologies licensed to us. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement, misappropriation or other violation could prevent us from commercializing our products or force us to cease some of our operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of others could have a similar negative impact on our 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. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

We may need to obtain licenses from others to advance our research or allow commercialization of our products or technology without infringing, misappropriating or otherwise violating the intellectual property or proprietary rights of those other parties. It is possible that we may be unable to obtain such licenses at a reasonable cost or on reasonable terms, if at all. In that event, 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 of our products or continue to utilize our technology, which could harm our business, financial condition, results of operations, and prospects.

In addition, license, collaboration, development, research services and similar agreements can impose various development, diligence, commercialization, payment and other obligations on us. License agreements may require us to meet development timelines, or to exercise commercially reasonable efforts to develop and/or commercialize certain products. Despite our efforts, future licensors might conclude that we have materially breached our obligations under such agreements or our sublicensees may fail to fulfill their obligations to us or materially breach related sublicense agreements, and our future licensors might therefore terminate the license agreements or otherwise modify our rights under those agreements, thereby removing or limiting our ability to develop and commercialize tests and technology covered by these license agreements or resulting in litigation. If our licenses are terminated, or if the underlying patents or other intellectual property fail to provide the anticipated market exclusivity, competitors or other parties may have the freedom to seek regulatory approval of, and to market, tests highly similar to ours, or we may be required to cease commercialization of our products or use of our technology. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

In addition, the agreements under which we may license or otherwise obtain rights to intellectual property or technology from other parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations, which may lead to disputes between us and our future licensor, including:

- the scope of rights granted under the agreement and other interpretation-related issues;
- our financial and other obligations under the agreement;
- whether and the extent to which our test, product and/or technology infringe, misappropriate or otherwise violate the intellectual property of the future licensor that is not subject to the agreement;
- the sublicensing of patents and other rights;
- our diligence and other obligations under the agreement and what activities satisfy those obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of the intellectual property by our partners and our future licensors; and
- the priority of invention of patented technology.

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 have a material adverse effect on our business, financial condition, results of operations, and prospects. If we are required to engage in litigation to enforce or defend our rights under our license or other agreements, even if we are successful,

such litigation could require significant financial resources, divert the attention of management and harm our business. Moreover, if disputes over intellectual property 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 product or technology. Any of the foregoing could have a material adverse effect on our 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, subject us to possible litigation or otherwise negatively impact our business.

A portion of the software powering our CRC test incorporates open-source software, and we may incorporate open-source software into other offerings or products in the future. If an author or other party that distributes such open-source software were to allege that we had not complied with the conditions of one or more of these licenses, we could be required to incur significant legal expenses defending against such allegations. Further, the outcome of such litigation may be particularly uncertain in some cases, because there is little legal precedent governing the interpretation of certain terms of common open-source licenses. In addition, if we combine our proprietary software with open-source software in a certain manner, under some open-source licenses, under certain circumstances we could be required to release the source code of our proprietary software, which could substantially help our competitors develop products that are similar to or better than ours and harm our business. The use of open-source software can also lead to greater risks than use of commercial software, as open-source licensors generally do not provide warranties or controls on the origin of software, which may contain security vulnerabilities or infringing or broken code.

Developments in patent law could diminish the value of our future patents or otherwise have a negative impact on our business.

Changes in either the patent laws or interpretation of the patent laws in the U.S. or other jurisdictions could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 2013, in the U.S., the first to invent the claimed invention was entitled to the patent, while outside the U.S., the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act (the "America Invents Act") enacted in September 2011, the U.S. transitioned to a first-inventor-to-file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention.

This requires us to be cognizant of the time from invention to filing of a patent application. Since patent applications in the U.S. and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we were the first to either file any patent application related to our products or technologies or invent any of the inventions claimed in our patent applications or future patents.

In addition, the patent position of companies in our field is particularly uncertain. From time to time, the U.S. Supreme Court, other federal courts, the U.S. Congress, the USPTO, or applicable authorities in other jurisdictions may change the standards of patentability and any such changes could have a negative impact on our business.

There have been various precedential decisions regarding patentable subject matter, which may be relevant to patents in the medical diagnostics and computer-implemented applications space. As a result, our efforts to seek patent protection for our technologies and products may be impacted by the evolving case law and guidelines/procedures issued by the USPTO, or authorities in other jurisdictions based on such changes in the law.

Further, the U.S. Congress has periodically sought to pass bills concerning subject matter eligible for patent protection. We cannot fully predict the impact that any such new law may have on our ability to obtain patent protection on our products and technologies, and our ability to operate in view of the patents controlled by other parties. These and other substantive changes to U.S. and foreign patent law and policy could affect our susceptibility to patent infringement claims and our ability to obtain patents and, if obtained, to enforce or defend them, any of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

Patents have a limited lifespan in all jurisdictions around the world. In the U.S., 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. Extensions may be available for certain delays during the patent examination process, but the life of a patent, and the protection it affords, is limited. Even if patents covering our products or technology are obtained, once the patent life has expired for a product, we may be open to competition. Given the amount of time required for the development, testing and regulatory review of new products and technology, patents protecting such products or technology might expire before or shortly after such products are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products or technologies similar or identical to ours for a meaningful amount of time, or at all.

Future issued patents covering our products and other technologies could be found invalid or unenforceable if challenged in court or before administrative bodies in the U.S. and abroad.

If we initiate legal proceedings to enforce a future patent, the defendant could counterclaim that our asserted patent is invalid or unenforceable. In patent litigation in the U.S., defendant counterclaims alleging invalidity or unenforceability are commonplace. Other parties may raise claims challenging the validity or enforceability of our future patents before administrative bodies in the U.S. or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, inter partes review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (such as opposition proceedings). Such proceedings could result in the revocation of, cancellation of, or amendment to our future patents in such a way that they no longer cover our technologies or products.

European patent protection may be subject to the Unitary Patent system and the Unified Patent Court ("UPC"). The Unitary Patent allows a patentee, upon grant of a European patent, to obtain protection in participating EU Member States through a single request to the European Patent Office, rather than validating the patent separately in each country. Although this may reduce administrative burdens and costs, a competitor may be able to challenge a Unitary Patent in a single proceeding with effect across participating states.

The UPC provides a forum for infringement and validity proceedings involving Unitary Patents and certain European patents. The UPC is still developing, and the outcome of proceedings before it may be less predictable than proceedings in national courts. If we select Unitary Patent protection or do not opt out of UPC jurisdiction where permitted, an adverse UPC decision could weaken our patent protection in Europe.

The outcome of legal assertions of invalidity and unenforceability is unpredictable. For example, we cannot be certain that there is no invalidating prior publications or inventions of which we or the patent examiner were unaware during prosecution. If another party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our products or other technologies. Any such loss of patent protection could have a material adverse impact on our business, financial condition, results of operations and prospects.

We may be subject to claims asserting that our employees or contractors have infringed, misappropriated or otherwise violated the intellectual property or proprietary rights of their former employers or claims asserting an ownership interest in what we regard as our own intellectual property.

Our former, current, and future employees and contractors may have been previously employed at universities or other biotechnology, diagnostic technology or pharmaceutical companies, including our competitors or potential competitors and strategic partners. Although we try to ensure that our employees and contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that an employee or contractor has used or disclosed intellectual property or proprietary rights, including trade secrets or other proprietary information, of such employee's or contractor'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, while it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own, and any such agreement may not be self-executing. Such agreements may be breached, and we may be forced to bring claims against third parties or current or former employees or contractors, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

If we fail in defending 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.

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

During the course of any intellectual property litigation or proceeding, 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 products, 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 products, which could have a material adverse effect on our business.

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

Competitors or other parties may infringe, misappropriate or otherwise violate our future patents, trademarks, copyrights, trade secrets or other intellectual property. To counter infringement or other violations, we may be required to file claims, which can be expensive and time-consuming. Any such claims could provoke these parties to assert counterclaims against us, including claims alleging that we infringe, misappropriate or otherwise violate their patents or other intellectual property rights. In addition, in a patent infringement proceeding, a court or administrative body may decide that one or more of the patents we assert is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to prevent the other party from using the technology at issue on the

grounds that our patents do not cover the technology. Similarly, if we assert trademark infringement claims, a court or administrative body may determine that the marks we have asserted are invalid or unenforceable or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In such a case, we could ultimately be forced to cease use of such marks. In any intellectual property litigation, even if we are successful, any award of monetary damages or other remedy we receive may not adequately compensate us for the losses that we suffer. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during such litigation.

Further, we may be required to defend the validity of our future patents through procedures created to allow other parties to attack the validity of a patent at the USPTO. An adverse determination in any such submission or proceeding could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, an adverse party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action.

Our future patents may be challenged, narrowed, invalidated or circumvented. If our future patents are invalidated or otherwise limited or will expire prior to the commercialization of our products, other companies may be better able to develop products that compete with ours, which could adversely affect our competitive position, business prospects, results of operations and financial condition.

The following are non-limiting examples of litigation and other adversarial proceedings or disputes that we could become a party to involving our patent rights:

- we or our collaborators may initiate litigation or other proceedings against third parties to enforce our patent rights;
- other parties may initiate litigation or other proceedings seeking to invalidate our patents or to obtain a declaratory judgment that their products or technology do not infringe our future patents or that such patents are invalid or unenforceable;
- other parties may initiate oppositions, inter partes review, post-grant review, or reexamination proceedings challenging the validity or scope of our patent rights, requiring us or our collaborators and/or future licensors to participate in such proceedings to defend the validity and scope of our patents;
- there may be a challenge or dispute regarding inventorship or ownership of future patents identified as being owned by us;
- at our initiation or at the initiation of another party, the USPTO may initiate an interference between patent applications or future patents owned by us and those of our competitors or other parties, requiring us or our collaborators and/or future licensors to participate in an interference proceeding to determine the priority of invention, which could jeopardize our patent rights; or
- other parties may seek approval to market products similar to our products prior to expiration of relevant future patents owned by us, requiring us to defend and enforce our future patents, including by filing lawsuits alleging patent infringement.

These lawsuits and proceedings would be costly and could affect our results of 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 future patents are invalid or not infringed by another party's activities, or that the scope of certain issued claims must be limited. An adverse outcome in a litigation or proceeding involving our future patents could limit our ability to assert such patents against competitors and may curtail or preclude our ability to exclude other 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 competitors and other parties pursuing intellectual property protections in our technology space. Any of these occurrences could adversely affect our business, financial condition, results of operations and prospects.

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

Our current or future trademarks or trade names may be challenged, infringed, circumvented or declared generic or descriptive or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in foreign jurisdictions. Although we would typically be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. In addition, other parties may file for registration of trademarks similar or identical to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. If they succeed in registering or developing common law rights in such trademarks, and if we are not successful in challenging such rights, we may not be able to use these trademarks to develop brand recognition of our own technologies and products. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively, and our business may be adversely affected. We may license our trademarks and trade names to other parties, such as distributors. Although the applicable agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and trade names by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names.

If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected and our business could be harmed.

We rely on patent protection as well as a combination of trademark, copyright, and trade secret protection and other contractual restrictions to protect our proprietary technologies and other intellectual property rights, all of which provide limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. If we fail to protect our intellectual property, other parties may be able to compete more effectively against us and we may incur substantial litigation costs in our attempts to recover or restrict use of our intellectual property, which may not be entirely successful, if at all.

However, trade secrets and/or confidential know-how are difficult to maintain as confidential. To maintain the confidentiality of this type of information, it is our policy to enter into confidentiality agreements with our employees, consultants, advisors, collaborators, contractors, and others upon the commencement of their relationships with us. These agreements require that all confidential information developed by the individual(s) or made known to the individual by us during the course of the individual's relationship or work with us be kept confidential and not disclosed to third parties. Our agreements with employees and our personnel policies also provide that any inventions conceived by the individual in the course of rendering services to us shall be our exclusive property. However, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms, intentionally or unintentionally. Thus, despite such agreement, such inventions may become assigned to third parties. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets or other confidential information. To the extent that our employees, consultants, contractors or others use technology or know-how owned by third parties in their work for us, disputes may arise between us and those third parties as to the rights in related inventions. To the extent that an individual who is not obligated to assign rights in intellectual property to us or a current or future licensor is rightfully an inventor of intellectual property, we may need to obtain an assignment or a license to that intellectual property from that individual, or a third party or from that individual's assignee. Such assignment or license may not be available on commercially reasonable terms or at all. The disclosure of our trade secrets could impair our competitive position and may materially harm our business, financial condition and results of operations.

Enforcing a claim that a third party obtained illegally and is using trade secrets and/or confidential know-how is expensive, time consuming and unpredictable. The enforceability of confidentiality agreements and theft of trade secret claims may vary from jurisdiction to jurisdiction. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. As such, adequate remedies may not exist in the event of unauthorized use or disclosure of our proprietary information.

In addition, others may independently discover or develop our trade secrets and proprietary information, and the existence of our own trade secrets affords no protection against such independent discovery. Such persons may even apply for patent protection in respect of the same. If successful in obtaining such patent protection, such persons could limit our use of our trade secrets and/or confidential know-how. Under certain circumstances and to guarantee our freedom to operate, we may also decide to publish some know-how to prevent others from obtaining patent rights covering such know-how.

Risks Related to Ownership of Our Stock

Anti-takeover provisions in our Certificate of Incorporation and our Bylaws and Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the market price of our Common Stock.

Our Certificate of Incorporation and our Bylaws contain provisions that could depress the market price of our Common Stock by acting to discourage, delay or prevent a change in control of our company or changes in our management that our stockholders may deem advantageous. These provisions, among other things, include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board are elected at one time;
- a prohibition on stockholder actions through written consent, which requires that all stockholder actions be taken at a meeting of stockholders;
- a requirement that special meetings of stockholders be called only by our Board acting pursuant to a resolution approved by the affirmative vote of a majority of the directors then in office;
- advance notice requirements for stockholder proposals and nominations for election to our Board;
- a requirement that no member of our Board may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than two-thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action; and
- the authority of our Board to issue preferred stock on terms determined by our Board without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

In addition, Section 203 of the DGCL prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person that together with its affiliates owns, or within the last three years has owned, 15% of

our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

Any provision of our Certificate of Incorporation, our Bylaws or Delaware law that has the effect of delaying or preventing a change in control could limit the opportunity for our stockholders 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.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our Common Stock depends in part on the research and reports that securities or industry analysts publish about us or our business. If industry analysts cease coverage of us or fail to publish reports on us regularly, the trading price for our common stock could be adversely affected. If one or more of the analysts who cover us downgrade our common stock or publish inaccurate or unfavorable research about our business, our common stock price would likely decline.

We do not intend to pay dividends on our capital stock.

We have never declared or paid any cash dividends on our capital stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, our ability to pay cash dividends on our capital stock may be prohibited or limited by the terms of any current or future debt financing arrangement. Any return to stockholders will therefore be limited to the increase, if any, in the price of our common stock.

General risk factors

If we fail to establish and maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be reevaluated frequently. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with GAAP. We have started the process of documenting, reviewing and improving our internal controls and procedures for compliance with Section 404 of the Sarbanes-Oxley Act. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock.

We will be required to disclose changes made in our internal controls and procedures on a quarterly basis and our management will be required to assess the effectiveness of these controls annually. However, for as long as we are an emerging growth company or a non-accelerated filer, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act. An independent assessment of the effectiveness of our internal controls over financial reporting could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls over financial reporting could lead to restatements of our financial statements and require us to incur the expense of remediation.

Unfavorable global economic conditions could adversely affect our business, financial condition, stock price and results of operations.

U.S. and global markets have experienced extreme volatility and disruptions (including as a result of actual or perceived changes in interest rates, inflation and macroeconomic uncertainties), which has included severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, high inflation, uncertainty about economic stability, global supply chain disruptions, and increases in unemployment rates. International trade disputes, including threatened or implemented tariffs by the Trump administration and threatened or implemented tariffs by foreign countries in retaliation, could adversely impact our business. Trade disputes could also adversely impact supply chains which could now or in the future increase costs for us or delay delivery of key inventories and supplies. Trade disputes can also be highly disruptive to global financial markets. The length and impact of the ongoing trade disputes and military conflicts are highly unpredictable. We continue to assess the legislation as it develops to determine whether it could have an effect on our contractual relationships. Furthermore, any disruptions to our supply chain as a result of unfavorable global economic conditions, including due to geopolitical conflicts or public health crises, could negatively impact the timely execution of our commercialization activities or future clinical trials. In addition, current inflationary trends in the global economy may impact salaries and wages, costs of goods and transportation expenses, among other things, and recent and potential future disruptions in access to bank deposits or lending commitments due to bank failures may create market and economic instability. We

cannot anticipate all of the ways in which the foregoing, and the current economic climate and financial market conditions generally, could adversely impact our business.

We may be a party to litigation in the normal course of business or otherwise, which could affect our business and financial position.

From time to time, we are a party to or otherwise involved in legal proceedings, claims and government investigations, and other legal matters arising in the ordinary course of our business or otherwise. Additionally, the distribution, sale, use, and results of our product could lead to liability claims. Legal proceedings can be complex and take many months, or even years, to reach resolution, with the final outcome depending on a number of variables, some of which are not within our control. From time to time, we may also be compelled to protect our business interests through the initiation of litigation against others. Litigation, whether offensive or defensive, is subject to significant uncertainty and may be expensive, time-consuming, and disruptive to our operations.

Although we will vigorously defend and advocate for ourselves in such legal proceedings, their ultimate resolution and potential financial and other impacts on us are uncertain. For these and other reasons, we may choose to settle legal proceedings and claims, regardless of their actual merit. If a legal proceeding is resolved against us, it could result in significant compensatory damages, and in certain circumstances punitive or trebled damages, disgorgement of revenue or profits, remedial corporate measures or injunctive relief imposed on us. Even if litigation is resolved in our favor, costs and disruptions to the Company may have a negative impact on business. If our existing insurance does not cover the amount or types of damages awarded, or if other resolutions or actions taken as a result of a legal proceeding were to restrain our ability to operate, our financial position, results of operations or cash flows could be materially adversely affected. Any claim brought against us, with or without merit, could increase our liability insurance rates or prevent us from securing insurance coverage in the future. In addition, legal proceedings, and any adverse resolution thereof, can result in adverse publicity and damage to our reputation, which could adversely impact our business.

The amounts we record for legal contingencies can result from a complex series of judgments about future events and uncertainties and can rely heavily on estimates and assumptions. While we have accrued for certain potential legal liabilities, there is no guarantee that additional costs will not be incurred beyond the amounts accrued.

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

Our federal net operating loss ("NOL") carryforwards may be unavailable to offset future taxable income because of restrictions under U.S. tax law. Under the Tax Cuts and Jobs Act, as amended by the Coronavirus Aid, Relief, and Economic Security Act, our federal NOLs may be carried forward indefinitely, but for taxable years beginning after December 31, 2020, the deductibility of federal NOL carryforwards generated in tax years beginning after December 31, 2017 is limited to 80% of our current year taxable income. As of December 31, 2025, we had available federal NOL carryforwards of approximately $893.0 million, which are indefinite, and $21.2 million with 2036-2037 expiration years, as well as available state NOL carryforwards of approximately $825.1 million with 2036-2045 expiration years.

In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change" (generally defined as a cumulative change in the corporation's ownership by "5-percent shareholders" that exceeds 50 percentage points (by value) over a rolling three-year period), the corporation's ability to use its pre-change NOL carryforwards and certain other pre-change tax attributes to offset its post-change taxable income may be limited. Similar rules may apply under state tax laws. We may have experienced such ownership changes in the past, and we may experience ownership changes in the future as a result of shifts in our stock ownership, some of which are outside our control. We have not conducted any studies to determine annual limitations, if any, that could result from such changes in the ownership. There is also a risk that due to regulatory changes, such as suspensions on the use of NOL carryforwards, or other unforeseen reasons, our existing NOL carryforwards could expire or otherwise be unavailable to offset future income tax liabilities. Because our ability to utilize our NOL carryforwards is uncertain, this could have a material adverse effect on our cash flows and results of operations.

Changes in tax laws or regulations or exposure to tax liabilities could adversely affect our financial condition and results of operations.

We are subject to tax in multiple U.S. tax jurisdictions and in foreign tax jurisdictions as we continue to expand internationally. As we grow, the development of our tax strategies requires additional expertise and may impact how we conduct our business. Our future effective tax rates could be unfavorably affected by changes in, or interpretations of, tax rules and regulations in the jurisdictions in which we do business or by changes in the valuation of our deferred tax assets and liabilities. Furthermore, we provide for certain tax liabilities that involve significant judgment. We are subject to the examination of our tax returns by federal, state, and foreign tax authorities, which could focus on our intercompany transfer pricing methodology as well as other matters. If our tax strategies are ineffective or we are not in compliance with domestic and international tax laws, our financial position, operating results, and cash flows could be adversely affected.

We may be materially adversely affected by the recent and ongoing military action between Russia and Ukraine.

On February 24, 2022, Russian military forces launched a military action in Ukraine, and sustained conflict and disruption in the region is likely. Although the length, impact and outcome of the ongoing military conflict in Ukraine is highly unpredictable, this conflict could lead to significant market and other disruptions, including significant volatility in commodity prices and supply of energy

resources, instability in financial markets, supply chain interruptions, political and social instability, changes in consumer or purchaser preferences as well as increase in cyberattacks and espionage. Russia's recognition of two separatist republics in the Donetsk and Luhansk regions of Ukraine and subsequent military action against Ukraine have led to an unprecedented expansion of sanction programs imposed by the U.S., the European Union, the United Kingdom, Canada, Switzerland, Japan and other countries against Russia, Belarus, the Crimea Region of Ukraine, the so-called Donetsk People's Republic and the so-called Luhansk People's Republic.

The situation is rapidly evolving as a result of the conflict in Ukraine, and the U.S., the European Union, the United Kingdom and other countries may implement additional sanctions, export controls or other measures against Russia, Belarus and other countries, regions, officials, individuals or industries in the respective territories. Such sanctions and other measures, as well as the existing and potential further responses from Russia or other countries to such sanctions, tensions and military actions, could adversely affect the global economy and financial markets and could adversely affect our business, financial condition and results of operations.

We do not have experience operating as a public company subject to U.S. federal securities laws and may not be able to adequately develop and implement the governance, compliance, risk management and control infrastructure and culture required for a public company, including compliance with the Sarbanes-Oxley Act.

We do not have experience operating as a public company subject to U.S. federal securities laws. Our officers and directors lack experience in managing a public company subject to U.S. federal securities laws, which makes our ability to comply with applicable laws, rules and regulations uncertain. Our failure to comply with all applicable laws, rules and regulations could subject us to U.S. regulatory scrutiny or sanction, which could harm our reputation and share price.

Prior to the closing of the Business Combination on July 20, 2026, we were not required to prepare or file periodic or other reports with the SEC or to comply with the other requirements of U.S. federal securities laws. Following the closing, we are subject to the reporting requirements of the Exchange Act and are required to establish and maintain disclosure controls and procedures and internal control over financial reporting under U.S. federal securities laws, including the Sarbanes-Oxley Act. We may experience errors, mistakes and lapses in processes and controls, resulting in failure to meet requisite U.S. standards.

As a public company subject to U.S. federal securities laws, we will incur significant legal, accounting, insurance, compliance, and other expenses. Compliance with reporting, internal control over financial reporting and corporate governance obligations may require members of our management and our finance and accounting staff to divert time and resources from other responsibilities to ensure these new regulatory requirements are fulfilled.

If we fail to adequately implement the required governance and control framework, we may fail to comply with the applicable rules or requirements associated with being a public company subject to U.S. federal securities laws. Such failure could result in the loss of investor confidence, could harm our reputation, and cause the market price of our Common Stock to decline.

Due to inadequate governance and internal control policies, misstatements or omissions due to error or fraud may occur and may not be detected, which could result in failures to make required filings in a timely manner or result in making filings containing incorrect or misleading information. Any of these outcomes could result in SEC enforcement actions, monetary fines or other penalties, as well as damage to our reputation, business, financial condition, operating results and stock price.

The price of our Common Stock may be volatile.

The price of our Common Stock may fluctuate due to a variety of factors, including:

- changes in the industries in which we and our customers operate;
- variations in our operating performance and the performance of our competitors in general;
- actual or anticipated fluctuations in our quarterly or annual operating results;
- publication of research reports by securities analysts about us or our competitors or our industry;
- the public's reaction to our press releases, our other public announcements and our filings with the SEC;
- our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market;
- additions and departures of key personnel;
- changes in laws and regulations affecting our business;
- failure to comply with laws or regulations, including the Sarbanes-Oxley Act, or failure to comply with the requirements of the relevant U.S. stock exchange;
- actual, potential or perceived control, accounting or reporting problems;
- commencement of, or involvement in, litigation involving our company;
- changes in our capital structure, such as future issuances of securities or the incurrence of additional debt;
- the volume of shares of our Common Stock available for public sale;
- general economic and political conditions such as recessions, interest rates, fuel prices, foreign currency fluctuations, international tariffs, social, political and economic risks and acts of war or terrorism; and
- the other factors described in this "Risk Factors" section or the section entitled "Cautionary Note Regarding Forward-Looking Statements."

These market and industry factors may materially reduce the market price of our Common Stock regardless of our operating performance.

Future sales, or the perception of future sales, by us or our stockholders in the public market could cause the market price for our securities to decline.

The sale of our securities in the public market, or the perception that such sales could occur, could harm the prevailing market price of our securities. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate. The September 8, 2026 conversion of the Abbott/Exact convertible note into 3,364,814 shares of our Common Stock increased the number of shares outstanding. If those shares become eligible for resale, or if investors expect such sales, the sale or perception of sale could adversely affect the market price of our Common Stock.

Shares of Common Stock reserved for future issuance under our equity incentive plans will become eligible for sale in the public market once those shares are issued, subject to provisions relating to various vesting agreements, lock-up agreements and, in some cases, limitations on volume and manner of sale applicable to affiliates under Rule 144, as applicable. The compensation committee of our board of directors may determine the exact number of shares to be reserved for future issuance under our equity incentive plans at its discretion. We filed registration statements on Form S-8 under the Securities Act to register shares of common stock or securities convertible into or exchangeable for shares of common stock issued pursuant to its equity incentive plans and such Form S-8 registration statements became effective upon filing. Accordingly, shares registered under such registration statements are available for sale in the open market.

In the future, we may also issue our securities in connection with investments or acquisitions. The number of shares of common stock issued in connection with an investment or acquisition could constitute a material portion of our then-outstanding shares of common stock. Any issuance of additional securities in connection with investments or acquisitions may result in additional dilution to our stockholders.

We are an emerging growth company and a smaller reporting company within the meaning of the Securities Act, and if we take advantage of certain exemptions from disclosure requirements available to "emerging growth companies" or "smaller reporting companies," this could make our securities less attractive to investors and may make it more difficult to compare our performance with other public companies.

We are an "emerging growth company" within the meaning of the Securities Act, as modified by the JOBS Act, and we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and 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, our stockholders may not have access to certain information they may deem important. We could be an emerging growth company for up to five years from the date of PCSC's initial public offering in June 2024, although circumstances could cause us to lose that status earlier, including if the market value of our Common Stock held by non-affiliates exceeds $700 million as of any June 30 before that time, in which case we would no longer be an emerging growth company as of the following December 31. We cannot predict whether investors will find our Common Stock less attractive because we will rely on these exemptions. If some investors find our Common Stock less attractive as a result of our reliance on these exemptions, the trading price of our Common Stock may be lower than they otherwise would be, there may be a less active trading market for our securities and the trading price of our Common Stock may be more volatile.

Further, Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a Securities Act registration statement declared effective or do not have a class of securities registered under the Exchange Act) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that a company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such election to opt out is irrevocable. We have elected not to opt out of such extended transition period which means that when a standard is issued or revised and it has different application dates for public or private companies, we, as an emerging growth company, can adopt the new or revised standard at the time private companies adopt the new or revised standard. This may make comparison of our financial statements with those of another public company that is neither an emerging growth company nor an emerging growth company that has opted out of using the extended transition period difficult or impossible because of the potential differences in accounting standards used.

Additionally, we are a "smaller reporting company" as defined in Item 10(f)(1) of Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We will remain a smaller reporting company until the last day of the fiscal year in which (i) the market value of our Common Stock held by non-affiliates exceeds $250 million as of the prior June 30, or (ii) our annual revenues exceeded $100 million during such completed fiscal year and the market value of our Common Stock held by non-affiliates exceeds $700 million as of the prior June 30. To the extent we take advantage of such reduced disclosure obligations, it may also make comparison of our financial statements with other public companies difficult or impossible.

We may fail to maintain the listing of our Common Stock on Nasdaq, which could limit investors' ability to make transactions in our securities and subject us to additional trading restrictions.

An active trading market for our Common Stock may not be sustained. Although our Common Stock is listed on The Nasdaq Capital Market, we may not maintain our listing and Nasdaq may take steps to delist our Common Stock. If we fail to meet the listing requirements and Nasdaq delists our Common Stock, we could face significant material adverse consequences, including:

- a limited availability of market quotations for our securities;
- reduced liquidity for our securities;
- a determination that our Common Stock is a "penny stock" which will require brokers trading in our Common Stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities;
- a limited amount of news and analyst coverage; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

The National Securities Markets Improvement Act of 1996, which is a federal statute, prevents or preempts the states from regulating the sale of certain securities, which are referred to as "covered securities." If we fail to meet listing standards and our Common Stock is delisted, such securities would not qualify as covered securities and we would be subject to regulation in each state in which we offer our securities because states are not preempted from regulating the sale of securities that are not covered securities.

Reports published by analysts, including projections in those reports that differ from our actual results, could adversely affect the price and trading volume of our Common Stock.

Securities research analysts may establish and publish their own periodic projections for our company. These projections may vary widely and may not accurately predict the results we actually achieve. Our share price may decline if our actual results do not match the projections of these securities research analysts. Similarly, if one or more of the analysts who write reports on us downgrades our stock or publishes inaccurate or unfavorable research about our business, our share price could decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, our share price or trading volume could decline.

While we expect research analyst coverage, if no analysts commence coverage of us, the market price and volume for our Common Stock could be adversely affected.

We are subject to changing law and regulations regarding regulatory matters, corporate governance and public disclosure that have increased and will continue to increase our costs and the risk of non-compliance.

We are subject to rules and regulations by various governing bodies, including, for example, the SEC, which are charged with the protection of investors and the oversight of companies whose securities are publicly traded, and to new and evolving regulatory measures under applicable law. Our efforts to comply with new and changing laws and regulations have resulted in, and likely will continue to result in, increased general and administrative expenses and a diversion of management time and attention.

Moreover, because these laws, regulations and standards are subject to varying interpretations, their application in practice may evolve over time as new guidance becomes available. This evolution may result in continuing uncertainty regarding compliance matters and additional costs necessitated by ongoing revisions to our disclosure and governance practices. If we fail to address and comply with these regulations and any subsequent changes, we may be subject to penalty and our business may be harmed.

Our Certificate of Incorporation designates a state or federal court located within the State of Delaware as the sole and exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, stockholders, employees or agents.

Our Certificate of Incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for state law claims for (i) any derivative action or proceeding brought on behalf of the Company, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the DGCL or the Certificate of Incorporation or Bylaws, (iv) any action to interpret, apply, enforce or determine the validity of the Certificate of Incorporation or Bylaws, or (v) any action asserting a claim against us governed by the internal affairs doctrine. The foregoing provisions will not apply to any claims arising under the Exchange Act or the Securities Act and, unless the Company consents in writing to the selection of an alternative forum, the federal district courts of the United States of America will be the sole and exclusive forum for resolving any action asserting a claim arising under the Securities Act.

This choice of forum provision in our Certificate of Incorporation may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, or other employees, which may discourage lawsuits with respect to such claims. There is uncertainty as to whether a court would enforce such provisions, and the enforceability of similar choice of forum provisions in other companies' charter documents has been challenged in legal proceedings. It is possible that a court could find these types of provisions to be inapplicable or unenforceable, and if a court were to find the choice of forum provision

contained in our Certificate of Incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations and financial condition.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

(a) Recent Sales of Unregistered Equity Securities

During the quarter ended September 30, 2026, Exact Sciences Corporation ("Exact") converted the outstanding principal and accrued interest under the convertible note, totaling $50,472,222.22, into 3,364,814 shares of the Company's common stock at a conversion price of $15.00 per share. The Company paid Exact $12.22 in cash in lieu of a fractional share. The shares were issued in reliance on the exemption from registration provided by Section 3(a)(9) of the Securities Act.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

(a) None

(b) None

(c) During the three months ended September 30, 2026, none of our directors or officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted or terminated any "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as those terms are defined in Item 408 of Regulation S-K.

Item 6. Exhibits

The following documents are filed as part of this Form 10-Q.

Exhibit Number	Exhibit Description	Form	File No.	Exhibit	Filing Date
2.1**	Business Combination Agreement, dated as of December 5, 2025, by and among Perceptive Capital Solutions Corp., StarNet Merger Sub I, Corp., StarNet Merger Sub II, LLC and Freenome Holdings, Inc. (incorporated by reference to Annex A to the Registrant's proxy statement/prospectus filed on June 17, 2026)	S-4	333-295377	Annex A	6/17/2026
2.2**	Amendment No. 1 to Business Combination Agreement, dated as of July 20, 2026, by and among Perceptive Capital Solutions Corp., StarNet Merger Sub I, Corp., StarNet Merger Sub II, LLC and Freenome Holdings, Inc.	Form 8-K	001-42126	2.2	7/24/2026
3.1**	Certificate of Incorporation of Freenome, Inc.	Form 8-K	001-42126	3.1	7/24/2026
3.2**	Amended and Restated Bylaws of Freenome, Inc.	Form 8-K	001-42126	3.2	7/24/2026
4.3**	Specimen Common Stock Certificate of Freenome, Inc.	S-4	333-295377	4.3	4/28/2026
10.1+**	Freenome, Inc. 2026 Equity Incentive Plan and forms of award agreements thereunder	Form 8-K	001-42126	10.15	7/24/2026
10.2+**	Freenome, Inc. 2026 Employee Stock Purchase Plan.	Form 8-K	001-42126	10.16	7/24/2026
10.3+**	Freenome, Inc. Senior Executive Severance Plan	Form 8-K	001-42126	10.21	7/24/2026
10.4+**	Freenome, Inc. Senior Executive Cash Incentive Bonus Plan	Form 8-K	001-42126	10.22	7/24/2026
10.5+**	Freenome, Inc. Non-Employee Director Compensation Policy	Form 8-K	001-42126	10.23	7/24/2026
10.6+**	Form of Director Indemnification Agreement	Form 8-K	001-42126	10.24	7/24/2026
10.7+**	Form of Officer Indemnification Agreement	Form 8-K	001-42126	10.25	7/24/2026
31.1*	Certification Pursuant to Rule 13a-14(a) or Rule 15d-14(a) of Securities Exchange Act of 1934				Filed herewith
31.2*	Certification Pursuant to Rule 13a-14(a) or Rule 15d-14(a) of Securities Exchange Act of 1934				Filed herewith
32.1***	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				Furnished herewith
32.2***	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				Furnished herewith
101.INS*	Inline XBRL Instance Document				Filed herewith
101.SCH*	Inline XBRL Taxonomy Extension Schema Document				Filed herewith
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document				Filed herewith
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document				Filed herewith

101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document	Filed herewith
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document	Filed herewith
104*	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101).	Filed herewith

* Filed herewith.
** Previously Filed.
*** Furnished herewith. The certifications furnished in Exhibit 32.1 and Exhibit 32.2 are deemed to be furnished with this Quarterly Report on Form 10-Q and will not be deemed to be "filed" for purposes of Section 18 of the Exchange Act, except to the extent that the Registrant specifically incorporates it by reference.
+ Indicates management contract or compensatory plan.

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.

FREENOME, INC.

Date: November 12, 2026

By: /s/ Aaron Elliott

Aaron Elliott

Chief Executive Officer

(*Principal Executive Officer*)

Date: November 12, 2026

By: /s/ Linh H. Le

Linh H. Le

Chief Financial Officer

(*Principal Financial and Accounting Officer*)

EXHIBIT 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Aaron Elliott, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Freenome, Inc. (the "registrant");

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

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

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

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

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

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

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

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

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

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

Date: November 12, 2026

By: /s/ Aaron Elliott

Aaron Elliott

Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Linh H. Le, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Freenome, Inc. (the "registrant");

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

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

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

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

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

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

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

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

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

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

Date: November 12, 2026

By: /s/ Linh H. Le

Linh H. Le

Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Freenome, Inc. (the "Company") on Form 10-Q for the fiscal quarter ended September 30, 2026, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 12, 2026

/s/ Aaron Elliott

Name: Aaron Elliott

Title: Chief Executive Officer

(Principal Executive Officer)

EXHIBIT 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Freenome, Inc. (the "Company") on Form 10-Q for the fiscal quarter ended September 30, 2026, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 12, 2026

/s/ Linh H. Le

Name: Linh H. Le

Title: Chief Financial Officer

(Principal Financial and Accounting Officer)