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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2026

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

For the transition period from _____ to _____

Commission File Number: 000-56821

IONETIX CORPORATION
(Exact name of registrant as specified in its charter)

Delaware	**41-2828779**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
3130 Sovereign Drive Lansing, Michigan 48911	**(517) 252-4069**
(Address of principal executive offices) (Zip Code)	(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act: None.

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

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

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

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

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

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

As of October 31, 2026, the registrant had 106,525,238 shares of its common stock, par value $0.0001 per share, issued and outstanding.

IONETIX CORPORATION

INDEX TO FORM 10-Q

	SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS	ii
	PART I — FINANCIAL INFORMATION	1
Item 1.	Financial Statements (Unaudited)	1
	Condensed Consolidated Balance Sheets	2
	Condensed Consolidated Statements of Operations	3
	Condensed Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)	4
	Condensed Consolidated Statements of Cash Flows	6
	Notes to Condensed Consolidated Financial Statements	7
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	26
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	34
Item 4.	Controls and Procedures	34
	PART II — OTHER INFORMATION	35
Item 1.	Legal Proceedings	35
Item 1A.	Risk Factors	35
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	72
Item 3.	Defaults Upon Senior Securities	72
Item 4.	Mine Safety Disclosures	72
Item 5.	Other Information	72
Item 6.	Exhibits	73
	Signatures	74

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q (this "Quarterly Report") contains "forward-looking statements" within the meaning of 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"). Forward-looking statements relate to, among others, our plans, objectives and expectations for our business, operations and financial performance and condition, and can be identified by terminology such as "may," "should," "expect," "intend," "plan," "anticipate," "believe," "estimate," "predict," "will," "could," "project," "target," "potential," "continue" and similar expressions that do not relate solely to historical matters or actual results. Forward-looking statements are based on management's beliefs and assumptions and on information currently available to management. Although we believe that the expectations reflected in forward-looking statements are reasonable, such statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by forward-looking statements.

Forward-looking statements include, but are not limited to, statements about:

- our ability to achieve profitability, continue as a going concern, and sustain growth;
- our ability to raise additional capital to fund our operations, develop our technology, and maintain sufficient liquidity, and the availability and terms of any such financing;
- our ability to adequately control the costs associated with our operations;
- our pursuit of emerging, highly regulated markets and our ability to commercialize our products and services at scale, including the development of sales, marketing, and distribution capabilities;
- the competitive and rapidly evolving nature of our industry, including the risk that competing products or technologies may limit our commercial opportunities;
- our reliance on third parties, including suppliers of specialized radioactive isotopes and other key raw materials, licensing partners, manufacturing and service providers, government entities, independent investigators, research institutions, and strategic partners, and our ability to maintain and expand such relationships;
- the unique manufacturing, logistics, and operational challenges associated with the short half-life and time-sensitive nature of delivery of radioactive isotopes used in our business;
- clinical trials and preclinical studies pursued by us or our pharmaceutical partners, including the cost, timing, and uncertainty of regulatory approval, and the risk that preliminary or interim data may not be predictive of final results;
- our ability to obtain and maintain required regulatory approvals, licenses, and permits, including for companion diagnostics, imaging agents, or other enabling tools;

- the impact of current and future laws and regulations, including those related to nuclear medicine, radiopharmaceuticals, semiconductors, nuclear energy, environmental and health and safety standards, and healthcare reimbursement and reform;
- changes to applicable policies, regulations, mandates, and funding levels of the government entities that regulate our business or with whom we do business, including the potential repayment of government grants;
- our ability to protect, maintain, and enforce our intellectual property rights, domestically and internationally, and the scope and duration of such protection;
- potential cybersecurity risks and information technology disruptions affecting our operational systems, infrastructure, and proprietary information, whether caused by us or third-party vendors;
- our ability to attract, retain, and motivate key personnel, including senior management, and our management team's ability to achieve our business objectives, including managing rapid growth and the transition to operating as a public company;
- any acquisitions, partnerships, joint ventures, or indebtedness we may pursue or incur, and the associated risks to our operations and financial condition;
- risks associated with operating internationally, including regulatory differences, intellectual property uncertainties, supply chain disruptions, tariffs, trade disputes, and compliance with foreign laws;
- the impact of global macroeconomic conditions, geopolitical tensions, climate-related events, pandemics, and other disruptions on our business, supply chain, and customers;
- product liability, litigation, and indemnification risks associated with the testing, manufacture, or use of our products or product candidates;
- the development of an active trading market for our common stock and the potential volatility of the market price of our securities;
- other risks and uncertainties, including those discussed under Part II, Item 1A, "Risk Factors" in this Quarterly Report.

We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, operating results, business strategy, short-term and long-term business operations and objectives, and financial needs. These forward-looking statements are subject to a number of risks, uncertainties, and assumptions, including those described under Part II, Item 1A, "Risk Factors" in this Quarterly Report. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make.

You should not rely upon forward-looking statements as predictions of future events. The events and circumstances reflected in the forward-looking statements may not be achieved or occur. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, performance, or achievements. We undertake no obligation to update any of these forward-looking statements for any reason after the date of this Quarterly Report or to conform these statements to actual results or revised expectations, except as required by law.

You should read this Quarterly Report and the documents that we have filed with the U.S. Securities and Exchange Commission (the "SEC") as exhibits to this Quarterly Report, with the understanding that our actual future results, performance, and events and circumstances may be materially different from what we expect.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Quarterly Report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

PART I — FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited)

Ionetix Corporation

INDEX TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

Table of Contents

Condensed Consolidated Balance Sheets	2
Condensed Consolidated Statements of Operations	3
Condensed Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)	4
Condensed Consolidated Statements of Cash Flows	6
Notes to Condensed Consolidated Financial Statements	7

Ionetix Corporation

Condensed Consolidated Balance Sheets
(Amounts in thousands, except share and per share data)
(Unaudited)

	September 30, 2026	December 31, 2025
Assets		
Current assets		
Cash	$ 5,574	$ 279
Accounts receivable, net	1,922	1,253
Inventory, net	284	293
Prepaid expenses and other current assets	1,593	570
Total current assets	9,373	2,395
Inventory, non-current	3,117	3,096
Property and equipment, net	25,906	27,214
Leases right-of-use assets	1,134	1,431
Other non-current assets	1,118	848
Total assets	$ 40,648	$ 34,984
Liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)		
Current liabilities		
Accounts payable	$ 792	$ 6,773
Accrued expenses and other current liabilities	1,778	1,990
Short-term operating lease liabilities	382	440
Short-term debt	—	5,753
Total current liabilities	2,952	14,956
Long-term liabilities		
Operating lease liabilities, non-current	759	993
Other non-current liabilities	2,334	2,601
SAFE liability	—	4,086
Total long-term liabilities	3,093	7,680
Total liabilities	$ 6,045	$ 22,636
Commitments and contingencies (Note 9)		
Redeemable convertible preferred stock, $0.0001 par value; No shares authorized, issued and outstanding as of September 30, 2026; 78,739,567 shares authorized and 72,794,660 shares issued and outstanding as of December 31, 2025; aggregate liquidation preference of $0 and $167,038 as of September 30, 2026 and December 31, 2025, respectively	—	191,199
Stockholders' equity (deficit)		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized, no shares issued and outstanding as of September 30, 2026. No shares authorized, issued, or outstanding as of December 31, 2025.	—	—
Common stock, $0.0001 par value; 510,000,000 shares authorized and 106,313,117 shares issued and outstanding as of September 30, 2026; 110,048,016 shares authorized and 13,118,276 shares issued and outstanding as of December 31, 2025.	11	2
Additional paid-in capital	248,332	7,710
Accumulated deficit	(213,740)	(186,563)
Total stockholders' equity (deficit)	34,603	(178,851)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 40,648	$ 34,984

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

Ionetix Corporation

Condensed Consolidated Statements of Operations
(Amounts in thousands, except share and per share data)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	**2025**	**2026**	**2025**
Revenue	$ 1,244	$ 1,141	$ 3,496	$ 4,814
Operating expenses				
Cost of revenue	1,026	1,224	3,942	4,377
Selling, general and administrative	4,414	2,504	10,629	8,123
Research and development	854	1,311	2,269	3,956
Total operating expenses	6,294	5,039	16,840	16,456
Loss from operations	(5,050)	(3,898)	(13,344)	(11,642)
Interest income (expense), net	60	(925)	(254)	(2,505)
Other income (expense), net	53	(1,869)	(13,575)	(2,920)
Loss before provision for income taxes	(4,937)	(6,692)	(27,173)	(17,067)
Provision for income taxes	—	—	4	6
Net loss	$ (4,937)	$ (6,692)	$ (27,177)	$ (17,073)
Weighted-average shares used in computing net loss per share attributable to common stockholders	109,999,870	12,786,148	75,945,785	12,702,432
Net loss per share attributable to common stockholders, basic and diluted	$ (0.04)	$ (0.52)	$ (0.36)	$ (1.34)

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

Ionetix Corporation

Condensed Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)

(Amounts in thousands, except share data)

(Unaudited)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated	Total Stockholders' Equity
	Shares	Amount	Shares	Par Value	Capital	Deficit	(Deficit)
Balance December 31, 2025	145,182,811	$ 191,199	26,163,296	$ 3	$ 7,709	$ (186,563)	$ (178,851)
Retroactive application of reverse recapitalization	(72,388,151)	—	(13,045,020)	(1)	1	—	—
Balance December 31, 2025, adjusted	72,794,660	191,199	13,118,276	2	7,710	(186,563)	(178,851)
Net loss	—	—	—	—	—	(6,941)	(6,941)
Conversion of SAFEs to Series F redeemable convertible preferred stock	2,222,913	6,668	—	—	—	—	—
Exercise of stock options	—	—	320,764	—	100	—	100
Issuance of common stock warrants	—	—	—	—	2,822	—	2,822
Exercise of common stock warrants	—	—	1,323,214	—	26	—	26
Stock-based compensation	—	—	—	—	125	—	125
Balance March 31, 2026	75,017,573	$ 197,867	14,762,254	$ 2	$ 10,783	$ (193,504)	$ (182,719)
Net loss	—	—	—	—	—	(15,299)	(15,299)
Conversion of Legacy Ionetix redeemable convertible preferred stock into common stock upon the Merger	(75,017,573)	(197,867)	75,017,573	8	197,859	—	197,867
Issuance of common stock in connection with the Merger and private placement offering, net of transaction cost of $4,082	—	—	10,777,268	1	28,249	—	28,250
Issuance of common stock in connection with the subsequent private placement offering, net of transaction cost of $108	—	—	185,000	—	447	—	447
Issuance of common stock to JDEV shareholders in connection with the Merger	—	—	4,400,000	—	(20)	—	(20)
Issuance of common stock in connection with the Termination Agreement	—	—	277,696	—	833	—	833
Issuance of common stock warrants in settlement of a contingent equity arrangement	—	—	—	—	9,692	—	9,692
Issuance of placement agent warrants (equity component)	—	—	—	—	1,520	—	1,520
Issuance costs – placement agent warrants (non-cash)	—	—	—	—	(1,520)	—	(1,520)
Conversion of Legacy Ionetix Preferred Stock Warrants into the Company's Common Stock Warrants upon the Merger	—	—	—	—	99	—	99
Exercise of stock options	—	—	126,353	—	33	—	33
Exercise of common stock warrants	—	—	707,598	—	14	—	14
Stock-based compensation	—	—	—	—	151	—	151
Balance June 30, 2026	—	—	106,253,742	$ 11	$ 248,140	$ (208,803)	$ 39,348
Net loss	—	—	—	—	—	(4,937)	(4,937)
Exercise of stock options	—	—	17,902	—	12	—	12
Exercise of common stock warrants	—	—	41,473	—	1	—	1
Stock-based compensation	—	—	—	—	179	—	179
Balance September 30, 2026	—	—	106,313,117	$ 11	$ 248,332	$ (213,740)	$ 34,603

Ionetix Corporation

Condensed Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)

(Amounts in thousands, except share data)

(Unaudited)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated	Total Stockholders' Equity
	Shares	Amount	Shares	Par Value	Capital	Deficit	(Deficit)
Balance December 31, 2024	100,608,468	$ 104,634	24,788,845	$ 2	$ 3,474	$ (146,892)	$ (143,416)
Retroactive application of reverse recapitalization	(50,163,383)	—	(12,359,719)	(1)	1	—	—
Balance December 31, 2024, adjusted	50,445,085	104,634	12,429,126	1	3,475	(146,892)	(143,416)
Net loss	—	—	—	—	—	(2,391)	(2,391)
Issuance of common stock warrants	—	—	—	—	121	—	121
Exercise of stock options	—	—	4,074	—	3	—	3
Stock-based compensation	—	—	—	—	183	—	183
Balance March 31, 2025	50,445,085	$ 104,634	12,433,200	$ 1	$ 3,782	$ (149,283)	$ (145,500)
Net loss	—	—	—	—	—	(7,990)	(7,990)
Exercise of stock options	—	—	43,660	—	21	—	21
Stock-based compensation	—	—	—	—	106	—	106
Balance June 30, 2025	50,445,085	$ 104,634	12,476,860	$ 1	$ 3,909	$ (157,273)	$ (153,363)
Net loss	—	—	—	—	—	(6,692)	(6,692)
Exercise of preferred stock warrant for Series F redeemable convertible preferred stock	55,154	304	—	—	—	—	—
Issuance of common stock warrants	—	—	—	—	121	—	121
Exercise of common stock warrants	—	—	376,050	1	7	—	8
Stock-based compensation	—	—	—	—	100	—	100
Balance September 30, 2025	50,500,239	$ 104,938	12,852,910	$ 2	$ 4,137	$ (163,965)	$ (159,826)

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

Ionetix Corporation

Condensed Consolidated Statements of Cash Flows
(Amounts in thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2026	**2025**
Cash flows from operating activities:		
Net loss	$ (27,177)	$ (17,073)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	2,612	2,461
Amortization of operating right-of-use assets	334	358
Stock-based compensation	455	389
Amortization and write-off of debt discount and issuance costs	862	366
Provision for credit losses	251	—
Provision for inventory reserve	107	—
Change in fair value of SAFE liability	134	2,932
Change in fair value of derivative liabilities	21	(19)
Gain on extinguishment of make-whole derivative liabilities	(132)	—
Change in fair value of warrant liability	(72)	10
Loss on non-cash investor agreement settlement expense	10,525	—
Non-cash loss on issuance of SAFEs and common stock warrants	2,217	—
Loss on abandoned financing transaction	345	—
Other	(14)	(24)
Changes in operating assets and liabilities:		
Accounts receivable, net	(920)	(678)
Loan receivable, net	—	(63)
Inventory, net	(108)	624
Prepaid expenses and other assets	(1,082)	(82)
Accounts payable	(1,674)	1,074
Accrued expenses and other liabilities	(67)	1,332
Operating lease liabilities	(328)	(353)
Net cash used in operating activities	(13,711)	(8,746)
Cash flows from investing activities:		
Purchases of property and equipment	(5,551)	(2,910)
Net cash used in investing activities	(5,551)	(2,910)
Cash flows from financing activities:		
Proceeds from issuance of common stock in connection with the Merger and private placement offering, net of paid transaction cost	28,250	—
Proceeds from issuance of common stock in connection with the subsequent private placement offering, net of paid transaction cost	447	—
Proceeds from issuance of SAFEs	2,448	5,356
Proceeds from promissory notes, net of issuance costs	725	440
Proceeds from related party advances	710	1,814
Proceeds from an investor advance	175	—
Proceeds from financing agreements, net of issuance costs	106	—
Proceeds from exercise of stock options	145	24
Proceeds from exercise of common stock warrants	41	8
Repayment on 2023 Term Loan	(5,665)	—
Repayment on promissory notes	(1,568)	(26)
Repayment of related party advances	(380)	(760)
Repayment of an investor advance	(175)	—
Repayment of financing agreements	(106)	—
Payment for deferred transaction costs related to pending financing	(60)	—
Proceeds from exercise of preferred stock warrant	—	154
Net cash provided by financing activities	25,093	7,010
Net increase (decrease) in cash and restricted cash	5,831	(4,646)
Cash and restricted cash, beginning of period	432	5,338
Cash and restricted cash, end of period	$ 6,263	$ 692
Components of cash and restricted cash		
Cash	5,574	526
Restricted cash in prepaid expenses and other current assets	12	12
Restricted cash, non-current in other non-current assets	677	154

Total cash and restricted cash	6,263	692
Supplemental cash flow disclosure:		
Cash paid for income taxes	$ 4	$ 41
Cash paid for interest	$ 715	$ 615
Non-cash investing and financing activities:		
Conversion of Legacy Ionetix redeemable convertible preferred stock into common stock upon the Merger	$ 197,867	$ —
Issuance of common stock warrants in settlement of a contingent equity arrangement	$ 9,692	$ —
Issuance of preferred stock upon conversion of SAFEs	$ 6,668	$ —
Issuance of common stock warrants in connection with issuance of SAFEs and promissory notes	$ 2,822	$ 242
Issuance of placement agent warrants in connection with the private placement offering	$ 1,520	$ —
Issuance of common stock in connection with the Termination Agreement	$ 833	$ —
Conversion of related party advance into promissory note	$ 330	$ —
Property and equipment included in accounts payable	$ 234	$ 4,558
Conversion of Legacy Ionetix Preferred Stock Warrants into the Company's Common Stock Warrants upon the Merger	$ 99	$ —
Transfer of inventory to property and equipment	$ 36	$ 30
Deferred transaction costs included in accrued expenses	$ 20	$ —
Issuance of common stock to JDEV shareholders in connection with the Merger	$ 20	$ —
Asset retirement obligations incurred and capitalized	$ 15	$ 63
Transfer of prepaid deposit to property and equipment	$ —	$ 1,242

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

1. Description of Business

Organization and Business

Ionetix Corporation (the "Company" or "Ionetix") is a cyclotron technology platform company providing full-service radioisotope production and end-to-end radiopharmaceutical manufacturing solutions. With its proprietary compact superconducting cyclotron technology, the Company manufactures short-lived diagnostic radioisotopes used in positron emission tomography imaging. The Company also manufactures therapeutic radioisotopes for targeted alpha therapy ("TAT"), an emerging cancer therapy utilizing alpha radionuclides. TAT delivers high-energy alpha particles to cancer cells and the tumor microenvironment to treat cancer while preserving healthy tissue. Ionetix was incorporated in the state of Delaware on December 28, 2009, and maintains its principal office in Lansing, Michigan.

Merger

On April 9, 2026, JDEV Acquisition Corp. ("JDEV" and after the Merger, Ionetix), JDEV Merger Subsidiary ("Merger Sub") and Ionetix Corporation, the privately held operating company (referred to herein as "Legacy Ionetix"), completed the merger contemplated by the Agreement and Plan of Merger and Reorganization dated April 9, 2026 (the "Merger Agreement"), pursuant to which Merger Sub merged with and into Legacy Ionetix, with Legacy Ionetix continuing as the surviving corporation and a wholly owned subsidiary of the Company (the "Merger"). In connection with the Merger, JDEV was renamed Ionetix Corporation.

The Merger was accounted for as a reverse recapitalization, with Legacy Ionetix treated as the accounting acquirer and JDEV treated as the acquired company for financial reporting purposes. Accordingly, the historical financial information presented for periods prior to the Merger represents the accounts of Legacy Ionetix and its consolidated subsidiaries.

At the effective time of the Merger, each outstanding share of Legacy Ionetix common stock and redeemable convertible preferred stock was converted into the right to receive shares of the Company's common stock based on a conversion ratio of 0.5014 (the "Conversion Ratio"). In addition, all outstanding Legacy Ionetix options and warrants were assumed by the Company and converted into options and warrants, respectively, to purchase shares of the Company's common stock, with the number of underlying shares and exercise price adjusted based on the Conversion Ratio.

All share and per-share amounts presented for periods prior to the Merger have been retrospectively adjusted, where applicable, to reflect the Conversion Ratio. Unless otherwise indicated or the context otherwise requires, references in these notes accompanying the condensed consolidated financial statements to "Ionetix" and "the Company" refer to the business and operations of Legacy Ionetix prior to the Merger and to Ionetix Corporation and its consolidated subsidiaries following the Merger. See Note 10, Redeemable Convertible Preferred Stock, Note 11, Stockholders' Equity (Deficit), Note 12, Stock Option Plan, and Note 13, Common Stock Warrants, for additional information regarding the Company's equity instruments.

Liquidity

The Company has incurred net losses since inception, including net losses of $4.9 and $6.7 million for the three months ended September 30, 2026 and 2025, respectively, and $27.2 and $17.1 million for the nine months ended September 30, 2026 and 2025, respectively, and has an accumulated deficit of $213.7 million as of September 30, 2026. As of September 30, 2026, the Company had $5.6 million in cash and $0.7 million in restricted cash.

On October 26, 2026, the Company completed the initial closing of a private placement offering of its common stock for gross proceeds of $0.7 million. See Note 17. The Company expects to fund its projected operating requirements through a combination of existing cash, anticipated revenues from its products and services, and additional financing activities.

The Company expects to continue to incur losses and negative cash flows for the foreseeable future as it continues to invest in research and development, manufacturing, sales and marketing efforts, and site deployment activities to support the growth of its business. If the Company does not perform in line with its operating plan, its capital resources may be depleted more rapidly than expected, and the Company may need to obtain additional financing sooner than anticipated. There can be no assurance that such financing will be available on acceptable terms, or at all.

These conditions raise substantial doubt about the Company's ability to continue as a going concern for one year from the date these condensed consolidated financial statements are issued. The condensed consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

2. Basis of Presentation and Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States ("U.S. GAAP") for interim financial information and include the accounts of the Company and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

In the opinion of management, the accompanying unaudited condensed consolidated financial statements include all adjustments, consisting of normal recurring adjustments, necessary for a fair presentation of the financial position, results of operations and cash flows for the periods presented. The results of operations for the interim periods are not necessarily indicative of the results that may be expected for the full fiscal year or any future period. There were no items of other comprehensive income (loss) during the periods presented. Accordingly, net loss equaled comprehensive loss for all periods presented.

Significant Accounting Policies

The Company's significant accounting policies, including the recent accounting pronouncements adopted and recently issued accounting standards not yet adopted, are described in Note 2 of the "Basis of Presentation and Summary of Significant Accounting Policies" to the audited consolidated financial statements as of and for the fiscal years ended December 31, 2025 and 2024, included as Exhibit 99.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 16, 2026. Other than the early adoption of ASU 2025-10 described below, there have been no material changes to these policies during the nine months ended September 30, 2026.

Recently Adopted Accounting Pronouncements

In December 2025, the Financial Accounting Standards Board ("FASB") issued ASU 2025-10, Government Grants (Topic 832): Accounting for Government Grants Received by Business Entities, which establishes recognition, measurement and presentation guidance for government grants received by business entities. The Company early adopted ASU 2025-10 effective January 1, 2026 using the modified prospective transition method. The adoption did not have a material impact on the Company's condensed consolidated financial statements. See "Government Grants" below.

Segment Reporting

The Company operates as a single operating and reportable segment. The Company's Chief Operating Decision Maker ("CODM") is its Chief Executive Officer, who reviews financial information presented on a consolidated basis for purposes of financial performance review and allocation of resources. Net loss is the primary measure of segment profit or loss that the CODM reviews when assessing consolidated performance. Revenue from customers and significant segment expenses are presented in the Company's condensed consolidated statements of operations. The CODM does not evaluate segment performance using balance sheet information. All of the Company's long-lived assets and revenue are concentrated in the United States.

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with GAAP requires management to make certain estimates and assumptions that affect the amounts reported and disclosed in the Company's condensed consolidated financial statements and accompanying notes. The Company regularly evaluates estimates and assumptions including, but not limited to, determination of allowance for credit losses, valuation of inventory, valuation and estimated useful lives of long-lived assets, valuation of SAFE liability, valuation of derivative liability, valuation of common stock prior to the Company becoming publicly traded and preferred stock warrants, stock-based compensation, the incremental borrowing rate applied to leases, and income tax related estimates. Actual results could differ materially from those estimates.

Restricted Cash

Restricted cash consists of (i) a certificate of deposit pledged as collateral under certain contractual arrangements, which is classified as long-term restricted cash, (ii) funds subject to regulatory restrictions administered by the Office of Foreign Assets Control ("OFAC"), which are classified as short-term restricted cash based on the expected duration of the restriction, and (iii) funds held to satisfy financial assurance requirements imposed by applicable federal and state regulatory authorities for certain of the Company's radioisotope production facilities, including decommissioning obligations.

Restricted cash is classified as current or non-current based on the nature and expected duration of the restrictions. As of September 30, 2026, restricted cash of $12 was included in prepaid expenses and other current assets, and $677 was included in other non-current assets in the condensed consolidated balance sheets.

Transaction Costs

Transaction costs consist of legal, accounting, placement agent fees, and other direct and incremental costs incurred in connection with the Company's equity financing transactions. Such costs are deferred and capitalized while the related financing transaction is in process and recorded as a reduction of additional paid-in capital upon completion of the transaction.

During the nine months ended September 30, 2026, the Company completed the Merger and related private placement offerings and recorded $4.2 million of transaction costs as a reduction of additional paid-in capital.

As of September 30, 2026, the Company had deferred $0.1 million of transaction costs, primarily legal fees, related to a private placement offering of its common stock that was in process as of that date. The initial closing of the offering occurred in October 2026 (see Note 17). These costs are expected to be recorded as a reduction of additional paid-in capital upon completion of the financing transaction.

Significant Customers

The following table summarizes customers that accounted for 10% or more of revenue or accounts receivable:

	Revenue		Revenue	
	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Customer A	31%	31%	33%	19%
Customer B	15%	23%	20%	20%
Customer C	18%	21%	18%	13%
Customer D	16%	20%	17%	12%
Customer E	*	*	*	34%
Customer F	18%	*	*	*

	Accounts Receivable	
	September 30, 2026	December 31, 2025
Customer A	13%	20%
Customer B	46%	49%
Customer C	17%	18%
Customer D	*	11%
Customer F	13%	*

* *Represents less than 10%*

Accounts Receivable, Net

Accounts receivable are stated net of an allowance for credit losses. The following table summarizes accounts receivable, net:

	September 30, 2026	December 31, 2025
Gross accounts receivable	$ 4,302	$ 3,382
Allowance for credit losses	(2,380)	(2,129)
Accounts receivable, net	$ 1,922	$ 1,253

The allowance for credit losses is estimated using historical collection experience, the aging of receivables, customer-specific information, current economic conditions, and management's expectations regarding collectability. Receivables sharing similar risk characteristics are evaluated collectively, while receivables exhibiting specific credit risk indicators are evaluated individually.

The Company recognized a provision for credit losses of $133 and $251 during the three and nine months ended September 30, 2026, respectively. No provision for credit losses was recognized during the three and nine months ended September 30, 2025.

Revenue Recognition

The Company recognizes revenue when control of goods or services is transferred to customers in an amount that reflects the consideration to which the Company expects to be entitled. Revenue is recognized either at a point in time or over time depending on the nature of the performance obligation.

The Company generates revenues primarily from (i) diagnostic drug and medical radioisotopes sales, (ii) cyclotron system and parts sales (including installation and acceptance), and (iii) consulting services and system support services.

The following table presents revenue disaggregated by major product and service lines for the three and nine months ended September 30, 2026 and 2025:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Diagnostic drug and medical radioisotopes sales	$ 1,236	$ 1,100	$ 3,474	$ 3,161
Cyclotron system and parts sales	8	41	22	1,653
Total	$ 1,244	$ 1,141	$ 3,496	$ 4,814

The Company's performance obligations are typically part of contracts that have an original expected duration of one year or less. As such, the Company does not disclose the aggregate amount of the transaction price allocated to performance obligations that are unsatisfied (or partially satisfied) as of the end of the reporting period. The Company did not record any revenue related to performance obligations satisfied (or partially satisfied) in previous periods, during the three and nine months ended September 30, 2026 and 2025.

Government Grants

The Company is party to a cost-reimbursement subaward, funded by the U.S. Department of Energy, under which it is reimbursed for allowable costs incurred in performing certain research activities, up to the approved subaward budget. Government grants are recognized when it is probable that the Company will comply with the conditions attached to the grants and that the grants will be received. Grants related to income are recognized in the periods in which the related eligible costs are incurred. The Company presents such grants within other income (expense), net, and the related research and development costs are presented on a gross basis within research and development expenses. During the three and nine months ended September 30, 2026, the Company recognized grant income of $53. No grant income was recognized during the three and nine months ended September 30, 2025.

Other income (expense), net

Other income (expense), net consists of changes in the fair value of the Company's financial instruments measured at fair value, including the SAFE liability, preferred stock warrant liability, and derivative liabilities, losses recognized upon the issuance of equity-classified instruments where the aggregate fair value of instruments issued exceeds the proceeds received, losses recognized in connection with the settlement of investor agreements, the write-off of unamortized debt discount and issuance costs upon the repayment of debt, government grant income and other non-operating gains and losses incidental to the Company's primary business activities. Changes in fair value of these instruments are recognized in earnings as a component of other income (expense), net in the condensed consolidated statements of operations.

3. Fair Value Measurement

Certain assets and liabilities are carried at fair value. Fair value is defined as the price that would be received for an asset or paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants at the measurement date.

Valuation techniques used to measure fair value require the Company to maximize the use of observable inputs and minimize the use of unobservable inputs. The fair value hierarchy distinguishes between market participant assumptions based on market data from independent sources (observable inputs) and an entity's own assumptions based on the best information available (unobservable inputs). The fair value hierarchy consists of three broad levels, which gives the highest priority to observable inputs (Level 1) and the lowest priority to unobservable inputs (Level 3). The three levels of the hierarchy are described below:

Level 1 – Valuations based on quoted prices in active markets for identical assets or liabilities.

Level 2 – Valuations based on inputs other than quoted prices included within Level 1 that are observable for the asset or liability, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data.

Level 3 – Valuations based on inputs that are supported by little or no market activity that are significant to determining the fair value of assets or liabilities, including pricing models, discounted cash flow methodologies, and similar techniques.

Prior to the Merger, the Company's financial liabilities measured at fair value on a recurring basis consisted of SAFE liability, preferred stock warrant liabilities, and derivative liabilities. In connection with or prior to the Merger, all such instruments were converted, settled or derecognized. Accordingly, no financial liabilities measured at fair value on a recurring basis remained outstanding as of September 30, 2026. Cash, accounts receivable, accounts payable, and accrued expenses and other current liabilities are carried at amounts that approximate fair value due to the short-term nature of these instruments.

The following table sets forth, by level, within the fair value hierarchy, the financial liabilities carried at fair value on a recurring basis as of December 31, 2025:

	Fair value measurements as of December 31, 2025			
	Level 1	**Level 2**	**Level 3**	**Total**
SAFE liability	$ —	$ —	$ 4,086	$ 4,086
Warrant liability	—	—	171	171
Derivative liability	—	—	111	111
Total	$ —	$ —	$ 4,368	$ 4,368

All recurring fair value measurements were classified within Level 3 due to the use of significant unobservable inputs. During the nine months ended September 30, 2026 and 2025, there were no transfers or reclassifications between fair value measurement levels of assets or liabilities.

The following table presents a roll-forward of the aggregate fair values of the Company's Level 3 financial liabilities for the nine months ended September 30, 2026.

	SAFE liability	**Warrant liability**	**Derivative liability**
Balance as of December 31, 2025	$ 4,086	$ 171	$ 111
Issuances	2,448	—	—
Change in fair value	134	(72)	21
Settlement	(6,668)	(99)	(132)
Balance as of September 30, 2026	$ —	$ —	$ —

The change in fair value of SAFE liability, preferred stock warrant liability, and derivative liability is included in other income (expense), net in the condensed consolidated statements of operations.

4. Condensed Consolidated Balance Sheets Details

Inventory, Net

Inventory consists of sub-assemblies, components, raw materials, and work-in-process. Inventory not expected to be sold or consumed within one year, including inventory expected to be capitalized into property and equipment as cyclotron systems are completed, is classified as inventory, non-current. The composition of inventory, non-current as of September 30, 2026 and December 31, 2025 is as follows:

	September 30, 2026	December 31, 2025
Sub-assemblies, components, and raw materials	$ 2,611	$ 2,504
Work-in-process	1,695	1,683
Inventory, gross	$ 4,306	$ 4,187
Less: allowance for inventory obsolescence	(905)	(798)
Total Inventory, net	3,401	3,389
Less: inventory, current	(284)	(293)
Inventory, non-current	$ 3,117	$ 3,096

The Company maintains an allowance for inventory obsolescence to reduce the carrying value of slow-moving, obsolete, or damaged inventory to its estimated net realizable value. The allowance is based on historical write-offs, current inventory aging, and management's assessment of future demand. No allowance for inventory obsolescence was recorded against inventory included in total current assets during the three and nine months ended September 30, 2026 or September 30, 2025.

Activity in the allowance for inventory obsolescence, related solely to inventory, non-current is as follows:

	Amount
Balance as of December 31, 2025	$ 798
Provision charged to cost of revenue	107
Balance as of September 30, 2026	$ 905

No provision for inventory obsolescence was charged to cost of revenue for the three and nine months ended September 30, 2025.

Prepaid Expenses and Other Current Assets

The composition of prepaid expenses and other current assets as of September 30, 2026 and December 31, 2025 is as follows:

	September 30, 2026	December 31, 2025
Prepaid insurance	$ 469	$ —
Inventory deposits	472	435
Installation deposit	433	—
Prepaid software subscriptions	137	52
Other prepaid expenses and other current assets	82	83
Total	$ 1,593	$ 570

Property and Equipment, Net

The composition of property and equipment, net as of September 30, 2026 and December 31, 2025 is as follows:

	September 30, 2026	December 31, 2025
Specialized technical equipment	$ 9,393	$ 9,393
Production and laboratory equipment	7,386	7,198
Computer equipment	375	319
Computer software	302	302
Leasehold improvements	13,784	13,760
Construction in progress	9,478	8,452
Total property and equipment	40,718	39,424
Less accumulated depreciation	(14,812)	(12,210)
Property and equipment, net	$ 25,906	$ 27,214

Construction in progress represents costs incurred for leasehold improvements, including a facility expansion at a leased premises, and a cyclotron system that were not substantially complete and ready for their intended use as of September 30, 2026 and December 31, 2025. Construction in progress includes direct costs of acquisition, installation, and other expenditures necessary to bring the assets to the condition necessary for their intended use. No depreciation is recorded on construction in progress until the related assets are substantially complete and placed into service.

Depreciation expense was $0.8 million for each of the three months ended September 30, 2026 and 2025, and $2.6 million and $2.4 million for the nine months ended September 30, 2026 and 2025, respectively.

Accrued Expenses and Other Current Liabilities

The composition of accrued expenses and other current liabilities as of September 30, 2026 and December 31, 2025 is as follows:

	September 30, 2026	December 31, 2025
Accrued compensation and benefits	$ 830	$ 569
Customer deposits	600	600
Other accrued expenses and other current liabilities	348	431
Accrued interest	—	390
Total	$ 1,778	$ 1,990

Other Non-Current Liabilities

The composition of other non-current liabilities as of September 30, 2026 and December 31, 2025 is as follows:

	September 30, 2026	December 31, 2025
Customer deposits	$ 1,000	$ 1,000
Government grant obligation	750	750
Asset retirement obligation	584	568
Other	—	283
Total	$ 2,334	$ 2,601

5. Short-Term Debt

2023 Term Loan and Warrants

In February 2023, the Company entered into a term loan agreement with a principal amount of $5.5 million (the "2023 Term Loan"), bearing interest at 17% per annum with an existing investor of Legacy Ionetix who is a related party. See Note 16 for additional information regarding related party transactions.

In connection with the issuance of the 2023 Term Loan, the Company issued 220,000 warrants to purchase shares of Legacy Ionetix Series F redeemable convertible preferred stock at an exercise price of $1.40 per share (the "Preferred Stock Warrants"). The Preferred Stock Warrants expire in February 2033. The Preferred Stock Warrants were classified as a liability and were remeasured at fair value at each reporting date, with changes in fair value recognized in other income (expense), net in the condensed consolidated statements of operations (see Note 3 Fair Value Measurement). The Company recognized a gain of $0 and $72 from the change in the fair value of the Preferred Stock Warrants for the three and nine months ended September 30, 2026, respectively, and a loss of $17 and $10 for the three and nine months ended September 30, 2025, respectively. In August 2025, the investor exercised 110,000 of the Preferred Stock Warrants. In connection with the Merger, all the remaining Legacy Ionetix Preferred Stock Warrants were assumed by the Company and converted into warrants to purchase 55,154 shares of the Company's common stock, with the number of underlying shares and exercise price adjusted based on the Conversion Ratio. Upon conversion, the warrants met the criteria for equity classification, and the related liability of $99 was reclassified to additional paid-in capital as of the Merger date. As of September 30, 2026, warrants to purchase 55,154 shares of the Company's common stock remained outstanding.

In connection with subsequent amendments, the Company issued an aggregate of 1,250,000 common stock warrants to purchase Legacy Ionetix common stock, which were equity classified and were recorded as a debt discount amortized to interest expense over the remaining term of the loan at the time of each amendment. Of these warrants, 750,000 were exercised in August 2025, and the remaining 500,000 were exercised in March 2026. The shares issued upon exercise were converted into shares of the Company's common stock in connection with the Merger based on the Conversion Ratio. No term loan-related common stock warrants were outstanding as of September 30, 2026.

In connection with the Merger, the Company repaid the 2023 Term Loan in full, including all outstanding principal and accrued interest, and wrote off the remaining unamortized debt discount and issuance costs to other income (expense), net. Total interest expense and write-off of the debt discount related to the 2023 Term Loan were $0 and $376 for the three months ended September 30, 2026 and 2025, respectively, and $447 and $1,042 for the nine months ended September 30, 2026 and 2025, respectively.

Promissory Notes

In April 2025 and March 2026, the Company issued unsecured promissory notes with an aggregate principal amount of $1,495 to a board member of Legacy Ionetix and an existing investor, bearing interest at 11% to 15% per annum, of which $330 arose from the conversion of a related party advance. Certain of the notes issued in March 2026 included equity-classified warrants to purchase an aggregate of 420,000 shares of Legacy Ionetix common stock at an exercise price of $0.01 per share, with an aggregate fair value of $605 that was recorded as a debt discount. Warrants for 300,000 shares were exercised in March 2026, and the shares issued were converted into 150,420 shares of the Company's common stock at the Merger. The remaining warrants for 120,000 shares were converted into warrants to purchase 60,168 shares of the Company's common stock at an exercise price of $0.02 per share at the Merger and were exercised in May 2026. No such warrants were outstanding as of September 30, 2026.

In connection with the Merger, the Company repaid all outstanding promissory notes in full, including all outstanding principal and accrued interest. As a result of the repayment, the Company wrote off the remaining unamortized debt discount and issuance costs to other income (expense), net. Total interest expense and write-off of the debt discount related to the promissory notes were $0 and $12 for the three months ended September 30, 2026 and 2025, respectively, and $668 and $23 for the nine months ended September 30, 2026 and 2025, respectively.

Financing Agreements

In March 2026, the Company entered into two insurance premium financing agreements with an unrelated third party with an aggregate principal amount of $106. The agreements were repaid in full in connection with the Merger. Related interest expense was not material.

6. Convertible Notes

2023 Notes and 2024 Note

During 2023 and 2024, the Company issued unsecured convertible promissory notes with aggregate principal amounts of $10.0 million each (the "2023 Notes" and "2024 Note," respectively). The 2024 Note included an embedded conversion feature that was bifurcated and accounted for as a derivative liability, remeasured to fair value at each reporting date, with changes in fair value recognized in other income (expense), net in the condensed consolidated statements of operations.

On October 31, 2025, all outstanding principal and accrued interest under the 2023 Notes and 2024 Note were converted into shares of Legacy Ionetix Series F redeemable convertible preferred stock at $1.40 per share pursuant to a conversion agreement (the "Conversion Agreement") and the transaction was accounted for as a debt extinguishment. No interest expense or change in fair value of the embedded conversion feature was recognized during the three and nine months ended September 30, 2026. For the three and nine months ended September 30, 2025, the Company recognized aggregate interest expense of $409 and $1,202 on these instruments, respectively, and a gain from the change in fair value of the embedded conversion feature of $27 and $19, respectively.

Make-Whole Provision

The Conversion Agreement included a one-time make-whole provision that could have required the Company to issue additional shares of Legacy Ionetix Series F redeemable convertible preferred stock if the price per share in the Company's next equity financing was below a stated threshold. The Company determined that the make-whole provision represented a derivative liability. The derivative liability was initially recorded at its estimated fair value of $1.0 million on October 31, 2025 and was remeasured at fair value at each reporting date, with changes in fair value recognized in other income (expense), net in the condensed consolidated statements of operations. The derivative liability was $40 as of December 31, 2025, and the Company recognized a change in fair value of $8 during the nine months ended September 30, 2026, substantially all of which was recognized during the three months ended March 31, 2026.

In April 2026, the make-whole right and certain other investor rights were terminated pursuant to a termination agreement (the "Termination Agreement") in exchange for 277,696 shares of common stock with a fair value of $833, based on the $3.00 per share price of the contemporaneous private placement. The difference between the fair value of the shares issued and the carrying amount of the derivative liability derecognized was recognized in other income (expense), net. See Note 11.

7. SAFE Liability

The Company issued Simple Agreements for Future Equity ("SAFEs") for aggregate principal proceeds of $45.7 million that entitled holders to receive shares of Legacy Ionetix redeemable convertible preferred stock upon the occurrence of a qualifying equity financing event at a 15% discount to the price per share paid by other investors in such financing.

The SAFEs were freestanding financial instruments and were classified as liabilities, as the SAFEs represented an obligation to issue a variable number of shares for a fixed monetary amount. The SAFEs were initially recorded at fair value upon issuance and subsequently remeasured to fair value at each reporting date, with changes in fair value recognized in the condensed consolidated statements of operations.

During the three months ended March 31, 2026, the Company issued SAFEs with aggregate proceeds of $2.4 million, together with equity-classified common stock warrants. The SAFE liability and the warrants were recorded at their issuance-date fair values of $2.4 million and $2.2 million, respectively, and the excess of their aggregate fair value over the proceeds received was recognized as an upfront loss of $2.2 million in other income (expense), net. The Company recognized a loss on the change in fair value of the SAFE liability of $134 during the nine months ended September 30, 2026, all of which was recognized during the three months ended March 31, 2026, as all outstanding SAFEs were converted into shares of Legacy Ionetix Series F redeemable convertible preferred stock on March 31, 2026. During the three and nine months ended September 30, 2025, the Company issued SAFEs, without common stock warrant coverage, with aggregate proceeds of $1.5 million and $5.4 million, respectively. The Company recognized a loss on the change in fair value of the SAFE liability of $1.9 million and $2.9 million for the three and nine months ended September 30, 2025, respectively.

Election to Convert SAFEs

On October 31, 2025, holders of SAFEs with an aggregate carrying value of $50.7 million elected to settle their SAFEs into shares of Legacy Ionetix Series F redeemable convertible preferred stock at a conversion price of $1.40 per share. The Company accounted for the transaction as an extinguishment of the SAFE liability and, in connection with the conversion, recognized a freestanding make-whole derivative liability as described below.

On March 31, 2026, all remaining outstanding SAFEs were converted into shares of Legacy Ionetix Series F redeemable convertible preferred stock at $1.40 per share. The SAFE liability was remeasured to fair value immediately prior to conversion, and the Legacy Ionetix Series F redeemable convertible preferred stock was recorded at an amount equal to that fair value. No additional gain or loss was recognized upon conversion.

Make-Whole Provision

In connection with the October 31, 2025 SAFE conversion, the Company recognized a freestanding derivative liability. The make-whole derivative liability was $71 as of December 31, 2025 and was derecognized upon termination of the make-whole right in connection with the Merger in April 2026, with no liability outstanding as of September 30, 2026. The Company recognized a change in fair value of $13 during the nine months ended September 30, 2026, substantially all of which was recognized during the three months ended March 31, 2026. No change in fair value was recognized during the three and nine months ended September 30, 2025, as the make-whole provision did not exist prior to October 31, 2025.

Contingent Equity Arrangement Associated with a SAFE

In connection with a SAFE issued in 2023, the Company entered into an arrangement that provided the investor with the right to receive a warrant upon the occurrence of certain future events, for which no amount had been recognized in the Company's historical financial statements prior to the Merger.

In connection with the Merger, the Company settled the arrangement by terminating the contingent right and related arrangements and issuing a new ten-year warrant to purchase 6,443,076 shares of Legacy Ionetix common stock at an exercise price of $0.01 per share. In connection with the Merger, such warrant was assumed by the Company and converted into a warrant to purchase 3,230,558 shares of the Company's common stock at an exercise price of $0.02 per share, based on the Conversion Ratio. The new warrant is classified within stockholders' equity. The Company determined the fair value of the new warrant at issuance to be $9.7 million, which was recognized as expense in other income (expense), net, with a corresponding increase to additional paid-in capital during the nine months ended September 30, 2026.

8. Operating Leases

The Company leases various facilities under operating leases. Leased facilities include manufacturing facilities, radiopharmaceutical production facilities, and office spaces. The Company combines lease and non-lease components; therefore, there is no allocation of lease payments to non-lease components. Short-term leases with an initial term of 12 months or less are recognized on a straight-line basis over the lease term.

The components of total lease costs for operating leases during the three and nine months ended September 30, 2026 and 2025 are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Operating lease cost	$ 114	$ 144	$ 394	$ 420
Variable lease cost	68	35	152	86

The supplemental cash flow information related to operating leases during the three and nine months ended September 30, 2026 and 2025 is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Cash payment for operating lease	$ 120	$ 143	$ 395	$ 415
Operating lease liabilities arising from obtaining new operating lease ROU assets during the period	88	—	250	817

The weighted-average remaining lease terms and discount rates for operating leases as of September 30, 2026 and 2025 are as follows:

	September 30, 2026	September 30, 2025
Weighted-average remaining lease term (years)	3.2	3.9
Weighted-average discount rate	6.7%	6.8%

Future minimum lease payments under non-cancellable leases as of September 30, 2026, are as follows:

	Amount
Remainder of 2026	$ 118
2027	437
2028	330
2029	239
2030	142
Thereafter	—
Total undiscounted lease payments	1,266
Less: Imputed interest	(125)
Operating lease liabilities	$ 1,141

9. Commitments and Contingencies

Litigation and Claims

From time to time, the Company may be involved in legal proceedings in the normal course of business. The Company assesses the need to record a liability for litigation and contingencies. Reserve estimates are recorded when and if it is determined that a loss-related matter is both probable and reasonably estimable.

Litigation Settlement and Revenue Impact

The Company was party to litigation associated with a prior commercial arrangement. In January 2026, the Company resolved the matter by entering into a supply agreement with the customer. Under the terms of the agreement, the customer may purchase specified radioisotopes at a per-unit contractual discount until aggregate discounts total $2.8 million (the “Settlement Credit”). The credit is nonrefundable and does not require the customer to make minimum purchase commitments.

The Company concluded that the Settlement Credit represents consideration payable to a customer within the scope of ASC 606, Revenue from Contracts with Customers. Accordingly, the Settlement Credit will be recognized as a reduction of transaction price and recorded as a reduction of revenue as the customer exercises its right to purchase product at the discounted price. Revenue will continue to be recognized upon transfer of control of the product to the customer. As of September 30, 2026, no portion of the Settlement Credit had been utilized.

Purchase Commitments

As of September 30, 2026, the Company did not have any significant noncancelable purchase commitments.

10. Redeemable Convertible Preferred Stock

No shares of redeemable convertible preferred stock were outstanding as of September 30, 2026. Redeemable convertible preferred stock as of December 31, 2025 was comprised of the following.

Series	Original issue price	Shares authorized	Issued and outstanding	Carrying value	Liquidation preference
	(Per share)				
A	$ 0.10	6,160,056	6,160,056	$ 645	$ 645
B	0.42	3,760,500	3,760,500	1,575	1,575
C	1.70	2,507,000	2,507,000	4,250	4,250
D	1.99	2,056,141	2,056,141	4,101	4,101
E	2.23	11,367,454	11,367,454	25,392	25,392
F	2.79	52,888,416	46,943,509	155,236	131,075
		78,739,567	72,794,660	$ 191,199	$ 167,038

Share amounts and per share original issue prices presented above have been retroactively adjusted to reflect the Conversion Ratio.

In connection with the Merger, all outstanding shares of Legacy Ionetix redeemable convertible preferred stock, as so adjusted, were converted into shares of the Company's common stock. See Note 1 for additional information.

11. Stockholders' Equity (Deficit)

The Company's capital structure following the Merger, which was accounted for as a reverse recapitalization (see Note 1), is described below.

Preferred Stock

As of September 30, 2026, the Company was authorized to issue 10,000,000 shares of preferred stock, par value $0.0001 per share. No shares of preferred stock were issued or outstanding as of September 30, 2026. Legacy Ionetix's redeemable convertible preferred stock outstanding as of December 31, 2025 was classified outside of stockholders' equity (deficit) as temporary equity and is discussed in Note 10.

Common Stock

As of September 30, 2026, the Company was authorized to issue 510,000,000 shares of common stock, par value $0.0001 per share, of which 106,313,117 shares were issued and outstanding. As of December 31, 2025, Legacy Ionetix was authorized to issue 219,481,484 shares of Legacy Ionetix common stock, par value $0.0001 per share, of which 26,163,296 shares were issued and outstanding. After giving effect to the Conversion Ratio, these amounts correspond to 110,048,016 authorized shares and 13,118,276 shares of the Company's common stock issued and outstanding, as presented in the condensed consolidated balance sheets.

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Holders of common stock are entitled to receive dividends, if any, as may be declared by the Board of Directors, subject to the preferential rights of holders of any outstanding preferred stock. No dividends were declared or paid during the three and nine months ended September 30, 2026 or 2025.

Conversion of Redeemable Convertible Preferred Stock

Immediately prior to the Merger, Legacy Ionetix had 149,616,222 shares of redeemable convertible preferred stock outstanding, before giving effect to the Conversion Ratio. In connection with the Merger, all outstanding shares of Legacy Ionetix redeemable convertible preferred stock were converted into 75,017,573 shares of the Company's common stock. The carrying value of the redeemable convertible preferred stock at the Merger closing date of $197.9 million was reclassified from temporary equity to permanent equity.

Following the Merger, no shares of redeemable convertible preferred stock remained issued or outstanding.

Common Stock Issued in Connection with the Merger

In connection with the Merger and reverse recapitalization, the Company issued 4,400,000 shares of common stock to holders of JDEV common stock. Because the Merger was accounted for as a reverse recapitalization, the issuance of shares to JDEV stockholders was reflected as part of the recapitalization of Legacy Ionetix and recorded within stockholders' equity.

Private Placement Offering

In connection with the Merger and a subsequent closing in June 2026, the Company issued an aggregate of 10,962,268 shares of common stock at a purchase price of $3.00 per share in private placement offerings, resulting in aggregate gross proceeds of $32.9 million.

Transaction costs attributable to the private placement offerings were recorded as a reduction of additional paid-in capital. See Note 2 "Transaction Costs" for additional information.

In connection with the private placement offerings, the Company issued warrants to purchase an aggregate of 876,983 shares of common stock to the placement agent at an exercise price of $3.00 per share. The placement agent warrants are classified as stockholders' equity. See Note 13 for additional information.

Common Stock Issued Pursuant to Termination Agreement

In April 2026, the Company entered into the Termination Agreement with an investor pursuant to which certain investor rights, including a make-whole right, were terminated. As consideration for the termination, the Company issued 277,696 shares of common stock to the investor. The shares were measured at a fair value of $833 based on the $3.00 per share price of the contemporaneous private placement offering.

The Company recorded the issuance of the common stock within stockholders' equity. The difference between the fair value of the common stock issued and the carrying amount of the related derivative liability derecognized in connection with the Termination Agreement was recognized in other income (expense), net in the condensed consolidated statements of operations. See Note 6 and Note 7 for additional information regarding the related make-whole provisions and derivative liabilities.

As of September 30, 2026, the Company had reserved shares of common stock for future issuance as follows:

	September 30, 2026
Outstanding stock options	6,742,311
Outstanding common stock warrants	8,280,246
Shares available for future issuance under the 2026 Equity Incentive Plan	5,174,415
Total	20,196,972

12. Stock Option Plan

Equity Incentive Plan

In 2010, the Company adopted the 2010 Equity Compensation Plan (the "2010 Plan"). There have been no issuances under the 2010 Plan since the adoption of the 2016 Equity Incentive Plan (the "2016 Plan"). The 2010 Plan expired in 2025, and all options available for issuance under the 2010 Plan upon expiration were moved to the 2016 Plan. Accordingly, no shares are available for future issuance under the 2010 Plan as of September 30, 2026.

In 2016, the Company's Board of Directors adopted the 2016 Plan under which incentive stock options ("ISOs"), nonqualified stock options ("NSOs"), stock appreciation rights ("SARs"), restricted stock, and restricted stock units ("RSUs") may be granted to employees, directors, and consultants.

In connection with the Merger, the Company adopted the 2026 Equity Incentive Plan (the "2026 EIP") effective on April 9, 2026. Pursuant to the Merger Agreement, the 2016 Plan was terminated effective as of the closing of the Merger, and no further awards may be granted thereunder. All outstanding Legacy Ionetix stock options were assumed by the Company under the 2026 EIP and converted into options to purchase shares of the Company's common stock, with the number of underlying shares and exercise price adjusted based on the Conversion Ratio. The converted options otherwise continued to be subject to substantially the same terms and conditions applicable to such options immediately prior to the Merger. The 2026 EIP provides for the issuance of incentive awards of ISOs, NSOs, SARs, RSUs and Stock Bonus Awards ("SBAs"). ISOs may be granted only to employees. The maximum aggregate number of shares of common stock that may be issued under the 2026 EIP is 11,935,631 shares.

Stock option

Stock option activity during the nine months ended September 30, 2026 is as follows:

	Number of options	Weighted average exercise price	Weighted average remaining contractual life (years)	Aggregate intrinsic value
Balance as of December 31, 2025	14,162,648	$ 0.31	6.41	$ 2,541
Retroactive application of reverse recapitalization	(7,061,496)			
Balance as of December 31, 2025, adjusted	7,101,152	0.62	6.41	2,541
Options granted	646,357	2.55		
Options exercised	(465,019)	0.31		1,151
Options cancelled	(540,179)	0.55		
Balance as of September 30, 2026	6,742,311	$ 0.83	6.48	$ 14,610
Vested and expected to vest at September 30, 2026	6,742,311	$ 0.83	6.48	$ 14,610
Exercisable at September 30, 2026	4,617,129	$ 0.57	5.41	$ 11,215

The options granted during the three months ended September 30, 2026 and 2025 had a weighted-average grant-date fair value per share of $2.08 and $0.61, respectively, and the options granted during the nine months ended September 30, 2026 and 2025 had a weighted-average grant-date fair value per share of $2.03 and $0.60, respectively. The total fair value of options vested was $90 and $94 during the three months ended September 30, 2026 and 2025, respectively, and $398 and $367 during the nine months ended September 30, 2026 and 2025, respectively.

Fair Value Inputs

The fair value of stock options granted was estimated using the following weighted-average assumptions:

	Nine Months Ended September 30,	
	2026	**2025**
Expected term (in years)	6.1	5.7
Expected volatility	70.0%	65.4%
Risk-free rate	4.2%	4.1%
Dividend yield	—	—

Stock-Based Compensation

The Company's total stock-based compensation for the three and nine months ended September 30, 2026 and 2025 is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	**2025**	**2026**	**2025**
Cost of revenue	$ 17	$ 6	$ 51	$ 9
Research and development	13	13	37	37
Selling, general and administrative	149	81	367	343
Total stock-based compensation	$ 179	$ 100	$ 455	$ 389

As of September 30, 2026, the unrecognized stock-based compensation related to outstanding unvested options was $1.9 million and is expected to be recognized over a weighted average period of 2.7 years.

13. Common Stock Warrants

In connection with the Merger, all outstanding Legacy Ionetix common stock warrants were assumed by the Company and converted into warrants to purchase shares of the Company's common stock, with the number of underlying shares and exercise price adjusted based on the Conversion Ratio. The converted warrants otherwise continued to be subject to substantially the same terms and conditions applicable to such warrants immediately prior to the Merger.

The following table summarizes common stock warrant activity for the nine months ended September 30, 2026:

	Number of warrants	**Weighted Average Exercise Price**
Outstanding at December 31, 2025	10,176,273	$ 1.08
Retroactive application of reverse recapitalization	(5,073,888)	
Outstanding at December 31, 2025, adjusted	5,102,385	2.15
Issued	5,250,146	0.55
Exercised	(2,072,285)	0.02
Outstanding at September 30, 2026	8,280,246	$ 1.67

During the nine months ended September 30, 2026, the Company issued an aggregate of 5,250,146 common stock warrants, consisting of 876,863 common stock warrants issued in connection with SAFEs, as described in Note 7 SAFE Liability; 3,230,558 warrants issued upon settlement of a contingent equity arrangement associated with a SAFE, as described in Note 7, SAFE Liability; 210,588 common stock warrants issued in connection with promissory notes, as described in Note 5 Short-Term Debt; 876,983 common stock warrants issued to the placement agent in connection with the private placement financing, as described in Note 11, Stockholders' Equity (Deficit); and 55,154 warrants resulting from the conversion of the Legacy Ionetix preferred stock warrants upon the closing of the Merger, as described in Note 5, Short-Term Debt. The warrants issued in connection with SAFEs, promissory notes and the settlement of the contingent equity arrangement have an exercise price of $0.02 per share after giving effect to the Conversion Ratio and a contractual term of ten years. The warrants resulting from the conversion of the Legacy Ionetix preferred stock warrants have an exercise price of $2.79 per share after giving effect to the Conversion Ratio and a contractual term of ten years. The placement agent warrants have an exercise price of $3.00 per share and a contractual term of five years.

14. Income Taxes

The Company recorded current state income tax expense of $0 and $4 for the three and nine months ended September 30, 2026, respectively, and $0 and $6 for the three and nine months ended September 30, 2025, respectively, primarily related to minimum taxes payable in certain state jurisdictions. The Company incurred pre-tax losses for the three and nine months ended September 30, 2026 and 2025 and continues to maintain a full valuation allowance against its deferred tax assets due to its cumulative loss position and projected future losses. Accordingly, the Company's effective tax rate was 0.0% for each of the three and nine months ended September 30, 2026 and 2025. The Company's effective tax rate differs from the U.S. federal statutory rate of 21.0% primarily due to the valuation allowance recorded against the Company's net deferred tax assets.

15. Net Loss Per Share Attributable to Common Stockholders

Basic net loss per share attributable to the Company's common stockholders is computed by dividing the net loss attributable to the Company's common stockholders by the weighted-average number of shares of common stock outstanding during the period. Diluted net loss per share is the same as basic net loss per share for all periods presented because the effects of potentially dilutive items were anti-dilutive given the Company's net loss position in each period presented.

In connection with the Merger, all outstanding shares of Legacy Ionetix common stock and redeemable convertible preferred stock were converted into shares of the Company's common stock based on the Conversion Ratio. In addition, all outstanding Legacy Ionetix options and warrants were assumed by the Company and converted into options and warrants, respectively, to purchase shares of the Company's common stock, with the number of underlying shares and exercise price adjusted based on the Conversion Ratio. The weighted-average shares outstanding and net loss per share for periods prior to the Merger have been retroactively adjusted to reflect the Conversion Ratio.

The following table presents the calculation of basic and diluted net loss per share for the three and nine months ended September 30, 2026 and 2025:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Net loss attributable to common stockholders	$ (4,937)	$ (6,692)	$ (27,177)	$ (17,073)
Weighted-average shares outstanding, basic and diluted	109,999,870	12,786,148	75,945,785	12,702,432
Net loss per share, basic and diluted	$ (0.04)	$ (0.52)	$ (0.36)	$ (1.34)

The following outstanding potential shares of common stock were excluded from the calculation of diluted net loss per share because their effect would have been anti-dilutive for the periods presented:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Redeemable convertible preferred stock	—	50,500,239	—	50,500,239
Outstanding stock options	6,742,311	7,518,402	6,742,311	7,518,402
Preferred stock warrants	—	55,154	—	55,154
Common stock warrants	4,581,027	3,648,890	4,581,027	3,648,890
Convertible notes	—	3,946,497	—	3,946,497
SAFE liabilities	—	14,160,720	—	14,160,720
Total	11,323,338	79,829,902	11,323,338	79,829,902

16. Related Party Transactions

Operating Lease

The Company leases a building for the production of therapeutic radiopharmaceuticals and for research and development from one of the Company's investors. The terms of the lease were negotiated on an arm's-length basis. The lease commenced in February 2021 and expires in January 2031. The lease requires monthly base rent of $6 and is accounted for as an operating lease. Operating lease cost related to this lease was $18 for each of the three months ended September 30, 2026 and 2025, and $55 for each of the nine months ended September 30, 2026 and 2025. As of September 30, 2026 and December 31, 2025, the Company's operating lease right-of-use assets were $286 and $330, respectively, and total operating lease liabilities were $280 and $324, respectively. Of the total lease liabilities, $54 and $56 were classified as current liabilities as of September 30, 2026 and December 31, 2025, respectively, with the remaining $226 and $268 classified as long-term liabilities, respectively.

2023 Term Loan

The Company had an outstanding term loan balance with an existing investor who is a related party. In connection with the Merger, the term loan was repaid in full. See Note 5, Short-Term Debt, for additional information.

Related Party Advances and Promissory Notes

In January 2026, the Company received unsecured, non-interest-bearing advances of $330 from a board member of Legacy Ionetix and $30 from an executive officer. The $30 advance was repaid in February 2026, while the $330 advance was converted into an unsecured promissory note in March 2026. During March 2026, the Company also issued two additional unsecured promissory notes to the same board member with an aggregate principal amount of $575. In April 2026, the Company received an additional non-interest-bearing advance of $350 from the same board member. In connection with the Merger in April 2026, all outstanding promissory notes and advances from the board member were repaid in full, including all outstanding principal and accrued interest. This board member served on the board of directors of Legacy Ionetix at the time of these transactions and did not become a member of the Company's board of directors upon the closing of the Merger. As of September 30, 2026 and December 31, 2025, no related party advances were outstanding. See Note 5, Short-Term Debt, for additional information.

17. Subsequent Events

The Company has evaluated subsequent events through November 13, 2026, the date the condensed consolidated financial statements were issued.

The October 2026 Private Placement

On October 26, 2026, the Company completed the initial closing of a private placement offering of its common stock and issued 212,121 shares of common stock at $3.30 per share for gross proceeds of $700. In connection with the initial closing, the Company issued the placement agent warrants to purchase 16,970 shares of common stock at an exercise price of $3.30 per share with a five-year term. The warrants are equity-classified and had an estimated grant-date fair value of approximately $35.

Equity Awards

On October 23, 2026, the Company granted stock options to purchase an aggregate of 4,332,900 shares of common stock and 45,000 RSUs under the 2026 EIP to employees, officers and non-employee directors. On November 11, 2026, the Company granted additional stock options to purchase 58,000 shares of common stock under the 2026 EIP. The stock options have an exercise price of $3.00 per share and a contractual term of ten years and generally vest over one to four years. The RSUs vest on January 1, 2027. The aggregate grant-date fair value of these awards was approximately $9.2 million, which will be recognized over the requisite service periods.

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

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with the unaudited condensed consolidated financial statements for the three and nine months ended September 30, 2026 and 2025 and the related notes thereto, included in Part I, Item 1 of this Quarterly Report. The following discussion should also be read alongside the Management's Discussion and Analysis of Financial Condition and Results of Operations for the years ended December 31, 2025 and 2024 included in our Current Report on Form 8-K filed with the SEC on April 16, 2026, along with the corresponding audited financial statements for such periods contained therein, and the Management's Discussion and Analysis of Financial Condition and Results of Operations for the three and six months ended June 30, 2026 and 2025 included in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2026 filed with the SEC on August 12, 2026. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report, including information with respect to our plans and strategy for our business, includes forward-looking statements involving risks and uncertainties as described under the heading "Special Note Regarding Forward-Looking Statements" elsewhere in this Quarterly Report. You should review the section titled "Risk Factors" in Part II, Item 1A of our Quarterly Report on Form 10-Q for the quarter ended June 30, 2026 filed with the SEC on August 12, 2026, as supplemented by Part II, Item 1A of this Quarterly Report, for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements and could otherwise affect our intended plans of operations.

Overview

Background

Ionetix Corporation (following the Merger described below, "Ionetix" or the "Company") develops superconducting cyclotron technology to produce isotopes for medical and industrial purposes. The Company's business was founded in 2009, when Legacy Ionetix (as defined below) was incorporated in the State of Delaware on the premise that this novel cyclotron technology could produce isotopes in a smaller and more cost-effective footprint. Following the Merger described below, the Company continues that business as a public reporting company. Our mission is to produce otherwise hard-to-obtain isotopes, using a combination of our proprietary cyclotron technology and equipment sourced from third parties.

Our leadership team has a combined 50+ years of direct experience with nuclear medicines, cyclotron technology solutions and engineering. Our board members include experts in pharmaceutical and biotechnology research and development and manufacturing. We believe that the depth of our expertise and our cyclotron technology solutions uniquely position us to become the market leader in the manufacturing of isotopes for medical and industrial purposes.

The Merger

On April 9, 2026, a wholly owned subsidiary of JDEV Acquisition Corp. ("JDEV") merged with and into pre-Merger Ionetix Corporation ("Legacy Ionetix"), with Legacy Ionetix continuing as the surviving corporation and our wholly owned subsidiary (the "Merger"). In connection with the Merger, JDEV changed its name to Ionetix Corporation, and we continue the existing business operations of Legacy Ionetix as a public reporting company.

Contemporaneously with the closing of the Merger, we completed the initial closing of a private placement financing, and on June 1, 2026, we completed a subsequent closing on the same terms. In the aggregate, we sold 10,962,268 shares of common stock at a purchase price of $3.00 per share for gross proceeds of $32.9 million. Transaction costs totaled $4.2 million, resulting in net proceeds of approximately $28.7 million.

For additional information regarding the Merger and related transactions, see our Current Report on Form 8-K filed with the SEC on April 16, 2026, as amended by Form 8-K/A filed with the SEC on May 20, 2026.

The October 2026 Private Placement

On October 26, 2026, we completed the initial closing of a private placement offering of our common stock, pursuant to which we sold 212,121 shares of common stock at a purchase price of $3.30 per share, generating gross proceeds of $0.7 million.

Components of Results of Operations

Revenue

Our revenues are generated primarily from (i) diagnostic drug and medical radioisotopes sales, (ii) cyclotron system and parts sales, and (iii) consulting services and system support services.

Diagnostic drug and medical radioisotopes sales represent our principal source of revenue. Under these arrangements, customers place purchase orders pursuant to master sales agreements, with each delivered dose representing a distinct performance obligation. Revenue is recognized upon delivery, when control of the product transfers to the customer. Because these products are ordered based on clinical requirements and administered as part of patient care, demand is closely tied to real-time utilization. We began sales of therapeutic radioisotopes in late 2025, and we expect revenues from the sale of diagnostic drugs to continue to represent the primary driver of our business, with future growth influenced by the development and commercialization of additional isotopes, including therapeutic isotopes, as well as continuing utilization of PET imaging products.

Cyclotron system and parts revenues are generated from the delivery of equipment together with installation and related activities necessary to verify functionality in accordance with contractual specifications, as well as the sales of parts. For cyclotron system sales, these activities are combined into a single performance obligation, and revenue is recognized upon completion of installation and formal customer acceptance. Revenue from sales of spare parts is recognized upon delivery, when control transfers to the customer. Cyclotron system sales have historically been driven by customer-specific deployment needs and the timing of system installations. Because we do not intend to pursue cyclotron system sales in the future, we do not expect to generate revenue from cyclotron system sales. However, we expect to continue to generate revenue from sales of spare parts.

Consulting services and system support services are typically recognized over time as services are performed because the customer simultaneously receives and consumes the benefits of our performance. We measure progress using a cost-to-cost input method, recognizing revenue based on costs incurred relative to total estimated costs, with estimates updated as facts and circumstances change.

Operating Expenses

Cost of Revenue

Cost of revenue consists primarily of costs associated with the manufacture and delivery of our products and related services, including materials and components, personnel-related costs, production-related overhead and shipping and handling costs. Production-related overhead includes facility costs, utilities, depreciation of production equipment, and hosting and cloud infrastructure costs. Cost of revenue also includes manufacturing-related adjustments such as production variances, warranty costs, scrap, and write-downs of excess or obsolete components. As production volume and system deliveries increase, cost of revenue is expected to increase in absolute dollars.

Selling, General and Administrative

Selling, general and administrative expenses consist primarily of personnel-related costs, including salaries, health insurance, payroll taxes, and stock-based compensation. Selling, general and administrative expenses also include consulting and professional service fees and other general corporate and administrative expenses.

As we continue to grow our business and expand our commercial presence, we expect selling, general and administrative expenses to increase in absolute dollars. In addition, we expect selling, general and administrative expenses to increase in the near term as a result of operating as a public company, including costs associated with compliance with SEC reporting requirements, audit and legal fees, insurance, and other corporate governance and administrative expenses.

Research and Development

Research and development expenses consist of costs incurred in connection with our development activities and are expensed as incurred. These expenses primarily include personnel-related costs, such as salaries, stock-based compensation, health insurance, and other employee benefits. Research and development expenses also include depreciation and amortization of development equipment and related assets, legal and regulatory costs, and other expenses necessary to support our development activities.

We have invested, and intend to continue to invest, in research and development activities to support the expansion of our diagnostic isotope offerings and the advancement of therapeutic isotope programs, including alpha-emitting radionuclides. Research and development expenses may fluctuate from period to period based on the timing and scope of development initiatives, regulatory activities, and clinical supply programs. Beginning in December 2025, certain personnel and assets previously dedicated to research and development activities transitioned to operational activities as the related development activities progressed toward commercialization. We expect research and development expenses to increase in absolute dollars as we continue to invest in technology, production capabilities, and isotope development.

Interest Income (Expense), Net

Interest income (expense), net consists primarily of interest incurred on outstanding debt obligations, partially offset by interest income earned on our cash.

Other Income (Expense), Net

Other income (expense), net consists primarily of non-cash gains and losses from the fair value remeasurement of financial instruments, gains and losses associated with financing transactions, government grant income, and other non-operating items.

Provision for Income Taxes

We have incurred net losses since inception and maintain a full valuation allowance against our deferred tax assets. As a result, income tax expense was not material for the periods presented.

Results of Operations

The following table sets forth selected condensed consolidated statements of operations data for the periods indicated:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
	(in thousands)		(in thousands)	
Revenue	$ 1,244	$ 1,141	$ 3,496	$ 4,814
Operating expenses				
Cost of revenue	1,026	1,224	3,942	4,377
Selling, general and administrative	4,414	2,504	10,629	8,123
Research and development	854	1,311	2,269	3,956
Total operating expenses	6,294	5,039	16,840	16,456
Loss from operations	(5,050)	(3,898)	(13,344)	(11,642)
Interest income (expense), net	60	(925)	(254)	(2,505)
Other income (expense), net	53	(1,869)	(13,575)	(2,920)
Loss before provision for income taxes	(4,937)	(6,692)	(27,173)	(17,067)
Provision for income taxes	—	—	4	6
Net loss	$ (4,937)	$ (6,692)	$ (27,177)	$ (17,073)

Revenue

	Three Months Ended September 30,		Change	Nine Months Ended September 30,		Change
	2026	2025	%	2026	2025	%
	(in thousands)			(in thousands)		
Revenue	$ 1,244	$ 1,141	9%	$ 3,496	$ 4,814	-27%

Total revenue was $1.2 million for the three months ended September 30, 2026 compared to $1.1 million for the three months ended September 30, 2025, representing an increase of $0.1 million, or 9%. The increase was primarily driven by sales to a new customer, partially offset by lower sales at certain of our production sites. Revenue for both periods consisted primarily of diagnostic drugs and medical radioisotopes.

Total revenue was $3.5 million for the nine months ended September 30, 2026 compared to $4.8 million for the nine months ended September 30, 2025, representing a decrease of $1.3 million, or 27%. The decrease was primarily driven by a $1.6 million decrease in cyclotron system sales, reflecting the absence of cyclotron system sales in the current period, partially offset by higher diagnostic drug and medical radioisotopes sales. Because we do not intend to pursue cyclotron system sales in the future, we do not expect to generate revenue from cyclotron system sales in future periods. Diagnostic drug and medical radioisotopes sales were $3.5 million for the nine months ended September 30, 2026 compared to $3.2 million for the nine months ended September 30, 2025.

Cost of Revenue

	Three Months Ended September 30,		Change	Nine Months Ended September 30,		Change
	2026	2025	%	2026	2025	%
	(in thousands)			(in thousands)		
Cost of revenue	$ 1,026	$ 1,224	-16%	$ 3,942	$ 4,377	-10%

Cost of revenue was $1.0 million for the three months ended September 30, 2026 compared to $1.2 million for the three months ended September 30, 2025, representing a decrease of $0.2 million, or 16%. The decrease was primarily driven by a $0.1 million decrease in overhead allocation costs among production sites due to changes in revenue generation, and a $0.1 million decrease in the cost of spare parts sold.

Cost of revenue was $3.9 million for the nine months ended September 30, 2026 compared to $4.4 million for the nine months ended September 30, 2025, representing a decrease of $0.5 million, or 10%. The decrease was primarily driven by a $0.8 million decrease in costs associated with cyclotron system sales, as no cyclotron system sales were recognized during the current period, partially offset by a $0.3 million net increase in overhead costs allocated to cost of revenue, primarily related to a newly operational production site that commenced commercial activities in December 2025.

Selling, General and Administrative

	Three Months Ended September 30,		Change	Nine Months Ended September 30,		Change
	2026	2025	%	2026	2025	%
	(in thousands)			(in thousands)		
Selling, general and administrative	$ 4,414	$ 2,504	76%	$ 10,629	$ 8,123	31%

Selling, general and administrative expenses were $4.4 million for the three months ended September 30, 2026 compared to $2.5 million for the three months ended September 30, 2025, representing an increase of $1.9 million, or 76%. The increase was primarily driven by a $0.8 million increase in professional fees, primarily corporate legal fees and consulting fees associated with operating as a public company; a $0.3 million increase in personnel-related costs and a $0.2 million increase in depreciation expense, primarily reflecting employees and assets that were redeployed from research and development activities to support our newly operational production site, the costs of which were largely not allocated to cost of revenue during the period because production volumes at the site were lower while we completed an expansion of the facility, as well as stock-based compensation for new equity awards granted in 2026; a $0.2 million increase in insurance expense, mainly associated with the new public company insurance policies obtained in connection with the Merger on April 9, 2026; and a $0.1 million increase in the provision for credit losses.

Selling, general and administrative expenses were $10.6 million for the nine months ended September 30, 2026 compared to $8.1 million for the nine months ended September 30, 2025, representing an increase of $2.5 million, or 31%. The increase was primarily driven by a $1.0 million increase in professional fees, primarily corporate legal fees and consulting fees associated with operating as a public company; a $0.6 million increase in depreciation and amortization expense, as described above; a $0.4 million increase in personnel-related costs; a $0.4 million increase in insurance expense; and a $0.3 million increase in the provision for credit losses. These increases were partially offset by a $0.3 million increase in overhead costs allocated to cost of revenue, as described above under “Cost of Revenue.”

Research and Development

	Three Months Ended September 30,		Change	Nine Months Ended September 30,		Change
	2026	2025	%	2026	2025	%
	(in thousands)			(in thousands)		
Research and development	$ 854	$ 1,311	-35%	$ 2,269	$ 3,956	-43%

Research and development expenses were $0.9 million for the three months ended September 30, 2026 compared to $1.3 million for the three months ended September 30, 2025, representing a decrease of $0.4 million, or 35%. The decrease was primarily driven by a $0.3 million decrease in personnel-related costs and a $0.2 million decrease in depreciation expense, reflecting the transition of certain facility-related costs and employees from research and development activities associated with alpha-emitting isotopes to the newly operational production site beginning in December 2025, as the related facility progressed toward operational readiness.

Research and development expenses were $2.3 million for the nine months ended September 30, 2026 compared to $4.0 million for the nine months ended September 30, 2025, representing a decrease of $1.7 million, or 43%. The decrease was primarily driven by a $0.9 million decrease in personnel-related costs and a $0.5 million decrease in depreciation and amortization expense, resulting from the transition described above.

Interest Income (Expense), Net

	Three Months Ended September 30,		Change	Nine Months Ended September 30,		Change
	2026	2025	%	2026	2025	%
	(in thousands)			(in thousands)		
Interest income (expense), net	$ 60	$ (925)	-106%	$ (254)	$ (2,505)	-90%

Interest income, net was $0.1 million for the three months ended September 30, 2026, compared to interest expense, net of $0.9 million for the three months ended September 30, 2025, representing a change of $1.0 million, or 106%. The change was primarily driven by a $0.6 million decrease in interest expense and related amortization of deferred financing fees following the conversion of the convertible notes on October 31, 2025, and a $0.4 million decrease following the repayment in full of the 2023 Term Loan and promissory notes in connection with the Merger.

Interest expense, net was $0.3 million for the nine months ended September 30, 2026, compared to $2.5 million for the nine months ended September 30, 2025, representing a change of $2.2 million, or 90%. The change was primarily driven by a $1.6 million decrease in interest expense and related amortization of deferred financing fees following the conversion of the convertible notes on October 31, 2025 and a $0.7 million decrease in interest expense following the repayment in full of the 2023 Term Loan and promissory notes in connection with the Merger, which reduced interest-bearing obligations outstanding for a substantial portion of the 2026 period.

Other income (expense), net

	Three Months Ended September 30,		Change	Nine Months Ended September 30,		Change
	2026	2025	%	2026	2025	%
	(in thousands)			(in thousands)		
Other income (expense), net	$ 53	$ (1,869)	-103%	$ (13,575)	$ (2,920)	365%

Other income (expense), net was income of $0.1 million for the three months ended September 30, 2026, compared to other expense, net of $1.9 million for the three months ended September 30, 2025, a change of $2.0 million, or 103%. The change was primarily driven by the absence of fair value remeasurement changes related to SAFE liabilities following the conversion of all outstanding SAFEs into Legacy Ionetix Series F redeemable convertible preferred stock on March 31, 2026, compared to a $1.9 million loss from changes in the fair value of SAFE liabilities during the three months ended September 30, 2025, and $0.1 million of government grant income recognized during the three months ended September 30, 2026.

Other expense, net was $13.6 million for the nine months ended September 30, 2026, compared to $2.9 million for the nine months ended September 30, 2025, an increase of $10.7 million, or 365%. The increase was primarily driven by the $10.5 million non-cash loss recognized in connection with the settlement of investor agreements, a $2.2 million upfront loss recognized in connection with the issuance of SAFEs with common stock warrant coverage, and $0.9 million write-off of unamortized debt discount and issuance costs in connection with the repayment in full of the outstanding loans and notes. These increases were partially offset by lower fair value remeasurement losses related to SAFE liabilities, which were $0.1 million for the nine months ended September 30, 2026 compared to $2.9 million for the nine months ended September 30, 2025, following the conversion of all outstanding SAFEs into Legacy Ionetix Series F redeemable convertible preferred stock on March 31, 2026.

Liquidity and Capital Resources

Since inception, we have financed our operations primarily through the issuance of redeemable convertible preferred stock, SAFEs, convertible notes and short-term debt and, most recently, through the private placement financing completed in connection with the Merger (including the June 2026 subsequent closing) and the initial closing of the private placement offering of our common stock in October 2026, each as described above. Our primary requirements for liquidity and capital are to fund working capital, capital expenditures, research and development, manufacturing, sales and marketing, site deployment, commercial expansion and general corporate purposes.

We have incurred significant operating losses and negative cash flows since inception and expect to continue to incur losses for the foreseeable future. For the three and nine months ended September 30, 2026, we incurred a net loss of $4.9 million and $27.2 million, respectively. As of September 30, 2026, we had an accumulated deficit of $213.7 million and $5.6 million in cash and $0.7 million in restricted cash.

Based on our current operating plan, we believe that our existing cash, together with the proceeds from the initial closing of the private placement offering in October 2026, will not be sufficient to fund our operations for at least the next twelve months from the date the condensed consolidated financial statements included elsewhere in this Quarterly Report are issued. These conditions raise substantial doubt about our ability to continue as a going concern. To address these conditions, we intend to seek additional capital through equity or debt financings, strategic collaborations or other arrangements and, if necessary, to reduce or defer discretionary operating and capital expenditures. Our future capital requirements will depend on many factors, including the timing and extent of our research and development activities, the scale-up of manufacturing operations, the pace of commercial expansion and the timing of site deployments. There can be no assurance that additional financing will be available on favorable terms, or at all.

Cash Flows

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

	Nine Months Ended September 30,	
	2026	2025
	(in thousands)	
Net cash used in operating activities	$ (13,711)	$ (8,746)
Net cash used in investing activities	$ (5,551)	$ (2,910)
Net cash provided by financing activities	$ 25,093	$ 7,010

Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2026 was $13.7 million, which resulted from a net loss of $27.2 million, adjusted for non-cash charges of $17.7 million and net cash outflows from changes in operating assets and liabilities of $4.2 million. Non-cash charges of $17.7 million primarily consisted of losses of $10.5 million recognized on the settlement of a contingent equity arrangement and a termination agreement, initial loss of $2.2 million recognized in connection with the issuance of SAFEs with common stock warrant coverage, reflecting the excess of the aggregate fair value of the instruments issued over the proceeds received, depreciation and amortization of $2.6 million, amortization and write-off of debt discount and issuance costs of $0.9 million, and stock-based compensation of $0.5 million. Cash outflows from changes in operating assets and liabilities were $4.2 million, primarily due to a decrease of $1.7 million in accounts payable reflecting the timing of payments, an increase of $1.1 million in prepaid expenses and other assets reflecting insurance premiums under new public company policies and deposits paid to a vendor for an upcoming installation, and an increase of $0.9 million in accounts receivable.

Net cash used in operating activities for the nine months ended September 30, 2025 was $8.7 million, which resulted from a net loss of $17.1 million, adjusted for non-cash charges of $6.6 million and net cash inflows from changes in operating assets and liabilities of $1.8 million. Non-cash charges of $6.6 million primarily consisted of a $2.9 million loss on the change in the fair value of SAFE liabilities, depreciation and amortization expense of $2.5 million, stock-based compensation of $0.4 million, amortization of operating lease right-of-use assets of $0.4 million, and amortization of debt discount and issuance costs of $0.4 million. Net cash inflows from changes in operating assets and liabilities of $1.8 million were primarily due to a $1.3 million increase in accrued expenses and other liabilities, primarily reflecting the timing of accruals and settlements, a $1.1 million increase in accounts payable, reflecting the timing of payments, and a $0.6 million decrease in inventory, partially offset by a $0.7 million increase in accounts receivable and a $0.4 million decrease in operating lease liabilities.

Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2026 and 2025 was $5.6 million and $2.9 million, respectively, and consisted primarily of purchases of property and equipment to support ongoing operational and capacity expansion.

Financing Activities

Net cash provided by financing activities was $25.1 million for the nine months ended September 30, 2026. Cash inflows consisted primarily of $28.7 million of net proceeds from the private placement financing completed in connection with the Merger, including the June 2026 subsequent closing, together with $2.4 million from the issuance of SAFEs, $0.7 million from promissory notes and $0.7 million from related party advances. These were partially offset by repayments, principally $5.7 million on the 2023 Term Loan, $1.6 million of promissory notes and $0.4 million of related party advances.

Net cash provided by financing activities was $7.0 million for the nine months ended September 30, 2025, primarily consisting of $5.4 million of proceeds from the issuance of SAFEs, $1.8 million of proceeds from related party advances and $0.4 million of proceeds from promissory notes, partially offset by $0.8 million of repayments of related party advances.

Contractual Obligations and Commitments

As of September 30, 2026, our material contractual obligations consisted primarily of operating lease commitments.

Our operating lease obligations extend beyond September 30, 2026 in accordance with the respective lease terms. As of September 30, 2026, we had aggregate future minimum operating lease commitments of $1.3 million, of which $0.5 million is payable within the next 12 months. All short-term debt obligations outstanding prior to the Merger, including accrued interest, were repaid in full in connection with the closing of the Merger.

We do not have any off-balance sheet arrangements and have no material purchase commitments.

Critical Accounting Policies and Estimates

Our condensed consolidated financial statements are prepared in accordance with U.S. GAAP. The preparation of condensed consolidated financial statements also requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, costs and expenses, and related disclosures. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. Actual results could differ significantly from the estimates made by management. To the extent that there are differences between our estimates and actual results, our future financial statement presentation, financial condition, results of operations, and cash flows will be affected.

There have been no material changes to our critical accounting policies and estimates as compared to those described in the section titled “Critical Accounting Policies and Estimates” in Management’s Discussion and Analysis of Financial Condition and Results of Operations in our Current Report on Form 8-K filed with the SEC on April 16, 2026, as amended, except for the addition of our accounting policy for government grants, as described in Note 2, “Basis of Presentation and Summary of Significant Accounting Policies,” to the condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report.

Emerging Growth Company Status and Smaller Reporting Company Status

We are an emerging growth company and a smaller reporting company, as defined in Rule 12b-2 of the Securities Exchange Act of 1934, as amended, and we may rely on certain reduced disclosure requirements available to such companies. For additional information, see our Current Report on Form 8-K filed with the SEC on April 16, 2026*, as amended.*

Item 3. Quantitative and Qualitative Disclosures About Market Risk

As a smaller reporting company, as defined by Rule 12b-2 of the Exchange Act and in Item 10(f)(1) of Regulation S-K, we are not required to provide the information required by this Item.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO"), evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of the end of the period covered by this Quarterly Report. Disclosure controls and procedures are designed to ensure that information required to be disclosed in our 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 is accumulated and communicated to our management, including our CEO and CFO, as appropriate, to allow timely decisions regarding required disclosure.

Based on this evaluation, our CEO and CFO concluded that our disclosure controls and procedures were not effective as of the end of the period covered by this Quarterly Report due to the material weaknesses in our internal control over financial reporting described herein. The material weaknesses related primarily to our limited public-company accounting and financial reporting resources, including the need to further enhance the depth of our SEC reporting and U.S. GAAP expertise and the early stage of our development and documentation of systems, processes, and controls necessary to support reliable financial reporting.

Notwithstanding the identified material weaknesses, management believes that the condensed consolidated financial statements included in this Quarterly Report fairly present, in all material respects, our financial position, results of operations, and cash flows for the periods presented in conformity with U.S. generally accepted accounting principles.

Changes in Internal Control over Financial Reporting

We are engaged in the process of designing, implementing and enhancing our internal control over financial reporting in a manner commensurate with the scale of our operations following the Merger, including the enhancement of our internal and external technical accounting and financial reporting resources.

Other than the ongoing enhancement of our internal control over financial reporting described above, there were no changes in our internal control over financial reporting during the quarter ended September 30, 2026 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

Our management, including our CEO and CFO, recognizes that the effectiveness of any system of disclosure controls and procedures and internal control over financial reporting is subject to inherent limitations. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system will be achieved. These inherent limitations include, among others, the exercise of judgment in designing, implementing, operating and evaluating controls and procedures, the possibility that judgments in decision-making may be faulty, and the possibility that controls may not operate as intended due to error, changes in conditions, or other factors.

The design of any system of controls is also based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will operate effectively under all potential future conditions. Accordingly, any evaluation of controls is subject to inherent limitations and may not identify all control issues, if any. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with established policies or procedures may deteriorate. We intend to continue to monitor and, as necessary or appropriate, enhance our internal controls and procedures as our business develops.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may become involved in various lawsuits and legal proceedings that arise in the ordinary course of business. Litigation is subject to inherent uncertainties, and an adverse result in these or other matters may arise from time to time that may harm our business.

As of the date of this Quarterly Report, we are not aware of any pending legal proceedings to which we, or any of our officers or directors in their capacity as such, are a party or of which any of our property is the subject, nor are we aware of any such proceedings that are contemplated by any governmental authority.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. In addition to the other information set forth in this Quarterly Report, you should carefully consider the risk factors discussed below when considering an investment in our common stock, as well as the other information contained in this Quarterly Report. If any of the following risks occur, our business, financial condition, results of operations, and prospects could be materially and adversely affected. In that case, the market price of our common stock could decline, and you could lose some or all of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

Risk Factors Summary

- We have incurred losses since inception, and may continue to incur losses for the foreseeable future, which raises substantial doubt about our ability to achieve or sustain profitability.
- We will require additional capital to fund our operations, and such financing may not be available on acceptable terms, if at all.
- Our auditor's report includes a "going concern" explanatory paragraph.
- If we incur indebtedness under future credit facilities, the associated covenants and repayment obligations could restrict our operations and adversely affect our financial condition.
- We operate in a highly competitive market for the manufacturing and sale of radioactive isotopes, and we may be unable to compete effectively against companies with greater resources, more established commercial infrastructure, or more advanced technologies.
- We rely on a limited supply of key raw materials, and any disruption in the availability or cost of these materials could adversely affect our development and commercialization activities.
- We depend on a limited number of customers and potential customers to utilize our diagnostic products, which may constrain commercial opportunities, and our revenue and receivables are concentrated in these customers.

- We have only recently started selling therapeutic radioisotopes, and we depend on a limited number of pharmaceutical company customers to utilize our therapeutic radioisotopes. Our revenue from therapeutic isotope sales is subject to risks arising from the early-stage development status of our customers' radiotherapeutic product candidates.

- Our growth depends on the continued growth and development of the markets for radiodiagnostic and radiotherapeutic products, and if these markets fail to grow as expected, our business and prospects could be materially adversely affected.

- Some of our technologies, products, or product candidates are unproven and may not perform as expected or achieve market acceptance.

- Uncertainty regarding healthcare reimbursement and healthcare reform initiatives could adversely affect our ability to commercialize our products and achieve profitability.

- Our business is subject to extensive and evolving regulation, and failure to obtain or maintain required approvals, licenses, or permits could delay or prevent commercialization.

- Changes in laws, regulations, or regulatory interpretation could limit our markets, increase our costs or restrict our operations.

- Our pharmaceutical company customers must conduct clinical trials of their radiotherapeutic products, which are costly, time-consuming, and subject to delay, suspension, or failure.

- Adverse events or safety concerns could delay or prevent regulatory approval or limit commercial adoption.

- We may incur substantial product liability or indemnification claims related to the use of our products.

- We rely on third parties for manufacturing, supply, and other critical services, and disruptions could adversely affect our operations.

- The short half-life and time-sensitive nature of delivery of radioactive isotopes used in our business create unique manufacturing, logistics, and operational risks.

- We may face risks related to quality control, compliance with manufacturing standards, and product recalls.

- We may not be able to successfully scale production of any of our cyclotrons.

- We depend on our ability to protect and defend our intellectual property rights, and we may not be able to do so.

- Cybersecurity breaches or information technology disruptions could result in significant costs and materially impact our financial results.

- Our ability to rely on global supply chains for source components and/or raw materials may be impacted by tariffs, trade disputes, or other changes in trade policy or trade regulation.

- Our business is highly dependent on the continued service of certain members of our senior management.

- Our success depends on our ability to attract, retain, and motivate key personnel.
- Being a public company can be administratively burdensome and will significantly increase our legal and financial compliance costs.
- Our management as a group has limited experience operating a publicly traded company.
- If we fail to maintain effective internal control over financial reporting, investor confidence could be harmed.
- Because there is currently no established market for our common stock, stockholders may not be able to sell their shares when or at prices they want.
- Our common stock may not be eligible for listing or quotation on any securities exchange or over-the-counter trading system.
- Because the Merger was a reverse merger, we may not be able to attract the attention of major brokerage firms.
- We are an emerging growth company and a smaller reporting company, and any decision on our part to comply only with certain reduced reporting and disclosure requirements applicable to emerging growth companies and smaller reporting companies could make our common stock less attractive to investors.
- Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of our business, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.
- We do not intend to pay dividends for the foreseeable future.

Risks Related to Our Financial Condition and Capital Requirements

We have incurred losses since inception, and may continue to incur losses for the foreseeable future, which raises substantial doubt about our ability to achieve or sustain profitability.

Our ability to become profitable depends upon our ability to generate increasing revenues. Since inception we have not generated sufficient revenues to achieve profitability. We cannot offer assurance that we can or will be able to operate profitably.

We expect to continue to incur operating losses and negative cash flows for the foreseeable future as we incur significant expenses related to research and development, regulatory compliance, manufacturing readiness, commercialization planning, personnel expansion, and public company costs. There can be no assurance that we will ever achieve or maintain profitability. If we are unable to do so, our business, financial condition, and results of operations may be materially adversely affected.

While we have objectives for the future development of our business, ongoing risks and uncertainties may prevent us from achieving profitability or sustaining growth.

Even if we succeed in broadening our customer base or achieving greater market acceptance, there is no assurance that our revenues will reach levels sufficient to attain profitability. Should we achieve profitability, maintaining or increasing it over time may prove challenging. Any inability to become or remain profitable could negatively impact our valuation and limit our capacity to secure funding, grow our operations, diversify our product portfolio, or continue as a going concern. Furthermore, as a company operating in a dynamic and rapidly evolving industry, we face ongoing risks and uncertainties that can disrupt our financial projections and anticipated revenues, especially when unexpected delays, shifting circumstances, or changing market conditions arise. If we are unable to effectively address these challenges, our operating results may significantly deviate from internal forecasts or from analyst or investor expectations, potentially harming our business and causing declines in the value of our securities. Ineffective management of growth could hinder the execution of our business strategy and have a substantial adverse impact on our prospects, financial stability, operational performance, and cash flow.

We must successfully manage our anticipated growth.

We intend to invest significantly in order to expand our business from an early-stage company to a company capable of supporting large-scale commercial activities. Any failure to manage our growth effectively could materially and adversely affect our business, prospects, financial condition, and operating results. We expect our expansion to require:

- launching commercialization of our products and services, as well as those commercialized by our pharmaceutical company customers;
- forecasting production and revenue;
- controlling expenses and investments in anticipation of expanded operations;
- hiring and training new personnel; and
- expanding and enhancing administrative infrastructure, systems, and processes.

In particular, our strategy contemplates significant capital expenditures for cyclotron systems, radiopharmaceutical production facilities, and related equipment and infrastructure. These long-lived assets may be costly to develop, install, and maintain, and may be difficult to repurpose or monetize if utilization, revenue growth, or customer demand at the associated sites is lower than we expect. If we are unable to achieve sufficient revenue or cash flows from these investments, we may not recover our capital outlays, which could adversely affect our liquidity, financial condition, and results of operations.

If our operations continue to grow, of which there can be no assurance, we will need to continue to expand our sales and marketing, research and development, commercial strategy, permitting and licensing, products and services, and manufacturing, supply, and operations functions. These efforts will require us to invest significant financial and other resources. There is no guarantee that we will be able to scale our business as currently planned or within the planned timeframe. The continued expansion of our business may in the future require additional operational facilities, as well as space for administrative support, and there is no guarantee that we will be able to find suitable locations for such facilities if needed. Our continued growth could increase the strain on our resources, and we could experience operating difficulties, including difficulties in hiring and training employees, delays in production, challenges in scaling-up operations, and difficulty sourcing adequate raw materials, such as the radium-226 (“Ra-226”) we use to produce Ac-225. These difficulties may divert the attention of management and key employees and impact financial and operational results. If we are unable to drive commensurate growth, these costs could result in decreased margins, which could have a material adverse effect on our business, financial condition, and results of operations.

We will require additional capital to fund our operations, and such financing may not be available on acceptable terms, if at all.

Our operations and growth plans will require substantial additional capital. We may seek additional funding through equity offerings, debt financings, collaborations, strategic partnerships, licensing arrangements, or other sources. Such financing may not be available when needed, on acceptable terms, or at all. Any future equity financing may result in dilution to our existing stockholders, while any debt financing may involve restrictive covenants that limit our operational flexibility. If we are unable to obtain adequate financing, we may be required to delay, reduce, or discontinue our development programs or other operations.

We have issued, and may in the future issue, various debt, equity, and financial instruments including but not limited to simple agreements for future equity ("SAFEs"), stock options, common and preferred stock warrants, secured and convertible debt, and other financial instruments. The fair values of these instruments are determined using valuation techniques that rely on significant unobservable inputs, including simulations, pricing models, assumptions about the timing and terms of future financing events, equity volatility, discount rates, and other factors. Changes in these assumptions and other market or company-specific conditions can result in significant non-cash gains or losses. These gains or losses may be large relative to our revenue and operating expenses, may cause our reported net loss and other results of operations to fluctuate significantly from period to period, and may make it difficult for investors to evaluate our underlying operating performance. In addition, the valuation of these instruments requires complex judgments and estimates that may be difficult to audit or verify, and any errors or changes in these estimates could result in additional volatility in our reported results or in restatements of our financial statements. Our stock price may also be adversely affected if investors perceive our capital structure or financial reporting as unusually complex or volatile.

Our auditor's report includes a "going concern" explanatory paragraph.

Our recurring losses from operations and financial condition raise substantial doubt about our ability to continue as a going concern. In our consolidated financial statements for the years ended December 31, 2025 and 2024, we concluded that our recurring losses from operations and need for additional financing to fund future operations raise substantial doubt about our ability to continue as a going concern. Similarly, our independent registered public accounting firm included an explanatory paragraph in its report on our consolidated financial statements for the year ended December 31, 2025 with respect to this uncertainty. In addition, in the condensed consolidated financial statements included in this Quarterly Report, we have concluded that these conditions raise substantial doubt about our ability to continue as a going concern. Our ability to continue as a going concern will require us to obtain additional funding. If we are unable to obtain sufficient funding, our business, prospects, financial condition and results of operations will be materially and adversely affected, and we may be unable to continue as a going concern. If we are unable to raise capital when needed or on acceptable terms, we would be forced to delay, limit, reduce or terminate our product development or future commercialization efforts for one or more of our products, or may be forced to reduce or terminate our operations. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our audited financial statements, and it is likely that investors will lose all or part of their investment. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors and other financing sources may be unwilling to provide additional funding to us on commercially reasonable terms, if at all.

If we incur indebtedness under future credit facilities, the associated covenants and repayment obligations could restrict our operations and adversely affect our financial condition.

We do not currently have any outstanding borrowings, but we may in the future obtain credit facilities or other forms of indebtedness to finance our operations, capital expenditures, or strategic initiatives. Any such indebtedness may be secured by substantially all of our assets and subject us to operating and financial covenants, including requirements to maintain certain financial ratios or to comply with other obligations that may limit our operational flexibility. If we breach any of these covenants or are otherwise unable to comply with the terms of our debt instruments, the lenders could declare a default, accelerate repayment of outstanding amounts, foreclose on collateral, or exercise other remedies, which could, in turn, force us to curtail or cease operations, sell assets on unfavorable terms, or seek additional capital on terms that may be dilutive or otherwise disadvantageous to our stockholders. Even if we remain in compliance, servicing debt may limit the cash flow available for other purposes, including funding our research and development, capital expenditures, and working capital needs.

Risks Related to Our Business and Industry

We operate in a highly competitive market for the manufacturing and sale of radioactive isotopes, and we may be unable to compete effectively against companies with greater resources, more established commercial infrastructure, or more advanced technologies.

The market for the manufacture and supply of radioactive isotopes — including both PET diagnostic isotopes and alpha-emitting therapeutic isotopes — is competitive and rapidly evolving. We face competition from a range of participants, including large multinational healthcare and radiopharmaceutical companies, government-affiliated entities, academic institutions, and other emerging commercial producers, many of which have significantly greater financial resources, longer operating histories, more established commercial infrastructure, and broader market recognition than we do. Our failure to compete effectively in either the diagnostic or therapeutic isotope markets could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In the market for PET diagnostic isotopes, commercial providers of PET radiopharmaceuticals in the United States include PETNET Solutions Inc. (a wholly owned subsidiary of Siemens Healthineers), Cardinal Health, Pharmalogic Holdings Corp., Sofie Biosciences, and Jubilant Radiopharma, among others. Hospitals and research institutions with significant programs — including Memorial Sloan Kettering, Stanford University, the Mayo Clinic, and the University of California San Francisco — may also produce PET isotopes internally for their own use, further reducing the addressable market for commercial suppliers. For our N-13 ammonia product specifically, we face competition from providers of Rb-82, a competing cardiac perfusion imaging agent manufactured commercially by Bracco and Jubilant Radiopharma. For Ga-68 Gozetotide, competitors include Novartis and Telix Pharmaceuticals. For PSMA PET diagnostics, several companies — including Telix Pharmaceuticals, Lantheus, Novartis, and Blue Earth Diagnostics (a Bracco company) — have received FDA approvals for competing PSMA PET diagnostic products. Competitors could also file Abbreviated New Drug Applications for N-13 ammonia, Ga-68 Gozetotide or other PET drugs for which we hold ANDAs, which could intensify competition and put downward pressure on pricing for those products. Because PET isotopes have relatively short half-lives and can generally be distributed within a metropolitan area from a single production site, the PET isotope market is inherently localized, which means competition in any given geography can be concentrated and intense.

In the market for therapeutic alpha-emitting isotopes, we face competition from both domestic and international producers of Ac-225 and At-211. In the United States, Ac-225 has historically been supplied through the U.S. Department of Energy ("DoE") and companies obtaining isotopes from the DoE, including TerraPower and Cardinal Health, though that supply is constrained by the DoE's finite inventory of Thorium-229 ("Th-229"). Other domestic commercial producers of Ac-225 include Niowave, SpectronRx, and Northstar Medical Radioisotopes. In Europe, PanTera in Belgium and AlfaRim in the Netherlands, as well as ITM Radiopharma and Eckert & Ziegler in Germany, have also announced plans to produce Ac-225, which could result in increased global supply and competitive pressure on pricing or market share. For At-211, while we are currently the only commercial supplier in the United States, Nusano has announced plans to enter the U.S. At-211 market and Telix Pharmaceuticals has announced plans, together with Ekalia (a joint venture of IBA and Framatome), to establish U.S. At-211 production capacity that is expected to also support third-party programs, and internationally, commercial At-211 is already available in Denmark, Germany, France, and Japan, and IBA has announced production plans for Europe. As domestic and international commercial production of At-211 matures, we may face significant competition that could reduce our ability to capture, or retain, the market share that we are currently seeking to establish.

Our competitive position is based in part on our proprietary superconducting cyclotron technology, which allows for a smaller production footprint and potentially faster, more cost-effective deployment compared to conventional cyclotron technologies. However, our cyclotrons generally produce less activity per hour than certain conventional cyclotrons, such as certain cyclotrons manufactured by GE Healthcare, which we believe limits their suitability for serving remote sites requiring large quantities of activity. If competitors develop or deploy technologies that are more productive, more cost-efficient, or more broadly deployable than ours, or if they are able to produce isotopes at lower cost or in greater volume, our competitive advantages could be diminished or eliminated. Additionally, our primary patent covering our superconducting cyclotron technology is set to expire in 2031, which could permit competitors to use similar technology thereafter and could further erode our competitive position. In addition, we do not have exclusive rights to superconducting cyclotron technology generally, and other companies, including IBA, manufacture superconducting cyclotrons. The cyclotron we use to produce Ac-225 is not a superconducting cyclotron and was purchased from a third-party manufacturer, and comparable systems are commercially available to our competitors. As a result, our competitive position in the production of Ac-225 depends significantly on our know-how, including with respect to beam transport, target design and radiation safety, rather than on the cyclotron itself.

Many of our current and potential competitors have access to substantially greater capital than we do and may be better positioned to invest in research and development, expand production capacity, develop regulatory approvals for new isotopes or manufacturing sites, or enter into strategic partnerships with pharmaceutical companies that develop radiotherapeutic product candidates. These competitors may be able to respond more rapidly to new technologies, regulatory developments, or shifts in customer requirements. Competitive pressures may also limit our ability to raise prices, and any inability to maintain revenue or raise prices to offset increases in costs could have a significant adverse effect on our gross margin. If we are unable to compete effectively on the basis of isotope quality, production capacity, delivery reliability, pricing, or the breadth of our product offering, our revenue could be materially lower than we expect, and our business, financial condition, and prospects could be materially adversely affected.

We rely on a limited supply of key raw materials, and any disruption in the availability or cost of these materials could adversely affect our development and commercialization activities.

Our business model depends on reliable access to key raw materials such as Ra-226. We currently purchase Ra-226 outright, but also obtain it from a third-party supplier pursuant to a tiered revenue-sharing arrangement under an agreement that has an initial term of three years and may be renewed annually by mutual agreement. Global supply of Ra-226 is limited and concentrated among a small number of suppliers, and there is no well-established commercial market or spot pricing for this material. These materials can be difficult and costly to procure, are subject to long lead times and regulatory and safety requirements, and, in some cases, are not widely available.

These materials, including Ra-226, may be lost during handling and processing, or as part of a waste stream. In addition, the procurement, possession, use, and transport of such materials are subject to stringent regulatory requirements, including licensing, security, and export control restrictions, which may further constrain availability or delay delivery. Manufacturing or processing outages, transportation or export restrictions, changes in applicable regulations, sanctions or other geopolitical developments, quality issues, or the financial or operational instability of one or more of our suppliers could reduce or eliminate our access to needed materials.

In certain cases, alternative sources may not exist or may require the development of new supply arrangements, including potential reliance on government-controlled inventories or facilities. We may not be able to qualify alternative suppliers on a timely basis, if at all, and any such qualification process may require significant time and expense and additional regulatory interaction. Any disruption in the supply or significant increase in the cost of these materials could delay or prevent our ability or our customers' ability to conduct development activities or to manufacture products at clinical or commercial scale, which could materially adversely affect our business, financial condition, and results of operations.

We depend on a limited number of customers and potential customers to utilize our diagnostic products, which may constrain commercial opportunities, and our revenue and receivables are concentrated in these customers.

Diagnostic products that use radioactive materials may be administered or used only at facilities that have appropriate nuclear medicine, radiation-safety, and imaging capabilities, and that hold and maintain the required licenses, permits, and trained personnel. As a result, our current and future customers will be limited to institutions that satisfy these requirements. In addition, if such centers are slow to adopt our technology, experience operational difficulties, or face regulatory or reimbursement challenges, the actual market penetration of our products may be materially lower than we expect.

In addition, a significant portion of our revenues and accounts receivable are concentrated in a small number of customers. For the nine months ended September 30, 2026, five customers accounted for 95% of our total revenue, with our largest customer representing 33% of our total revenue, while for the year ended December 31, 2025, five customers accounted for 99% of our total revenue, with our largest customer representing 29% of our total revenue. We have also occasionally provided financing or extended payment terms to certain customers, including loans to significant customers that were not repaid at maturity. If one or more of our key customers reduces or delays purchases of our products or services, fails to meet its payment obligations when due, experiences financial difficulties, or otherwise changes its purchasing patterns, our revenue, cash flows, and results of operations could be materially and adversely affected. Because our customer base is concentrated, any such event could have a disproportionate impact on us, and it may be difficult or time-consuming for us to replace lost business with other customers on acceptable terms, or at all.

We have only recently started selling therapeutic radioisotopes, and we depend on a limited number of pharmaceutical company customers to utilize our therapeutic radioisotopes. Our revenue from therapeutic isotope sales is subject to risks arising from the early-stage development status of our customers' radiotherapeutic product candidates.

We started sales of therapeutic radioisotopes in late 2025, and we expect to sell our therapeutic radioisotopes, including Ac-225 and At-211, primarily to a limited number of pharmaceutical companies that are engaged in the development and clinical testing of radiotherapeutic product candidates. Our ability to generate revenue from therapeutic isotope sales is therefore dependent in significant part on the continued progress of our customers' drug development programs, over which we have no control and into which we have limited visibility. Because most of the clinical trials that utilize or depend on our radioisotopes are designed, sponsored, and controlled by our pharmaceutical company customers, we generally do not control key aspects of such trials, including study design, timelines, enrollment strategies, site selection, and interactions with regulatory authorities. We may receive information on delays, protocol changes, or safety concerns only after our customers or collaborators have already made decisions that affect the pace or direction of development. As a result, it is difficult for us to predict or model the timing, likelihood, or scope of clinical success for programs that rely on our therapeutic isotopes, and negative or unexpected developments in those trials could occur without advance notice to us.

The concentration of our therapeutic isotope revenue among a small number of pharmaceutical company customers exposes us to heightened risks. If any one of these customers encounters setbacks in clinical development—whether due to adverse events or safety concerns, failure to meet primary or secondary endpoints, regulatory holds or other agency actions, enrollment challenges, or insufficient funding to continue a trial—demand for our therapeutic radioisotopes could be reduced or eliminated for that program with little or no advance notice. Similarly, if any such customer determines to discontinue, reprioritize, or partner out a program that uses our radioisotopes, abandons its radiotherapeutic pipeline, is acquired, or otherwise ceases operations, our revenue from therapeutic isotope sales could be materially and adversely affected. Because our therapeutic customer base is concentrated, the loss of, or significant reduction in orders from, any single customer could have a disproportionate impact on our results of operations, and it may be difficult or time-consuming for us to replace any lost business on acceptable terms, or at all.

Moreover, the commercial success of any of our pharmaceutical company customers' radiotherapeutic product candidates—even if those products ultimately receive regulatory approval—is not guaranteed and is subject to numerous factors outside of our control. Market acceptance will depend on, among other things, the clinical safety and effectiveness profile of the approved product, its reimbursement and coverage status, the availability of alternative treatments or competing therapeutic modalities, and the scope of any limitations or warnings in regulatory labeling. If the products of our pharmaceutical company customers fail to achieve broad market acceptance, or if acceptance is slower or more limited than anticipated, the demand for our therapeutic radioisotopes could be materially lower than we expect, which would adversely affect our business, financial condition, results of operations, and prospects.

The field of alpha-emitting radiotherapeutics is still in an early stage of development, and a significant portion of our therapeutic isotope revenue currently depends on customers that are conducting pre-commercial development and testing activities rather than commercial-scale production. To the extent that our customers' product candidates fail to progress through clinical development or fail to obtain regulatory approval, or that the growth of the broader radiotherapeutic market occurs more slowly than we expect, we may be unable to grow our therapeutic isotope revenue, and our business and prospects could be materially adversely affected.

Our growth depends on the continued growth and development of the markets for radiodiagnostic and radiotherapeutic products, and if these markets fail to grow as expected, our business and prospects could be materially adversely affected.

Our business depends in significant part on the continued growth and commercial development of the markets for radiodiagnostic and radiotherapeutic products. In the diagnostic market, our revenue is largely driven by demand for PET imaging procedures, which is in turn dependent on the continued adoption of PET-based imaging in clinical practice, the successful development and commercialization of new PET tracers, and the willingness of healthcare providers and payors to reimburse PET imaging procedures at adequate levels. In the therapeutic market, our revenue from sales of therapeutic radioisotopes, including Ac-225 and At-211, depends on the continued clinical development, regulatory approval, and commercial success of radiopharmaceutical drug candidates that use alpha-emitting isotopes. The field of alpha-emitting radiotherapeutics remains in an early stage of development, and there can be no assurance that it will achieve the broad clinical acceptance or commercial scale that we anticipate.

PET imaging is gaining traction in oncology and other high-value clinical applications, driven by tracer innovation, theranostics, and the integration of imaging with treatment planning. Specific segments of the PET imaging market, such as PSMA PET tracers and Alzheimer's disease PET imaging, have been projected by third-party industry analysts to grow substantially in the coming years. However, these projections are based on assumptions that may prove to be incorrect, and actual growth in the PET imaging market may be slower, more limited in scope, or concentrated in segments in which we do not have a competitive presence. If PET imaging does not achieve the level of adoption anticipated, or if reimbursement for PET imaging procedures is reduced or restricted, demand for our diagnostic isotope products could be materially lower than we expect.

In the therapeutic segment, the market for radiopharmaceuticals has been characterized as one of the fastest-growing categories among anticancer medicines, with the global radiopharmaceuticals market projected to grow to over $26 billion in sales by 2032, and the therapeutic segment estimated to achieve a total addressable market of $25 billion to $60 billion post-2030. However, these estimates and projections are based on assumptions about clinical success rates, regulatory approvals, market adoption, and reimbursement that may not be realized. The commercial validation demonstrated by approved beta-emitting radiopharmaceuticals such as Pluvicto and Lutathera — which have demonstrated meaningful clinical benefits in prostate cancer and certain neuroendocrine tumors, respectively — has generated significant optimism about the potential of the broader radiopharmaceutical class, including alpha-emitting agents. Nevertheless, alpha-emitting radiopharmaceuticals that use Ac-225 and At-211 remain in clinical development, and none have yet received FDA approval. The successful translation of early-stage clinical data into approved, commercially successful products is uncertain and depends on factors outside our control.

The commercial success of the radiotherapeutic market more broadly will depend on a range of factors, many of which are beyond our control, including the outcomes of ongoing and future clinical trials; the willingness of the FDA and comparable foreign regulatory authorities to approve radiopharmaceutical product candidates; the ability of pharmaceutical companies developing such candidates to raise sufficient capital to fund their programs through to commercialization; the availability of adequate third-party reimbursement for radiopharmaceutical therapies; the acceptance of radiopharmaceuticals by physicians, patients, and healthcare providers as a preferred or complementary modality to existing cancer treatments; and the pace of development of the specialized clinical infrastructure — including trained nuclear medicine specialists and appropriately licensed and equipped treatment centers — necessary to administer radiopharmaceutical therapies at commercial scale.

If either the radiodiagnostic or radiotherapeutic markets fail to develop or grow as we expect, develop more slowly than anticipated, or fail to achieve the scale necessary to support our business model, our revenue growth could be substantially limited. Furthermore, because our business model contemplates significant capital expenditures for cyclotron systems, radiopharmaceutical production facilities, and related infrastructure, a failure of the market to develop as expected could result in our being unable to recover such investments, which would have a material adverse effect on our business, financial condition, results of operations, and prospects.

Some of our technologies, products, or product candidates are unproven and may not perform as expected or achieve market acceptance.

We are investigating other possible uses of our superconducting cyclotron technology, including to remediate nuclear waste while simultaneously generating power, sterilization of medical instruments and devices, testing for equipment destined to be exposed to high radiation loads (e.g. materials proposed for use in fusion reactors or sent into space), and as a possible light source for next-generation lithography machines. These efforts are in early or developmental stages and may not perform as anticipated in real-world or commercial settings. Commercial applications may progress more slowly than projected or encounter delays and engineering changes that increase the expense and capital requirements for execution. Actual or perceived design, production, performance, or other quality issues could result in significant project delays and engineering changes that increase the expense and capital requirements for execution. This risk is pronounced in connection with the introduction of new technology. Some of the markets for our technology are not yet established and may not achieve the growth potential we expect or may grow more slowly than expected. If demand for our technology fails to develop sufficiently, our business and operations could suffer, and we would be unable to achieve profitability.

Uncertainty regarding healthcare reimbursement and healthcare reform initiatives could adversely affect our ability to commercialize our products and achieve profitability.

Governmental and third-party payors continue to seek to contain healthcare costs through various measures, including pricing controls, reimbursement limitations, and coverage restrictions. If adequate reimbursement is not available for our products or those of our customers, or if reimbursement levels are insufficient, demand for our products may be limited, even if they are approved for commercialization. Changes in healthcare laws, regulations, or reimbursement practices in the United States or internationally could also reduce the prices we are able to charge, impair our ability to raise capital and materially adversely affect our business and financial condition.

We do not currently have a fully developed sales, marketing, or distribution organization for commercial-scale deployment of our products.

To successfully commercialize any of our products, we will need to build internal sales, marketing, and distribution capabilities, or enter into strategic arrangements with third parties (particularly in international markets), which may be costly, time-consuming, and complex. Our arrangements in international markets may be exclusive arrangements with third parties for specific geographic regions.

We may be unable to establish effective commercialization arrangements on acceptable terms, or at all. Potential collaborators may prioritize their own products or fail to dedicate sufficient resources to our offerings. If we are unable to establish adequate commercialization capabilities, either independently or through third parties, we may be unable to generate meaningful revenue and may not achieve or sustain profitability.

Our market opportunity estimates may be inaccurate, and actual demand for our products or services may be lower than expected.

Our assumptions and the data underlying our – or our pharmaceutical company customers' – market estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, thereby reducing the predictive accuracy of our models or those of our pharmaceutical company customers. As a result, our estimates of the market potential for our products, as well as the expected growth rate for our revenues, may prove to be incorrect.

Risks Related to Regulatory Approval and Compliance

Our business is subject to extensive and evolving regulation, and failure to obtain or maintain required approvals, licenses, or permits could delay or prevent commercialization.

We are subject to extensive laws and regulations relating to various aspects of our business, including, but not limited to, licensing by the FDA and the NRC, as well as other federal, state, and foreign regulatory authorities governing, among other things, research, development, testing, manufacturing, labeling, storage, distribution, marketing, export, and sale of our products or those of our customers. Regulatory approval processes are complex, time-consuming, costly, and subject to significant uncertainty. There can be no assurance that the necessary approvals and licenses will be granted on a timely basis, if at all, which could significantly delay or prevent the commercialization of our products.

We are subject to two sets of FDA cGMP requirements depending on the type of product we manufacture. Production of PET drugs is regulated under cGMP requirements specific to PET drugs (21 CFR Part 212), which impose strict sterility testing, quality control, and laboratory requirements tailored to the unique properties of PET radiopharmaceuticals. Production of alpha-emitting isotopes is regulated under the cGMP requirements applicable to finished pharmaceuticals (21 CFR Parts 210 and 211), which are generally more comprehensive and impose additional requirements related to process validation, stability testing, and quality systems. Failure to comply with either set of cGMP requirements could result in warning letters, product seizures, injunctions, civil or criminal penalties, refusal to approve pending applications, or withdrawal of existing approvals. Our obligation to maintain compliance with both regulatory frameworks simultaneously increases the complexity and cost of our manufacturing operations and subjects us to additional risk. Our facilities and those of our customers are subject to inspection by FDA, NRC and other federal and state agencies. If any of our facilities or those of our customers are inspected and found to have objectionable conditions during the inspection, it could lead to an "official action indicated" (OAI), Form 483 observations, Notice of Violation, an FDA warning letter, or other enforcement action, which could negatively impact our business and damage our reputation. Failure to satisfy regulatory requirements on an ongoing basis could cause restriction or revocation of existing licenses and disrupt our ability to manufacture and commercialize our products.

Any future ANDA or NDA filings are subject to significant regulatory uncertainty, and we cannot guarantee that the FDA will approve our applications on the expected timeline, or at all. The FDA may refuse to approve our ANDA or any future ANDA for a variety of reasons, including failure to demonstrate bioequivalence, deficiencies in our chemistry, manufacturing, and controls data, unsatisfactory inspection outcomes at our manufacturing facilities, or unresolved patent or exclusivity issues relating to the reference listed drug.

Under the Hatch-Waxman Amendments, an ANDA applicant must address any patents listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") for the reference listed drug by making one of four patent certifications. If our ANDA includes a Paragraph IV certification—asserting that a listed patent is invalid, unenforceable, or will not be infringed—the reference product's NDA holder or patent owner may file a patent infringement lawsuit against us within 45 days of receiving notice, which could trigger a stay of FDA approval for up to 30 months or until a court decision or settlement is reached. Any such litigation could be costly and time-consuming and could significantly delay or prevent our ability to commercialize the product. Even in the absence of Paragraph IV litigation, other forms of regulatory exclusivity applicable to the reference listed drug, such as new chemical entity exclusivity or other statutory exclusivity periods, could delay the timing of our ANDA submission or approval.

In addition, the FDA may issue a complete response letter identifying deficiencies in our application that must be addressed before approval, which could require additional studies, data, or manufacturing changes and result in significant delays and expense. The FDA may also impose post-marketing requirements as a condition of approval. We cannot predict the timing or outcome of ANDA reviews, and any delays or adverse outcomes could materially affect our ability to commercialize our proposed generic products and could have a material adverse effect on our business, financial condition, and results of operations.

We are required to obtain site-specific FDA approval for each manufacturing location, and the loss of approval at any site or failure to obtain approval for new sites could materially harm our business. The FDA requires that each manufacturing site at which we produce drug products be individually approved and listed in the applicable NDA or ANDA. Each new site requires the submission of a prior approval supplement or an amendment to our existing application, along with a satisfactory pre-approval inspection. The process of preparing a new manufacturing site for FDA inspection and obtaining approval can take many months and involves significant cost, including the qualification and validation of equipment, processes, and analytical methods. If the FDA identifies deficiencies at a new or existing site during an inspection—or if we are unable to demonstrate that a site can consistently manufacture products that meet all applicable specifications and regulatory standards—the FDA could delay or deny approval for that site, require costly remediation efforts, or take enforcement action. Because many of our PET isotopes have short half-lives and must be produced on or near the point of care, the loss of FDA approval at even a single site could directly prevent us from serving patients at that location and could result in lost revenue and damage to our customer relationships.

Post-approval regulatory requirements impose ongoing obligations that are costly and could restrict our operations, and failure to comply with such requirements could result in enforcement action or loss of approval. In addition, we are required to register our manufacturing establishments and list our drug products with the FDA under 21 CFR Part 207. We must also maintain drug establishment registrations and drug product listings with applicable state agencies. Failure to comply with registration and listing requirements could subject us to enforcement action, including seizure, injunction, or civil penalties.

We face risks associated with FDA enforcement actions, including warning letters, recalls, seizures, injunctions, and civil or criminal penalties. If the FDA determines that we are not in compliance with applicable regulatory requirements, it has a range of enforcement tools available, including issuance of Form 483 inspectional observations, warning letters, untitled letters, and cyber letters; imposition of civil monetary penalties; product recalls, seizures, or detentions; consent decrees of permanent injunction; withdrawal of product approvals; refusal to approve pending applications; restrictions on marketing or manufacturing; debarment; and referral for criminal prosecution. The FDA may also place a clinical hold on ongoing clinical trials if it finds that trial participants are being exposed to unacceptable risks. Any such enforcement actions could be costly, damage our reputation, divert management attention, and materially adversely affect our business, financial condition, and results of operations. Even if we ultimately prevail in any enforcement proceeding, the cost and distraction of defending against such actions could be substantial.

In addition, we may be required to conduct voluntary or mandatory recalls of our products if they are found to be defective, adulterated, or misbranded, or if they pose an unacceptable risk to patients. Because our products include radioactive materials, any recall or product withdrawal may involve additional logistical complexities related to the safe handling and disposition of radioactive materials. Product recalls could result in lost revenue, significant remediation costs, negative publicity, and damage to our customer relationships.

Possession of radioactive materials is subject to NRC, state, and international regulations.

We currently have nine sites across the United States for the production of diagnostic radiopharmaceuticals, and two additional facilities in Lansing, Michigan, with one for the production of therapeutic radiopharmaceuticals and another for the development of our cyclotron technology. Each site is licensed by the U.S. Nuclear Regulatory Commission or a state equivalent under a radioactive materials license, which entitles us to possess specified isotopes up to the quantity limits set forth in the license. These licenses, issued by the NRC or “Agreement States” authorized under the Atomic Energy Act, impose requirements governing the possession, use, transfer, and disposal of radioactive materials, including radiation protection standards, security requirements, and incident reporting obligations. Foreign jurisdictions also have their own regulatory requirements for manufacturing and transporting radioisotopes.

Failure to comply with our radioactive materials licenses could result in product cancellations or delays or other regulatory actions. Our licenses have associated requirements for radioactive material handling and disposal procedures, emergency plans, and qualified personnel. We are subject to ongoing compliance obligations, including license fees, reporting requirements, and site inspections. Certain isotopes and quantities may also trigger additional security and incident reporting requirements under applicable regulations.

In addition, NRC and applicable Agreement State regulations may require financial assurance for decommissioning and the proper disposition of radioactive materials, which may increase our operating costs and impose additional financial obligations.

Non-compliance with our licenses or the underlying regulations can result in enforcement actions, including civil penalties, increased oversight, or orders modifying, suspending, or revoking licenses, which could result in the cancellation or delay of customer products; penalties or fines; and liability for accidents or contamination.

Inability to secure or maintain required licenses or approvals could result in product delays or cancellations. We will require additional NRC or state licenses for any future sites at which we produce radiopharmaceuticals, and certain activities—such as amendments to existing licenses, expansion of isotope inventories, changes in facility design or operations, or the addition of new production capabilities—may require prior regulatory approval, which may be subject to environmental review and public comment processes and could result in delays or additional compliance obligations. We will also be required to file state licenses or registrations for any future cyclotrons we deploy. Any future radioactive materials licenses may be difficult to obtain depending on the regulator and proposed radiopharmaceutical. This risk is higher for cyclotron deployment that differs substantially from our existing operations.

Additionally, the NRC or Agreement States may determine that the Merger or a future reorganization constitutes a change of control requiring prior regulatory approval, and obtaining such approval could impose additional costs, timing delays, or operational restrictions. Because our operations depend on maintaining and expanding NRC and Agreement State licenses, any delay or denial of required approvals could directly limit our ability to produce or supply isotopes at clinical or commercial scale.

We also hold radiation-producing machine licenses from Agreement States for the cyclotrons themselves. These state regulatory frameworks establish requirements for the installation, operation, inspection, and maintenance of radiation-producing equipment, including shielding, radiation safety controls, personnel training, and radiation dose limits for workers and the public. States typically require facility registration, periodic inspections, and compliance with radiation protection standards, and may impose corrective actions or operational restrictions in the event of non-compliance. Failure to obtain or maintain required machine registrations or to comply with applicable state requirements may result in enforcement actions, including fines, suspension of operations, or revocation of registrations, which could adversely affect Ionetix's ability to operate its production facilities.

Transportation of radioactive materials is subject to Department of Transportation and NRC Regulations.

Our business depends on the ability to safely and efficiently transport radioactive materials to customers and clinical sites. The shipment of these materials is regulated by the U.S. Department of Transportation and the U.S. Nuclear Regulatory Commission, as well as other national and international regulatory authorities governing the transport of dangerous goods.

Radioactive materials are shipped in different categories of packages depending on activity levels. Lower-activity materials (within specified regulatory limits) may be transported in Type A packages, which are designed to withstand normal conditions of transport and are certified by the shipper as meeting applicable DOT performance standards. Higher-activity materials must be transported in Type B packages, which are designed to withstand severe accident conditions and require a Certificate of Compliance issued by the NRC for the package design.

Changes to transportation regulations established by the International Atomic Energy Agency, including modifications to allowable activity limits (A1/A2 values) for Type A packages, packaging requirements, labeling standards, or shipping classifications, could require us to use more restrictive or costly transport methods, including increased reliance on Type B packages. Such changes could also reduce the quantity of radioactive material that may be shipped in a single package.

These developments could increase costs, limit distribution capabilities, delay deliveries, or reduce the usable activity available upon receipt due to radioactive decay. Any of these outcomes could adversely affect our business, operations, and financial results.

In addition, availability of qualified carriers and air transport for radioactive materials is limited and subject to carrier-specific restrictions, which could further constrain our ability to distribute products. Further, Ionetix utilizes third-party brokerage and transportation services to ensure compliance with international transportation and customs requirements. Reliance on such third-party providers may expose the company to operational or compliance risks if such providers fail to meet applicable regulatory requirements.

Changes in laws, regulations, or regulatory interpretation could limit our markets, increase our costs or restrict our operations.

Laws and regulations applicable to our business may change, and regulatory agencies may adopt new policies, interpretations, or enforcement priorities. Compliance with new or amended laws or regulations could require us to modify our operations, incur substantial additional costs, or delay development or commercialization efforts.

Changes in laws, the imposition of new or additional regulations, or the enactment of any new or more stringent legislation that impacts our business could require us to change the way our products are used or the way we operate and could have a material adverse effect on our sales, profitability, cash flows, and financial condition, and lead to regulatory delays that could impact our ability to obtain licenses, certificates, authorizations, permits, and other types of regulatory approvals.

Similarly, changes in the priorities, mandates, and funding levels of the governmental entities with which we interact could impact our relationships with such entities or their attitudes toward or level of support for our business; reduce the amount of funding available for government grants; reduce the number of staff available to review and issue the requisite regulatory approvals, permits, and licenses; influence the public's perception of our company and our industry; and influence decisions by clients, governmental agencies, or other industry participants with whom we do business.

Any such change thus carries the possibility of reducing demand for our – or our pharmaceutical company customers' – products and services or increasing our costs of operations, which could have a negative impact on our financial position, results of operations, or cash flows, but we cannot reasonably or reliably estimate whether such changes will occur, when they will occur, or if they will impact us. We may not be able to anticipate such changes or the impact of such changes.

In particular, the FDA has indicated that it is continuing to mature its guidance documentation with respect to PET drug inspections, and changes to FDA policies or inspection approaches that emerge during pre-approval or surveillance inspections could impose additional obligations or create obstacles to obtaining or maintaining approval for our products. Furthermore, changes to user fee programs, such as the Generic Drug User Fee Amendments ("GDUFA"), could affect the FDA's review timelines and resource allocation for ANDA reviews, which could impact the timing of approval for our pending and future generic drug applications.

We may be unable to meet the compliance standards of environmental, health, and safety laws applicable to our business, and our inability to do so may cause us to lose prospective business and adversely affect our financial condition and results of operations.

Maintaining compliance with evolving regulatory requirements is essential for our continued operations, yet the complexity and breadth of applicable environmental, health, and safety laws, rules, and regulations pose ongoing challenges. Any failure to meet these standards may not only disrupt our business but also undermine our reputation and future prospects.

In particular, we are subject to regulations governing laboratory procedures and the handling, use, storage, treatment, and disposal of hazardous materials and wastes, including radioactive materials and gas. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. 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, and any liability could exceed our resources.

Additionally, our use of facilities that use and produce radioactive materials subjects us to compliance with decommissioning and decontamination ("D&D") requirements when we close those facilities, exposing us to potentially significant costs to dispose of any radioactive waste. When one of such facilities reaches the end of its useful life or if we need to abandon such facility for any other reason, we are obligated under the laws and regulatory rules of the various jurisdictions in which we operate to decommission and decontaminate such facility. We have no experience with D&D, and the costs of such D&D may be substantial. Estimating the amount and timing of such future D&D costs includes, among other factors, country-specific requirements and projections as to when a facility will retire or the useful life of a facility. If we do not conduct D&D properly at any of our sites, we may suffer significant additional costs to remediate any D&D deficiencies, which could have a material adverse effect upon our business, financial condition, and results of operations. Although we have estimated our future D&D costs and recorded a liability for such costs, there can be no assurances that we will not incur material D&D costs beyond such estimates or our provisions.

Although we maintain 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. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous, or radioactive materials.

Failure to comply with laws applicable to our business and industry could expose us to significant liability, which may adversely affect our operations thereafter.

We are subject to a wide variety of laws, rules, and regulations relating to various aspects of our business, including, but not limited to: nuclear and radiological regulations governing the possession, use, production, and disposal of radioactive materials and components; the design, manufacture, operation, marketing, sale, distribution, and export of particle accelerator technologies and related equipment; employment and labor; tax; data security of the operational and information technology systems; health and safety; import and export control; zoning and environmental protection; intellectual property; antitrust and competition; consumer protection; and government contracting.

Our operations and relationships with healthcare professionals, investigators, vendors, customers, third-party payors, consultants, and other third parties may be subject to a wide range of healthcare fraud and abuse laws, false claims laws, anti-kickback statutes, transparency and reporting requirements, pharmaceutical manufacturer reporting requirements, and data privacy and security regulations, including, but not limited to, the following statutes: the False Claims Act, the Anti-Kickback Statute, the Food, Drug, and Cosmetic Act, and the Physician Payments Sunshine Act, as well as other analogous state and foreign laws. These laws and regulations govern both our direct and indirect business activities in the United States and internationally.

We are also subject to FDA regulations governing the labeling, advertising, and promotion of our approved drug products. The FDA requires that promotional materials for approved drugs be truthful, not misleading, and consistent with the approved labeling. We are prohibited from promoting our products for uses or in patient populations not described in the FDA-approved labeling (commonly referred to as "off-label" promotion). If the FDA determines that our promotional materials or practices constitute unlawful promotion, it could request that we modify our promotional materials, issue a warning or untitled letter, or initiate enforcement actions including product seizure, injunction, or civil or criminal penalties. In addition, the Federal Trade Commission and state attorneys general have authority to investigate and take action against misleading advertising practices, which could subject us to additional scrutiny and potential liability.

Failure to comply with these various rules, regulations, and laws could result in civil, criminal, or administrative penalties, sanctions, fines, costs, fees, regulatory enforcement measures, violations, reputational harm, public reprimands, exclusion from government programs, loss of certain privileges, imprisonment, or contractual damages, injunctions, or suspension or revocation of licenses and permits, as well as impact our ability to operate our business. If any of the physicians or other providers or entities with whom we expect to do business are found to be in violation of applicable laws, they may be subject to such consequences, as well, which could affect our ability to operate our business. Further, defending against any such actions can be costly, time-consuming, and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

We cannot guarantee that our measures to monitor these developments and the time and resources we spend to comply with these laws, regulations, and guidelines will be satisfactory to regulators or other third parties, such as our customers, who may also be subject to extensive government regulation.

Litigation or legal proceedings could expose us to significant liabilities, occupy a considerable amount of our management's time and attention, and harm our reputation.

We may, from time to time, be a party to various litigation claims and legal proceedings. We will evaluate these claims and proceedings to assess the likelihood of unfavorable outcomes and estimate, if possible, the amount of potential losses. Claims made or threatened by our suppliers, customers, competitors, or current or former employees could adversely affect our relationships, damage our reputation or otherwise adversely affect our business, financial condition, or results of operations. The costs associated with defending legal claims and paying damages could be substantial. Our reputation could also be adversely affected by such claims, whether or not successful.

Our customers could incur substantial costs as a result of violations of, or liabilities under, environmental laws.

The operations and properties of our customers are subject to a variety of federal, state, local, and foreign environmental, health, and safety laws and regulations governing, among other things, air emissions; wastewater discharges; management and disposal of hazardous, non-hazardous, and radioactive materials and waste; and remediation of releases of hazardous materials. We must design our technology so it complies with such laws and regulations.

Compliance with environmental requirements could require our customers to incur significant expenditures or result in significant restrictions on their operations, and the failure to comply with such laws and regulations, including failing to obtain any necessary permits, could result in substantial fines or enforcement actions, including regulatory or judicial orders enjoining or curtailing operations or requiring our customers to conduct or fund remedial or corrective measures, install pollution control equipment, or perform other actions. More vigorous enforcement by regulatory agencies, the future enactment of more stringent laws, regulations, or permit requirements (including relating to climate change), or other unanticipated events may arise in the future and adversely impact the market for our products, which could materially and adversely affect our business, financial condition and results of operations.

Risks Related to Clinical Development of Radiotherapeutic Products

Our pharmaceutical company customers must conduct clinical trials of their radiotherapeutic products, which are costly, time-consuming, and subject to delay, suspension, or failure.

Our business depends on the successful pursuit of clinical trials by our pharmaceutical company customers. Clinical trials can be delayed, suspended, or terminated for a variety of reasons, including the following:

- delays in or failure to obtain regulatory authorization to commence a clinical trial;
- delays in or failure to reach agreement on acceptable terms with prospective contract research organizations ("CROs") and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- difficulty in recruiting clinical trial investigators of appropriate competencies and experience;
- delays in establishing the appropriate dosage levels in clinical trials;
- delays in or failure to recruit and enroll suitable patients to participate in a clinical trial, as well as inclusion and exclusion criteria and patients' prior lines of therapy and treatment;
- lower than anticipated retention rates of patients in clinical trials;
- failure to have patients complete a trial or return for post-treatment follow-up;
- clinical sites deviating from trial protocol or dropping out of a clinical trial;
- patient adverse events or safety concerns;
- delays adding new investigators or clinical trial sites;
- third-party research contractors failing to comply with regulatory requirements or meet their contractual obligations to our customers in a timely manner, or at all;
- changes in regulatory requirements, policies, and guidelines;
- delivery of sufficient quantities of a product candidate for use in clinical trials;
- competing clinical trials for the given indication and patient population;
- the quality or stability of a product candidate falling below acceptable standards;
- CDMO manufacturing or other supply chain constraints;
- changes in the treatment landscape for our target indications in oncology that may make any of our current or future product candidates no longer relevant;

- third-party actions claiming infringement by product candidates in clinical trials outside the United States and obtaining injunctions; and

- business interruptions resulting from geo-political actions, including war and terrorism, import/export restrictions or changes to taxes and tariffs, natural disasters including earthquakes, typhoons, floods, and wildfires, or disease.

Moreover, clinical trials must be conducted in accordance with the FDA and comparable foreign regulatory authorities' legal requirements, regulations, and guidelines, and are subject to oversight by regulatory authorities and institutional review boards ("IRBs") or ethics committees at the medical institutions where the clinical trials are conducted.

Because most of the clinical trials that utilize or depend on our radioisotopes are designed, sponsored, and controlled by our pharmaceutical company customers, we generally do not control key aspects of such trials, including study design, timelines, enrollment strategies, site selection, and interactions with regulators. We may have limited visibility into the status or details of these trials, and we may receive information on delays, protocol changes, or safety concerns only after our customers or collaborators have already made decisions that affect the pace or direction of development. As a result, it is difficult for us to predict or model the timing, likelihood, or scope of clinical success for programs that rely on our technology, and negative or unexpected developments in these trials could occur without advance notice to us. If our customers' trials are delayed, suspended, or terminated, if they fail to meet their primary or secondary endpoints, or if regulators or IRBs raise safety or other concerns, demand for our products could be reduced or eliminated for affected programs, and our business, financial condition, results of operations, and prospects could be materially adversely affected.

Adverse events or safety concerns could delay or prevent regulatory approval or limit commercial adoption.

Safety or tolerability concerns could cause regulatory authorities, as applicable, to suspend or terminate a clinical trial if it is found that the participants are being exposed to unacceptable health risks, undesirable side effects, or other unfavorable characteristics of the product candidate, or if such undesirable effects or risks are found to be caused by a chemically or mechanistically similar therapeutic or therapeutic candidate. We could encounter delays if a pharmaceutical company customer's clinical trial is suspended or terminated by the IRBs or ethics committees of the institutions in which such trials are being conducted, by the data review committee or data safety monitoring board for such trial, or by the FDA, or comparable foreign regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including, but not limited to, failure to conduct the clinical trial in accordance with regulatory requirements or clinical protocols, inspection of the clinical trial operations or trial site by the FDA, or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product, changes in governmental regulations or administrative actions, or lack of adequate funding to continue the clinical trial.

We may incur substantial product liability or indemnification claims related to the use of our products.

The use of our products involves inherent risks of product liability claims, including claims arising from alleged injuries or adverse events. Although we maintain insurance coverage for certain risks, such coverage may be insufficient or unavailable on acceptable terms. In addition, we may be required to indemnify third parties, including clinical trial sites, investigators, or customers for certain claims. Any such claims or indemnification obligations could result in significant costs, divert management attention, and materially adversely affect our financial condition and prospects.

Risks Related to Manufacturing and Supply Chain

We rely on third parties for manufacturing, supply, and other critical services, and disruptions could adversely affect our operations.

We may rely on third-party manufacturers, suppliers, and service providers for critical components and raw materials, such as Ra-226. These materials may be difficult or costly to source, and our suppliers may be subject to capacity constraints, quality issues, regulatory compliance challenges, or business disruptions. Our third-party suppliers, manufacturers and service providers may fail to perform as expected, experience capacity constraints, quality issues, regulatory noncompliance, or business disruptions. If we or our suppliers are unable to produce materials that meet applicable specifications or regulatory standards, or if a supplier ceases operations or fails to perform, we may experience delays, increased costs, or the need to qualify alternative suppliers, which could require significant time and expense and materially adversely affect our business. Any interruption or failure in our supply chain could delay development, increase costs, or prevent commercialization.

The short half-life and time-sensitive nature of delivery of radioactive isotopes used in our business create unique manufacturing, logistics, and operational risks.

Many of the radioactive isotopes and radiopharmaceutical products we produce have short physical half-lives and limited usable shelf lives. As a result, we must produce, process, and deliver such materials and products within tight time windows and under strict quality, safety, and regulatory requirements. Any delay or failure in manufacturing, dose preparation, release testing, packaging, or transportation may render a given batch unusable or result in missed deliveries or losses. These constraints can increase waste, raise per-dose costs, and reduce effective capacity. They also make our operations more susceptible to outages or disruptions at any point in the production and distribution chain. If we or our logistics providers are unable to consistently meet these time-critical requirements, our reputation could be harmed, our relationships with customers and collaborators could be adversely affected, and our business and prospects could be materially adversely impacted.

We may face risks related to quality control, compliance with manufacturing standards, and product recalls.

We are required to establish and maintain validated systems to ensure that our products consistently meet all specifications and regulatory standards, and to test each product batch or lot prior to its release. For our PET drugs, we must comply with the cGMP requirements set forth in 21 CFR Part 212, which impose specific requirements regarding sterility testing, environmental monitoring, equipment validation, personnel training, and batch record documentation. For our alpha-emitting isotopes, we must comply with the more comprehensive cGMP requirements under 21 CFR Parts 210 and 211. Any failure to maintain adequate quality systems, including failure to properly investigate deviations, out-of-specification results, or customer complaints, could result in the distribution of products that do not meet required specifications. Such quality failures could lead to patient harm, product recalls, FDA enforcement actions (including warning letters, seizures, and injunctions), loss of customer confidence, and reputational damage.

We may not be able to successfully scale production of any of our cyclotrons.

If we cannot increase production of our cyclotrons, we may be unable to meet our revenue goals. Supply shortages for raw materials and/or the specialized components we require may constrain our production capabilities. Moreover, there are risks associated with scaling isotope production itself, including: (i) access to requisite raw materials; (ii) radiation safety restrictions; (iii) reliability issues; and (iv) lack of experienced staff, which may restrict our ability to produce isotopes for our customers.

In addition, scaling production to new sites requires us to obtain FDA approval for each additional manufacturing facility, including satisfactory completion of a pre-approval inspection. Any failure or delay in obtaining site-specific FDA approvals could prevent us from expanding our manufacturing footprint and limit our ability to meet growing demand.

Risks Related to Intellectual Property

We depend on our ability to protect and defend our intellectual property rights, and we may not be able to do so.

If we cannot protect, maintain, and, if necessary, enforce our intellectual property rights, our ability to develop and commercialize products will be adversely impacted. Our success, in large part, depends on our ability to protect and maintain the proprietary nature of our technology. We rely upon a combination of the intellectual property protections afforded by patents, trademarks and service marks, copyrights, and trade secret laws in the United States and other jurisdictions, as well as commercial agreements, such as confidentiality agreements, assignment agreements, and license agreements to establish, maintain, and enforce rights associated with our proprietary technologies. Our success depends in part on our ability to obtain and enforce patent protection for such solutions and technologies, but our patent applications may not result in issued patents, given the complexity of questions around patentability and the large number of patents and patent applications in related fields. Failure to obtain additional patent protection in connection with currently pending or future patent applications may have a material adverse effect on our ability to prevent others from commercially exploiting products similar to ours.

Further, our existing issued patents may be contested, challenged, circumvented, invalidated, or limited in scope in the future. The rights granted under our issued patents may not provide us with meaningful protection or competitive advantages, and some foreign countries provide significantly less effective patent enforcement as compared to the United States. In addition, the claims of our existing patents and any patents that issue from our currently pending or any future patent applications may be narrowed in scope during prosecution, challenged as invalid, or may simply not be broad enough to prevent others from developing technologies that are similar or that achieve results similar to ours if, for example, competitors “design around” our patents. We cannot provide assurance that our means of protecting our proprietary rights will suffice in affording the desired protection.

We rely on trade secrets and confidential information, which may be difficult to protect.

We rely upon unpatented trade secret protection and unpatented know-how, including cyclotron and magnet modeling, system cooling, radiation safety analysis, radiochemistry expertise, and systems engineering, as well as continuing technological innovation to develop our business and competitive position.

Trade secrets are difficult to protect. Trade secret protection, unlike patent protection, does not prevent others from independently developing or lawfully reverse engineering the same or similar know-how. If a competitor or other third party lawfully obtains or independently develops processes similar to ours, including with respect to cyclotron and magnetic modeling and system cooling, we would have no right to stop them, or anyone they share the information with, from using it to compete with us. Many of our competitors and potential competitors, including large multinational healthcare and radiopharmaceutical companies, government-affiliated entities and academic institutions, have significantly greater resources than we do. They may be able to invest heavily in research and development aimed at matching or exceeding our capabilities.

We may not be able to prevent the unauthorized disclosure or use of our trade secrets, know-how, or information that we consider to be confidential by our contractual counterparties, despite our efforts. If any of the suppliers, subcontractors, employees, consultants, or other third parties with whom we do business or otherwise collaborate breach or violate the terms of any of our agreements, we may not have adequate remedies for any such breach or violation, and we could lose the protections afforded by our trade secrets as a result. It is also possible that our trade secrets, know-how, or other proprietary information could be obtained by third parties as a result of breaches of our physical or electronic security systems. Even where remedies are available, enforcing a claim that a party illegally disclosed or misappropriated our trade secrets is expensive and time consuming, and the outcome is unpredictable.

Courts outside the United States are sometimes less willing to protect trade secrets. Additionally, our trade secrets could become known or be independently discovered by potential or existing competitors. 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, or those with whom they communicate, from using that technology or information to compete with us.

We have limited international protection over our intellectual property.

We do not have worldwide patent rights for our proprietary technologies. Accordingly, we may not be able to protect our intellectual property rights in certain jurisdictions. Our competitors may operate in countries where we do not have patent protection and can freely use our patented technologies and discoveries in such countries to the extent such technologies and discoveries are publicly known or disclosed in countries where we do have patent protection. As a result, the lack of global protection may limit our ability to prevent unauthorized use of our intellectual property and could negatively impact our competitive position.

We may need to defend ourselves against intellectual property infringement claims, which may be time-consuming and could cause us to incur substantial fees and costs.

Companies, organizations, or individuals, including any existing and potential competitors, may hold or obtain patents, trademarks and service marks, copyrights, or other intellectual property rights that would prevent, limit, or interfere with our ability to develop our intellectual property and make, use, develop, import, offer, or sell related equipment, which could make it more difficult for us to operate our company. From time to time, we may receive inquiries from holders of patents, trademarks or service marks, or copyrights inquiring whether we are infringing their proprietary rights. Companies, organizations, or individuals, including any existing and future competitors, may also seek court declarations affirming that they do not infringe our intellectual property rights. Companies holding patents or other intellectual property rights similar to our technology may bring proceedings alleging infringement of such rights or otherwise asserting their rights and seeking licenses. In addition, if it is determined that we have infringed a third party's intellectual property rights, we may be required to do, among other things, one or more of the following:

- cease making, using, offering to sell, selling, or importing our products and services that incorporate the challenged intellectual property;
- pay substantial damages;
- pay for and obtain a license from the holder of the infringed intellectual property right, which may not be available on reasonable terms or at all; or
- redesign part or all of our technology.

In the event of a successful claim of infringement against us and our failure or inability to obtain a license to the infringed technology, our business, prospects, operating results, and financial condition could be materially adversely affected. In addition, any litigation, or claims, whether or not valid, could result in substantial costs and diversion of resources and management's focus and attention.

Non-disclosure agreements with our employees, consultants, and contractors may be challenged or breached, resulting in misappropriation, misuse, or ongoing negotiation of ownership rights.

Our confidentiality, non-disclosure, and intellectual property assignment agreements with our employees, consultants, and contractors generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive intellectual property. These agreements may not be upheld, and requirements to assign intellectual property could be contested or violated. Moreover, there may be some circumstances where we are unable to negotiate for such ownership rights or where others misappropriate those rights.

We may be subject to claims that former employees, collaborators, or other third parties have an interest in our patents or other intellectual property as an owner, a joint owner, a licensee, an inventor, or a co-inventor. In the latter two cases, the failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our patented technology, or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship and ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property.

If we fail in defending any such claims, in addition to paying monetary damages, we may lose exclusive ownership of, or right to use or license, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other personnel.

Risks Related to Cybersecurity, Information Technology, and Data Protection

Security breaches and other disruptions could compromise our proprietary information and expose us to liability, which would cause our business and reputation to suffer.

We maintain various information technology systems and procedures to protect our trade secrets, technical knowhow, and other unpatented proprietary information relating to our product development and operating activities, and to restrict unauthorized access to the dissemination of our proprietary information. However, internal and external data security threats cannot be mitigated entirely. For example, current, departing or former employees or third parties could attempt to improperly use or access our computer systems and networks to copy, obtain, or misappropriate our proprietary information or otherwise interrupt our business. Additionally, members of our management team work remotely, which could have the effect of increasing the likelihood of cybersecurity breaches. Like others, we are also subject to significant system or network disruptions from numerous causes, including computer viruses and other cyber-attacks, facility access issues, new system implementations, and energy blackouts. Security breaches, computer malware, phishing, spoofing, and other cyber-attacks have become more prevalent and sophisticated in recent years. While we defend against these threats daily, we do not believe that such attacks have caused us any material damage to date. Because the techniques used by computer hackers and others to access or sabotage networks constantly evolve and generally are not recognized until launched against a target, we may be unable to anticipate, counter, or ameliorate all these techniques. As a result, our and our customers' proprietary information may be misappropriated, and we cannot predict the impact of any future incident. Any loss of such information could harm our competitive position, result in a loss of customer confidence in the adequacy of our threat mitigation and detection processes and procedures, cause us to incur significant costs to remedy the damages caused by the incident, and divert management and other resources. We routinely implement improvements to our network security safeguards, and we believe that we devote appropriate resources to the security of our information technology systems. However, we cannot provide assurance that our efforts will be sufficient to prevent or limit the damage from any future cyber-attack or network disruptions.

Cybersecurity breaches or information technology disruptions could result in significant costs and materially impact our financial results.

The costs related to cyber-attacks or other security threats or computer systems disruptions typically would not be fully insured or indemnified by others. In many cases, insurance coverage may be limited, subject to exclusions, or insufficient to cover all damages, including remediation expenses, legal fees, regulatory fines, and costs associated with restoring operations and reputation. Additionally, we may incur significant expenses related to forensic investigations, system upgrades, and increased cybersecurity measures following an incident. As a result, the occurrence of any of the events described above could result in the loss of competitive advantages derived from our intellectual property, impacting its financial value. Such losses may also include reduced revenue, diminished market share, and increased costs of doing business, which could negatively affect our profitability and cash flows. We may experience increased scrutiny from customers and regulators, which could lead to further operational and compliance costs, as well. Moreover, these events may result in the diversion of the attention of management and critical information technology and other resources, or otherwise adversely affect our internal operations and reputation or degrade our financial results and stock price. Ultimately, the cumulative effect of these risks and associated costs could materially impact our overall financial condition and long-term strategic objectives.

Risks Related to International Operations and Trade

Operating internationally exposes us to a range of risks, including regulatory differences, intellectual property uncertainties, financial and legal challenges, supply and workforce disruptions, and potential business interruptions, all of which could negatively impact our costs, commercialization, and profitability.

If we commercialize our products outside the United States, we may rely on third parties to market, distribute, or support our products in foreign jurisdictions. These marketing and distribution agreements may be exclusive for particular jurisdictions. International operations expose us to additional risks, including differing regulatory requirements for product approvals, reduced or uncertain protection of intellectual property rights, foreign currency fluctuations, tariffs and trade barriers, compliance with foreign tax and employment laws, and economic or political instability.

In addition, international operations may be subject to supply disruptions, workforce challenges, and business interruptions arising from geopolitical events, natural disasters, or public health crises. Any of these factors could increase our operating costs, delay commercialization efforts, or adversely affect our revenues and profitability.

Current and future geopolitical and macroeconomic events outside of our control, including changes in interest rates, levels of inflation, and foreign currency exchange rates, could adversely impact our business.

We face risks related to geopolitical events, international hostility, epidemics, outbreaks, and other macroeconomic events that are outside of our control. The occurrence of certain geopolitical events, including, but not limited to, those arising from terrorist activity, international hostility, public health crises, and the economic impact of global trade tensions, could significantly disrupt our business and operational plans, and adversely affect our results of operations, cash flows, financial condition, and liquidity. For instance, the ongoing conflicts in the Middle East and between Russia and Ukraine have caused and may continue to cause geopolitical instability and have adverse effects on the global economy, supply chains, and specific markets and industries. Although we are not able to enumerate all potential risks to our business resulting from these and other similar events, we believe that such risks include, without limitation, the following:

- disruption to our supply chain for materials essential to our business, including restrictions on importing and exporting products, including but not limited to radioactive material;

- difficulty obtaining required licenses or authorizations as a result of changes in trade policies or sanctions;

- customers, suppliers, and other third parties asserting that their non-performance under our contracts with them is permitted as a result of force majeure or other reasons;

- cybersecurity attacks, particularly as digital technologies may become more vulnerable and experience a higher rate of cyberattacks in the current environment of remote connectivity;

- any reductions of our workforce to adjust to market conditions, including severance payments, retention issues, and possible inability to hire employees when market conditions improve;

- logistical challenges, including those resulting from border closures and travel restrictions, as well as the possibility that our ability to achieve commercialization of our operations may be interrupted, limited, or curtailed;

- economic, political, and regulatory conditions domestically and internationally, including imposition of tariffs or other tax incentives or disincentives; and

- effects of sanctions and other penalties imposed on foreign countries by the United States, the European Union, and other countries.

We cannot reasonably estimate the period of time that these conditions will persist; the full extent of the impact they will have on our business, results of operations, cash flows, financial condition, and liquidity; or the pace or extent of any subsequent recovery.

Uncertain global macroeconomic and political conditions could materially adversely affect our business prospects, financial condition, results of operations, and cash flows.

Our results of operations could be materially affected by economic and political conditions in the United States and internationally, including inflation, deflation, fluctuations in interest rates, fluctuations in exchange rates, availability of capital, energy and commodity prices, trade laws, and the effects of governmental initiatives to manage economic conditions. Our business model is dependent on government entities and companies around the world adopting and entering into contracts for the implementation of our technologies and services. Adverse national and international economic conditions may reduce the future availability of funding counterparties have to spend on our services, which would negatively impact our revenues and our ability to commercialize our operations. Such conditions could also make it difficult or impossible for us to secure financing on acceptable terms or at all, and could materially increase the cost of our operations. Our cost estimates and assumptions are also sensitive to macroeconomic factors, and their accuracy could likely be impacted by unanticipated changes in such factors. It is not possible to accurately predict all of the potential adverse impacts on our business, if any, or how current and future economic conditions will affect our financial condition, operating results, and cash flow. Any of these macroeconomic conditions could negatively impact our strategic partners, suppliers, customers, and the industry as a whole, as well, which could then materially affect our business, financial condition, and results of operations.

Our ability to rely on global supply chains for source components and/or raw materials may be impacted by tariffs, trade disputes, or other changes in trade policy or trade regulation.

We plan to rely on global supply chains to source components and materials essential for our business. The imposition of new or increased tariffs, trade restrictions, or other changes in trade policy by the United States or other countries throughout the world could increase our costs of materials and components, require us to find additional or alternative suppliers, or force adjustments to our pricing structure and capital budget. These changes could reduce our profit margins, may impact our licenses, may require additional regulatory approval, or could otherwise disrupt our business operations. In particular, recent global trade tensions and policy shifts have created an unpredictable environment for businesses operating across international borders. Changes in trade agreements, sanctions, export controls, and customs regulations may limit our ability to source materials from - or distribute materials to - certain countries or entities, potentially forcing rapid and costly adjustments to our supply chain. Trade policies can change with limited notice, making long-term planning difficult and increasing operational costs. Any significant disruption to our supply chain resulting from tariffs or trade policy changes could have a material adverse effect on our business, financial condition, and ability to meet projected deadlines and milestones.

The direct and indirect impact on us and our value chain from severe weather and other effects of global climate change could adversely affect our business.

Our operations, and those of our value chain, may be adversely impacted by flooding, wildfires, high winds, drought, and other natural disasters and catastrophic events in the future. Global climate change is expected to increase the frequency and intensity of certain such events, as well as contribute to chronic changes (such as in weather patterns or water levels) that may result in various adverse impacts, including shutdown of our isotope manufacturing facilities. Even if these events do not directly impact us or our value chain, they may indirectly affect us through increased insurance, energy, or other costs. In addition, although the ongoing transition to non-carbon-based energy is creating significant opportunities for us and parts of our value chain, the transition also presents certain risks, including macroeconomic risks related to higher energy costs and energy shortages, among other things. These direct and indirect impacts from climate change could adversely affect our financial condition, operating results, supply chain, and cash flows.

We are subject to foreign laws and regulations, which could result in us facing criminal liability and other serious consequences for violations.

We are subject to the United States Foreign Corrupt Practices Act of 1977, as amended ("FCPA"), the United States Travel Act, and other anti-corruption, anti-bribery and anti-money laundering laws in countries throughout the world in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, business partners, third-party intermediaries, representatives, and agents from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to government officials, political candidates, political parties, or commercial partners for the purpose of obtaining or retaining business or securing an improper business advantage. The FCPA and other applicable laws and regulations also require that we keep accurate books and records and maintain internal controls and compliance procedures designed to prevent any such actions. While we have policies and procedures to address compliance with such laws, there can be no assurance that all of our employees, business partners, third-party intermediaries, representatives, and agents will not take actions in violation of our policies and applicable law, for which we may be ultimately held responsible.

Any violations of the laws and regulations described above may result in whistleblower complaints, adverse media coverage, investigations, civil and criminal fines and penalties, damages, settlements, prosecution, enforcement actions, imprisonment, the loss of export or import privileges, suspension or debarment from government contracts, tax reassessments, breach of contract and fraud litigation, reputational harm, court costs and legal fees, and other consequences, any of which could adversely affect our business, prospects, financial condition, and operating results. Such violations of these laws could subject us to legal proceedings in foreign jurisdictions, where unfamiliar legal systems, procedures, and requirements may present significant challenges and complexities compared to those in the United States. In addition, responding to any investigation or action will likely result in a significant diversion of management's attention and resources and significant defense costs and other professional fees.

Risks Related to Management and Personnel

Our business is highly dependent on the continued service of certain members of our senior management.

Our future success depends, in part, on the continued service, expertise, and institutional knowledge of members of our senior management team. The loss of the services of any of these individuals, whether due to resignation, termination, illness, or other reasons, could disrupt our operations, delay the execution of our business strategy, and have a material adverse effect on our business, financial condition, and results of operations. We may not be able to replace key personnel on a timely basis or with individuals of comparable experience, which could further adversely affect our prospects.

Our success depends on our ability to attract, retain, and motivate key personnel.

We depend on the expertise and efforts of our management team and other key personnel. Competition for qualified employees is intense, and the loss of key personnel or inability to recruit additional talent could impair our ability to execute our business strategy. In addition, adverse macroeconomic conditions, increased regulatory requirements, and uncertainties arising from global or domestic political or economic instability may further complicate our ability to attract and retain skilled professionals. These challenges can also increase compensation demands and turnover rates, making it more difficult to maintain a stable and effective workforce. Furthermore, our reliance on certain individuals means that any loss of their services, whether due to external factors such as health, relocation, or retirement, or internal factors such as organizational restructuring, could materially impact our business operations, strategic initiatives, and financial performance.

We also rely on third-party consultants, advisors, and service providers for specialized expertise, including regulatory, scientific, manufacturing, and commercialization activities. Many of these individuals or entities serve multiple clients and may have obligations or interests that compete with ours. If we are unable to retain qualified consultants, secure their services on acceptable terms, or ensure sufficient allocation of their time and attention to our business, our development and commercialization efforts could be delayed or impaired.

Conflicts of interest between our management, stockholders, and affiliates could adversely affect our business.

Conflicts of interest may arise between the personal or professional interests of members of our management, directors, or affiliated parties and the interests of our company or our stockholders. These interests may include, among others, equity ownership, compensation arrangements, consulting or advisory relationships, or business relationships with third parties. From time to time, we have entered into, and may in the future enter into, related-party transactions, including leases and financing arrangements with members of our board of directors (the "Board") or significant stockholders, which may give rise to perceived or actual conflicts of interest in connection with the negotiation and administration of such arrangements.

Such perceived or actual conflicts could influence decision-making and create incentives for management to act in ways that may not align with the best interests of our business or our stockholders. While our directors and officers owe fiduciary duties to the company under applicable law, the existence of such conflicts may make it more difficult to objectively evaluate transactions, strategic alternatives, or other matters, and could have a material adverse effect on our business, financial condition, or results of operations.

Conflicts of Interest Related to Placement Agent and Certain Stockholders

Certain of JDEV's pre-Merger stockholders are affiliated with, or have economic arrangements with, the placement agent engaged in connection with the Private Placement. In particular, members of Intuitive Venture Partners, LLC, a boutique venture investment firm, are registered representatives of the placement agent, and another of JDEV's pre-Merger stockholders is a director and registered representative of the placement agent. Pursuant to such arrangements, these stockholders are entitled to receive, directly or indirectly, a portion of the compensation payable to the placement agent in connection with the Private Placement, which may include cash fees and/or warrant consideration.

These relationships may create potential conflicts of interest by providing such stockholders with financial incentives that differ from, or are in addition to, those of other stockholders. For example, such stockholders may have an incentive to support or facilitate the Private Placement or related transactions on terms that may not be as favorable to JDEV or its unaffiliated stockholders as might otherwise be obtained in the absence of such arrangements.

JDEV was not a party to, and did not negotiate, these arrangements. Nevertheless, these relationships could influence the structure, timing or terms of the Private Placement and related transactions, and may adversely affect the interests of other stockholders.

Rapid growth could strain our organizational and operational capabilities.

If we expand our operations, we may face challenges related to managing growth, integrating new personnel, implementing systems and controls, and maintaining effective internal processes. Failure to manage growth effectively could adversely affect our business. In periods of rapid expansion, we may encounter difficulties in scaling our management structure, onboarding and training new staff, and maintaining compliance with evolving legal and regulatory requirements.

Additionally, the administrative burden associated with being a public company – including increased reporting obligations, internal control requirements, and legal compliance – may divert management's attention from core business activities and strategic planning. This heightened pressure can lead to inefficiencies, increased costs, and reduced morale among employees, potentially resulting in operational disruptions and diminished productivity. Inadequate resources, lack of experience in handling public company responsibilities, or insufficient internal controls could also expose us to greater risk of regulatory actions, reputational harm, and legal liabilities.

We may rely on consulting or other third-party arrangements for certain management or operational functions.

From time to time, we may rely on consulting agreements or other third-party arrangements to provide executive, financial, regulatory, scientific, or operational services. These individuals or entities are not our employees and may have other professional commitments or business relationships. If any such arrangement is terminated, expires, or otherwise becomes unavailable, we may experience disruptions to our operations or delays in executing our business plans. Our inability to continue to obtain these services, or to replace them on acceptable terms or in a timely manner, could have a material adverse effect on our business, financial condition, and results of operations.

Adverse external conditions may impact our management's ability to focus on business growth.

Uncertainties related to global macroeconomic and political conditions, trade policy changes, supply chain disruptions, data security and related regulatory requirements, and climate-related events may require our management to divert significant attention and resources toward crisis response, risk mitigation, and compliance efforts. This diversion can reduce the time and energy available for strategic development, innovation, and operational efficiency. Moreover, responding to investigations, legal actions, or regulatory compliance matters may create additional workload and stress for management, potentially impacting decision-making and leadership effectiveness. As a result, these adverse conditions may not only hinder our ability to achieve business objectives but also increase the risk of turnover among key personnel, further affecting our long-term prospects.

We depend on independent investigators, research institutions, and collaborators to conduct certain preclinical and clinical activities.

Third-party independent investigators, research institutions, and collaborators are not our employees and are not subject to our direct control. They may have competing professional obligations or relationships with other entities, including competitors, and may not devote sufficient time or resources to our programs. If these parties fail to comply with regulatory requirements, experience disruptions, or otherwise underperform, our development timelines could be delayed or our programs could be suspended or terminated.

Risks Related to Being a Public Company

Being a public company can be administratively burdensome and will significantly increase our legal and financial compliance costs.

As a public reporting company, we are subject to the information and reporting requirements of the Securities Act of 1933, as amended ("Securities Act"), the Securities Exchange Act of 1934, as amended ("Exchange Act"), and other federal securities laws, rules, and regulations related thereto, including compliance with the Sarbanes-Oxley Act of 2002 ("Sarbanes-Oxley Act") and the Dodd-Frank Wall Street Reform and Consumer Protection Act. Adhering to such extensive reporting, disclosure, and compliance obligations under United States securities laws may increase our legal, accounting, and administrative costs.

In addition, the listing requirements of any national securities exchange or other exchange and other applicable securities rules and regulations impose various requirements on public companies. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will significantly increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

Among other things, we are required to:

- maintain and evaluate a system of internal controls over financial reporting in compliance with the requirements of Section 404 of the Sarbanes-Oxley Act and the related rules and regulations of the SEC and the PCAOB;

- maintain policies relating to disclosure controls and procedures;

- prepare and distribute periodic reports in compliance with our obligations under federal securities laws;
- institute a more comprehensive compliance function, including with respect to corporate governance; and
- involve, to a greater degree, our outside legal counsel and accountants in the above activities.

The costs of preparing and filing annual and quarterly reports, proxy statements, and other information with the SEC and furnishing audited reports to stockholders are expensive and much greater than those of a privately-held company, and compliance with these rules and regulations will require us to hire additional financial reporting, internal controls, and other finance personnel, and will involve a material increase in regulatory, legal, and accounting expenses and the attention of the Board and management. In addition, being a public company makes it more expensive for us to obtain director and officer liability insurance. In the future, we may be required to accept reduced coverage or incur substantially higher costs to obtain this coverage. These factors could also make it more difficult for us to attract and retain qualified executives and members of the Board.

Our management as a group has limited experience operating a publicly traded company.

Our management team has a high degree of technical expertise but limited experience operating a publicly traded company subject to significant regulatory oversight and reporting obligations under United States securities laws. Their limited experience in dealing with the increasingly complex laws applicable to public companies could be a significant disadvantage in that it is likely that an increasing amount of their time may be devoted to these activities, which will result in less time being devoted to the management and growth of our company. We may not have adequate personnel with the appropriate level of knowledge, experience, and training in the accounting policies, practices, or internal control over financial reporting required of public companies. Any failure by us to effectively and efficiently meet our obligations as a publicly traded company could have a material adverse effect on our business, prospects, financial condition, and operating results, and/or result in legal liability or other negative consequences.

If we fail to maintain effective internal control over financial reporting, investor confidence could be harmed.

As a public company, we are required to maintain effective disclosure controls and internal control over financial reporting. Any material weaknesses or failures in these controls could result in inaccurate financial reporting, restatements, regulatory scrutiny, or a decline in the trading price of our securities.

Risks Related to Ownership of Our Securities

Because there is currently no established market for our common stock, stockholders may not be able to sell their shares when or at prices they want.

Our common stock is not listed on a national securities exchange or any other exchange, or quoted on an over-the-counter market. Therefore, there is no trading market, active or otherwise, for our common stock and our common stock may never be included for trading on any stock exchange, automated quotation system, or any over-the-counter market. Accordingly, our common stock is highly illiquid and stockholders will likely experience difficulty in re-selling such shares at times and prices that they may desire.

Our common stock may not be eligible for listing or quotation on any securities exchange or over-the-counter trading system.

We do not currently meet the initial quantitative listing standards of any national securities exchange or over-the-counter trading system. We can make no assurance that we will be able to meet the initial listing standards of any national securities exchange, or, if we do meet such initial listing standards, that we will be able to maintain any such listing. Further, the national securities exchanges have adopted so-called “seasoning” rules that will require that we meet certain requirements, including prescribed periods of time trading over-the-counter and minimum filings of periodic reports with the SEC, before we are eligible to apply for listing on such national securities exchanges. We intend to contact an authorized market maker for an over-the-counter quotation system for sponsorship of our common stock, but we cannot guarantee that such sponsorship will be approved and our common stock listed and quoted for sale.

Even if our common stock is quoted for sale on an over-the-counter quotation system, buyers may be insufficient in numbers to allow for a robust market and it may prove impossible for stockholders to sell their shares. In addition, an investor may find it difficult to obtain accurate quotations as to the market value of our common stock. Furthermore, if we fail to meet the criteria set forth in SEC regulations, various requirements would be imposed by law on broker-dealers who sell our securities to persons other than established customers and accredited investors. Consequently, such regulations may deter broker-dealers from recommending or selling our common stock, which may further affect its liquidity. This would also make it more difficult for us to raise additional capital.

The market price and trading volume of our common stock may be volatile and could decline significantly following the Merger.

The trading price of our securities may be highly volatile due to factors beyond our control. Such volatility could result in significant losses for investors. The quotation systems, including the OTCQB, or stock exchanges, including Nasdaq, on which our common stock may be quoted or on which our common stock may be listed in the future have from time to time experienced significant price and volume fluctuations. Even if an active, liquid, and orderly trading market develops and is sustained for our common stock following the Merger, the market price of our common stock may be volatile and could decline significantly. In addition, the trading volume in our common stock may fluctuate and cause significant price variations to occur. If the market price of our common stock declines significantly, stockholders may be unable to resell their shares at or above the market price of our common stock as of the date of the consummation of the Merger.

We can make no assurance that the market price of common stock will not fluctuate widely or decline significantly in the future in response to a number of factors, including, among others, the following:

- the realization of any of the risk factors presented in this Quarterly Report;
- actual or anticipated differences in our estimates, or in the estimates of analysts, for our revenues, results of operations, level of indebtedness, liquidity, or financial condition;
- additions and departures of key personnel;
- failure to comply with the requirements of the OTCQB market, or, following our potential uplisting, on Nasdaq;
- failure to comply with the Sarbanes-Oxley Act or other laws or regulations;
- future issuances, sales, resales, or repurchases or anticipated issuances, sales, resales, or repurchases, of our common stock;
- publication of research reports about us or our industry;
- the performance and market valuations of other similar companies;
- broad disruptions in the financial markets, including sudden disruptions in the credit markets;
- speculation in the press or investment community;
- actual, potential, or perceived control, accounting, or reporting problems; and
- changes in accounting principles, policies, and guidelines.

In the past, securities class-action litigation has often been instituted against companies following periods of volatility in the market price of their shares. This type of litigation could result in substantial costs and divert our management’s attention and resources, which could have a material adverse effect on us.

The designation of our securities as "penny stock" would limit the liquidity of our common stock.

Our common stock may be deemed a "penny stock" (as that term is defined under Rule 3a51-1 of the Exchange Act) in any market that may develop in the future. Generally, a "penny stock" is a common stock that is not listed on a securities exchange and trades for less than $5.00 a share. Prices often are not available to buyers and sellers, and the market may be very limited. Penny stock in start-up companies is among the riskiest equity investments. Broker-dealers who sell penny stock must provide purchasers with a standardized risk-disclosure document prepared by the SEC. The document provides information about penny stock and the nature and level of risks involved in investing in the penny stock market. A broker must also provide purchasers with bid and offer quotations and information regarding broker and salesperson compensation and make a written determination that the penny stock is a suitable investment for the purchaser and obtain the purchaser's written agreement to the purchase. Many brokers choose not to participate in penny stock transactions. If our common stock is deemed "penny stock," because of penny stock rules, there may be less trading activity in any market that develops for our common stock in the future and stockholders are likely to have difficulty selling their shares.

FINRA sales practice requirements may limit a stockholder's ability to buy and sell our common stock.

The Financial Industry Regulatory Authority ("FINRA") has adopted rules requiring that, in recommending an investment to a customer, a broker-dealer must have reasonable grounds for believing that the investment is suitable for that customer. Prior to recommending speculative or low-priced securities to their non-institutional customers, broker-dealers must make reasonable efforts to obtain information about the customer's financial status, tax status, investment objectives, and other information. Under interpretations of these rules, FINRA has indicated its belief that there is a high probability that speculative or low-priced securities will not be suitable for at least some customers. If these FINRA requirements are applicable to us or our securities, such requirements may make it more difficult for broker-dealers to recommend that at least some of their customers buy our common stock, which may limit the ability of our stockholders to buy and sell our common stock. This could ultimately have an adverse effect on the market for and price of our common stock.

Because we became a reporting company under the Exchange Act by means other than a traditional underwritten initial public offering, we may not be able to attract the attention of research analysts at major brokerage firms.

Because we did not become a reporting company by conducting an underwritten initial public offering of our common stock, and because we will not be listed on a national securities exchange, security analysts of brokerage firms may not provide coverage of us. In addition, investment banks may be less likely to agree to underwrite secondary offerings on our behalf than they might if we became a public reporting company by means of an underwritten initial public offering because they may be less familiar with our company as a result of more limited coverage by analysts and the media, and because we became public at an early stage in our development. Failure to receive research coverage or support in the market for our shares will have an adverse effect on our ability to develop a liquid market for our common stock.

Because the Merger was a reverse merger, we may not be able to attract the attention of major brokerage firms.

Additional risks may exist as a result of our becoming a public reporting company through a "reverse merger." Securities analysts and brokerage firms may be less likely to provide coverage of, or recommend investment in, our common stock and business because we became a public reporting operating company through a reverse merger. As a result, we cannot assure our stockholders that analyst coverage or investment recommendations will be available in the future.

If we do not establish and maintain effective internal controls and disclosure controls following the Merger, we risk impairing our ability to produce timely, accurate financial statements and comply with laws, which could result in material misstatements.

Following the consummation of the Merger, we became a publicly reporting company and are required, pursuant to Section 404(a) of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting on our annual report on Form 10-K. Effective internal control over financial reporting is necessary for reliable financial reports and, together with adequate disclosure controls and procedures, such internal controls are designed to prevent fraud. 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. Ineffective internal controls could also cause investors to lose confidence in reported financial information, which could have a negative effect on the trading price of our common stock.

The report by management will need to include disclosure of any material weaknesses identified in internal control over financial reporting. However, for as long as we are an "emerging growth company" under the Jumpstart Our Business Startups Act ("JOBS Act") following the consummation of the Merger, our independent registered public accounting firm will not be required to attest to the effectiveness of internal control over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act. Management's assessment of internal controls, when implemented, could detect problems with internal controls, and an independent assessment of the effectiveness of internal controls by our auditors could detect further problems that management's assessment might not, and could result in the identification of material weaknesses that were not otherwise identified. Undetected material weaknesses in internal controls could lead to financial statement restatements and require us to incur the expense of remediation. We are required to disclose changes made in internal controls and procedures on a quarterly basis. To comply with the public company requirements, we may need to undertake various actions, such as implementing new internal controls and procedures and hiring accounting or internal audit staff.

We are in the early stages of developing the system and processing documentation necessary to perform the evaluation needed to comply with Section 404. We may not be able to complete our evaluation, testing, and any required remediation in a timely fashion. During the evaluation and testing process, if we identify material weaknesses in internal control over financial reporting, we will be unable to assert that internal control over financial reporting is effective. If we are unable to assert that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an opinion on the effectiveness of our internal control, including as a result of the material weaknesses described above, we could lose investor confidence in the accuracy and completeness of financial reports, which would cause the price of our common stock to decline. We may also be subject to investigation or sanctions by the SEC. In addition, if we are unable to continue to meet these requirements, we may not be able to remain quoted on any over-the-counter trading system, or following any potential listing, listed on any securities exchange.

We are an emerging growth company and a smaller reporting company, and any decision on our part to comply only with certain reduced reporting and disclosure requirements applicable to emerging growth companies and smaller reporting companies could make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act, and, for as long as we continue to be an emerging growth company, we may choose to take advantage of exemptions from various reporting requirements applicable to other public companies but not to emerging growth companies, including:

- exemption from the requirement that our independent registered public accounting firm audit our internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act;
- reduced disclosure obligations regarding executive compensation in our periodic reports and annual report on Form 10-K; and
- exemptions from the requirements of holding non-binding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved.

Our status as an emerging growth company will end as soon as any of the following takes place:

- the last day of the fiscal year in which we have more than $1.235 billion in annual revenues;
- the date we qualify as a "large accelerated filer," with at least $700 million of equity securities held by non-affiliates;
- the date on which we have issued, in any three-year period, more than $1 billion in non-convertible debt securities; or
- the last day of the fiscal year ending after the fifth anniversary of the first sale of our common equity securities pursuant to an effective registration statement filed pursuant to the Securities Act.

We cannot predict if investors will find our securities less attractive if we choose to rely on any of the exemptions afforded emerging growth companies. If some investors find our common stock less attractive because we rely on any of these exemptions, there may be a less active trading market for our common stock, to the extent that such a market develops, and the market price of our common stock may be more volatile.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to avail ourselves of this provision of the JOBS Act. As a result, we will not be subject to new or revised accounting standards at the same time as other public companies that are not emerging growth companies. Therefore, our consolidated financial statements may not be comparable to those of companies that comply with new or revised accounting pronouncements as of public company effective dates.

We are also a "smaller reporting company" as defined in the Exchange Act. We may continue to be a "smaller reporting company" even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our voting and non-voting common stock held by non-affiliates is less than $250 million measured on the last business day of our second fiscal quarter, or our annual revenues are less than $100 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700 million measured on the last business day of our second fiscal quarter.

We may face risks related to securities litigation that could result in significant legal expenses and settlement or damage awards.

We may in the future become subject to claims and litigation alleging violations of the securities laws or other related claims, which could harm our business and require us to incur significant costs. Significant litigation costs could impact our ability to comply with certain financial covenants under any credit agreement we may enter into in the future. We are generally obliged, to the extent permitted by law, to indemnify our current and former directors and officers who are named as defendants in these types of lawsuits. Regardless of the outcome, litigation may require significant attention from management and could result in significant legal expenses, settlement costs, or damage awards that could have a material impact on our financial position, results of operations, and cash flows.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of our business, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Our restated certificate of incorporation and our amended and restated bylaws that became effective upon completion of the Merger contain provisions that could delay or prevent a change in control of our company. These provisions could also make it difficult for stockholders to elect directors who are not nominated by current members of the Board or take other corporate actions, including effecting changes in our management. These provisions:

- establish a classified board of directors so that not all members of our board are elected at one time;
- permit the board of directors to establish the number of directors and, unless the Board determines otherwise by resolution, to fill vacancies on the Board;
- provide that directors may only be removed "for cause" and only by the affirmative vote of the holders of at least two-thirds (2/3) of the voting power;
- require the affirmative vote of the holders of at least two-thirds (2/3) of the voting power to amend some provisions in our restated certificate of incorporation and amended and restated bylaws;
- authorize the issuance of "blank check" preferred stock that our board could use to implement a stockholder rights plan;
- eliminate the ability of our stockholders to call special meetings of stockholders;
- prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders;
- prohibit cumulative voting; and
- establish advance notice requirements for nominations for election to our board or for proposing matters that can be acted upon by stockholders at annual stockholder meetings.

In addition, our restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for: any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law ("DGCL"), our restated certificate of incorporation, or our amended and restated bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine.

Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all claims brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. Our restated certificate of incorporation provides that the federal district courts of the United States will, unless we consent in writing to an alternative forum, be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act ("Federal Forum Provision"). Our decision to adopt a Federal Forum Provision followed a decision by the Supreme Court of the State of Delaware holding that such provisions are facially valid under Delaware law. While there can be no assurance that federal courts or state courts will follow the holding of the Delaware Supreme Court or determine that the Federal Forum Provision should be enforced in a particular case, application of the Federal Forum Provision means that suits brought by our stockholders to enforce any duty or liability created by the Securities Act must be brought in federal court and cannot be brought in state court. While neither the exclusive forum provision nor the Federal Forum Provision applies to suits brought to enforce any duty or liability created by the Exchange Act, the Exchange Act creates exclusive federal jurisdiction over all claims brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. Accordingly, actions by our stockholders to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder also must be brought in federal court. Our stockholders will not be deemed to have waived our compliance with the federal securities laws and the regulations promulgated thereunder.

Any person or entity purchasing or otherwise acquiring or holding any interest in any of our securities shall be deemed to have notice of and consented to our exclusive forum provisions, including the Federal Forum Provision. These provisions may limit a stockholder's ability to bring a claim in a judicial forum of their choosing for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers, and other employees.

In addition, Section 203 of the DGCL may discourage, delay, or prevent a change in control of our company. Section 203 imposes certain restrictions on mergers, business combinations, and other transactions between us and holders of 15% or more of our common stock.

We do not intend to pay dividends for the foreseeable future.

We have never declared or paid any cash dividends on our capital stock, and we do not intend to pay any cash dividends on our securities in the foreseeable future. Any return on investment will depend on appreciation in the trading price of our securities, which may not occur. Additionally, any determination to pay dividends in the future will be at the discretion of the Board. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investments.

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

Our stock price and trading volume following our quotation on the OTCQB, if any, or following our potential listing on a securities exchange, if any, will be heavily influenced by the way analysts and investors interpret our financial information and other disclosures. Securities and industry analysts do not currently, and may never, publish research on our business. If few securities or industry analysts commence coverage of us, our stock price could be negatively affected. If securities or industry analysts downgrade our common stock, or publish negative reports about our business, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause our stock price to decline and could decrease the trading volume of our common stock.

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

Recent Sales of Unregistered Securities

During the three months ended September 30, 2026, the Company issued 41,473 shares of common stock upon the cash exercise of outstanding warrants at an exercise price of $0.02 per share, in reliance on the exemption from registration provided by Section 4(a)(2) of the Securities Act.

On October 26, 2026, the Company issued and sold an aggregate of 212,121 shares of common stock to accredited investors in a private placement at a purchase price of $3.30 per share, for aggregate gross proceeds of approximately $0.7 million. Network 1 Financial Securities, Inc. acted as placement agent and received a cash fee equal to 8% of the gross proceeds, or $56,000, and warrants to purchase 16,970 shares of common stock at an exercise price of $3.30 per share with a five-year term. The shares and warrants were issued in reliance on the exemption from registration provided by Section 4(a)(2) of the Securities Act and Rule 506(b) of Regulation D thereunder.

Use of Proceeds

Not applicable.

Issuer Purchases of Equity Securities

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Rule 10b5-1 Trading Arrangements

During the three months ended September 30, 2026, none of our directors or officers adopted, modified or terminated a “Rule 10b5-1 trading arrangement” or “non-Rule 10b5-1 trading arrangement,” each as defined in Item 408 of Regulation S-K.

Item 6. Exhibits

The exhibits listed in the following Exhibit Index are filed or furnished as part of, or incorporated by reference into, this Quarterly Report.

Exhibit No.	Description
10.1	Triple Net Lease Agreement, dated as of July 31, 2026, by and between Sonya Silverstein Rothstein, Julie M. Rothstein, Amy L. Rothstein and Susan H. Rothstein-Youakim, as co-trustees of the Sonya S. Rothstein Trust under agreement dated July 30, 2025, and Ionetix Radioisotopes, Inc. (incorporated by reference to Exhibit 10.26 to the Registration Statement on Form S-1 filed with the SEC on August 7, 2026)
31.1*	Certification of Chief Executive Officer Pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Exchange Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Chief Financial Officer Pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Exchange Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	Inline XBRL Instance Document — the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH*	Inline XBRL Taxonomy Extension Schema Document.
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

* Filed herewith
** Furnished herewith

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.

IONETIX CORPORATION

Date: November 13, 2026

By: /s/ Kevin Cameron

Kevin Cameron
Chief Executive Officer
(Principal Executive Officer)

Date: November 13, 2026

By: /s/ Phieu Phun

Phieu Phun
Chief Financial Officer
(Principal Financial and
Accounting Officer)

Exhibit 31.1

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

I, Kevin Cameron, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Ionetix Corporation;

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(s) 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(s) 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 13, 2026

By: */s/ Kevin Cameron*
Kevin Cameron
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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

I, Phieu Phun, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Ionetix Corporation;

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(s) 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(s) 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 13, 2026

By: */s/ Phieu Phun*
Phieu Phun
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
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 on Form 10-Q of Ionetix Corporation (the "Company") for the quarterly period ended September 30, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Kevin Cameron, Chief Executive Officer of the Company, 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; and

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

Date: November 13, 2026

By: */s/ Kevin Cameron*
Kevin Cameron
Chief Executive Officer
(Principal Executive Officer)

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

This certification is being furnished solely pursuant to 18 U.S.C. Section 1350 and is not being filed as part of the Report or as a separate disclosure document for purposes of Section 18 of the Securities Exchange Act of 1934, and shall not be deemed incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, except to the extent expressly set forth by specific reference in such filing.

Exhibit 32.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
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 on Form 10-Q of Ionetix Corporation (the "Company") for the quarterly period ended September 30, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Phieu Phun, Chief Financial Officer of the Company, 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; and

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

Date: November 13, 2026

By: */s/ Phieu Phun*
Phieu Phun
Chief Financial Officer
(Principal Financial and Accounting Officer)

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

This certification is being furnished solely pursuant to 18 U.S.C. Section 1350 and is not being filed as part of the Report or as a separate disclosure document for purposes of Section 18 of the Securities Exchange Act of 1934, and shall not be deemed incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, except to the extent expressly set forth by specific reference in such filing.